# PRIOR AUTHORIZATION DETAIL

## December 2020

**GENERAL DISCLAIMER:**

**Bright Health does not recognize the use of drug samples to meet clinical criteria requirements for prior drug use for drugs covered under the pharmacy benefit or drugs administered in the physician office or other outpatient setting. A physician's statement that samples have been used cannot be used as documentation of prior drug use.**

# ABILIFY

## Products Affected

- ABILIFY
- ABILIFY MAINTENA
- *aripiprazole oral solution*
- *aripiprazole oral tablet dispersible*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Schizophrenia, Acute bipolar mania, including manic and mixed episodes associated with bipolar disorder, Major Depressive Disorder, autistic disorder, Tourettes disorder, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SCHIZOPHRENIA (1) Prescriber attests patient has a diagnosis of Schizophrenia, AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, OR B. ACUTE BIPOLAR MANIA (1) Prescriber attests patient has a diagnosis of Acute bipolar mania, including manic and mixed episodes associated with bipolar disorder, AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, OR C. MAJOR DEPRESSIVE DISORDER (1) Prescriber attests patient has a diagnosis of Major Depressive Disorder, AND (2) Tried and failed, intolerance or contraindication of the formulary alternatives fluoxetine, paroxetine, sertraline, citalopram, Venlafaxine and bupropion (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history), AND (3) Trial and failure, intolerance or contraindication of the alternatives escitalopram and desvenlafaxine (Pristiq) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history), AND (4) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (5) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, AND (6) Must be used as adjunctive or add-on treatment to ADT and not as monotherapy, OR |
| **Age Restrictions** | Schizophrenia-13 years of age and older. Acute bipolar mania-10 years of age and older. MDD- 18 years of age and older. Autistic disorder, Tourettes-6 years of age and older. |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | D. AUTISTIC DISORDER (1) Prescriber attests patient has a diagnosis of autistic disorder, AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, AND (4) Tried and failed, intolerance, or contraindication to formulary stimulant medications methylphenidate, dextroamphetamine, amphetamine/dextroamphetamine (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) OR E. TOURETTES DISORDER (1) Prescriber attests patient has a diagnosis of Tourettes disorder AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet |

# ABILIFY DISCMELT NON FORMULARY

## Products Affected

- ABILIFY MYCITE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Schizophrenia, Acute bipolar mania, including manic and mixed episodes associated with bipolar disorder, Major Depressive Disorder, autistic disorder, Tourettes disorder, Medically accepted indications will also be considered for approval. Must have clinical swallowing difficulties (supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SCHIZOPHRENIA (1) Prescriber attests patient has a diagnosis of Schizophrenia, AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, OR B. ACUTE BIPOLAR MANIA (1) Prescriber attests patient has a diagnosis of Acute bipolar mania, including manic and mixed episodes associated with bipolar disorder, AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, OR C. MAJOR DEPRESSIVE DISORDER (1) Prescriber attests patient has a diagnosis of Major Depressive Disorder, AND (2) Tried and failed, intolerance or contraindication of the formulary alternatives fluoxetine, paroxetine, sertraline, citalopram, Venlafaxine and bupropion (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history), AND (3) Trial and failure, intolerance or contraindication of the alternatives escitalopram and desvenlafaxine (Pristiq) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history), AND (4) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (5) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, AND (6) Must be used as adjunctive or add-on treatment to ADT and not as monotherapy, OR |
| **Age Restrictions** | Schizophrenia-13 years of age and older. Acute bipolar mania-10 years of age and older. MDD- 18 years of age and older. Autistic disorder, Tourettes-6 years of age and older. |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | D. AUTISTIC DISORDER (1) Prescriber attests patient has a diagnosis of autistic disorder, AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet, AND (4) Tried and failed, intolerance, or contraindication to formulary stimulant medications methylphenidate, dextroamphetamine, amphetamine/dextroamphetamine (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) OR E. TOURETTES DISORDER (1) Prescriber attests patient has a diagnosis of Tourettes disorder AND (2) Tried and failed, intolerance or contraindication of the formulary alternative risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative Aripiprazole tablet AND F. Patient must have clinical swallowing difficulties (supported by documentation from the patients chart notes/medical records/electronic claim history Not approvable if electronic claim history demonstrates swallowable orals used AND |

# ABSTRAL/FENTORA/LAZANDA/ONSOLIS/SUBSYS NON FORMULARY

## Products Affected

- *fentanyl citrate buccal*
- FENTORA
- LAZANDA
- SUBSYS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis (including any applicable labs and /or tests) of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy (at least: 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer) for underlying persistent cancer pain, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BREAKTHROUGH CANCER PAIN (1) Prescriber attests patient has a diagnosis (including any applicable labs and /or tests) of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy (at least: 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer) for underlying persistent cancer pain AND (2) Must be on an adequate dose of a long-acting (maintenance, around-the-clock) opioid AND (3) An inadequate response, intolerance, or contraindication to a trial of immediate-release morphine at maximum tolerated dose for breakthrough pain AND (4) An inadequate response, intolerance, or contraindication to a trial of immediate-release oxycodone at maximum tolerated dose for breakthrough pain AND (5) An inadequate response or intolerance to a trial of fentanyl lozenge (Actiq) AND (6) Must be able to comply with instructions to keep medication out of the reach of children and to discard open units properly |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by oncologist or pain specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ACITRETIN

## Products Affected

- *acitretin*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe Psoriasis , Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PSORIASIS (1) Prescriber attests patient has a diagnosis of moderate to severe Psoriasis AND (2) Trial and failure, intolerance, or contraindication to, 90 day trial of Methotrexate AND (3) Trial and failure, intolerance, or contraindication to, 90 day trial of high dose topical steroid (i.e. betamethasone augmented, halobetasol) AND (4) Maximum of 2 capsules per day AND (5) For continuation of therapy, requires documentation of a positive response to therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a Dermatologist |
| **Coverage Duration** | Initial=3 months, Renewal=1 year |
| **Other Criteria** | None |

# ACTEMRA (TOCILIZUMAB) (SP)

## Products Affected

- ACTEMRA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderately to severely active Rheumatoid Arthritis, Giant Cell Arteritis (GCA), Systemic Juvenile Idiopathic Arthritis (SJIA), Polyarticular juvenile rheumatoid arthritis (PJIA), Cytokine Release Syndrome, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MODERATELY TO SEVERLY ACTIVE RHEUMATOID ARTHRITIS (1) Prescriber attests patient has a diagnosis of Moderately to severely active Rheumatoid Arthritis AND (2) Tried/failed/intolerance to at least one DMARD AND (3) Tried/failed/intolerance to methotrexate or to be taken in combination with continued methotrexate AND (4) Tried/failed/intolerance to Enbrel and Humira AND (5) Had a negative tuberculosis test or received treatment if tested positive AND (6) Has an absolute neutrophil count (ANC) greater than 2000/mm3 AND (7) Platelet count must be greater than 100,000/ mm3 AND (8) ALT and AST must not be 1.5 times the upper limit of normal B.GIANT CELL ARTERITIS (GCA) (1) Prescriber attests patient has a diagnosis of Giant Cell Arteritis (GCA) AND (2) Tried/failed/intolerance to one systemic corticosteroid AND (3) Had a negative tuberculosis test or received treatment if tested positive AND (4) Has an absolute neutrophil count (ANC) greater than 2000/mm3 AND (5) Platelet count must be greater than 100,000/ mm3 AND (8) ALT and AST must not be 1.5 times the upper limit of normal C. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) OR POLYARTICULAR JUVENILE RHEUMATOID ARTHRITIS (PJIA) (1) Prescriber attests patient has a diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA) or Polyarticular juvenile rheumatoid arthritis (PJIA) AND (2) Tried/failed/intolerance to one conventional therapy indicated for the diagnosis, including but not limited to, azathioprine, methotrexate, NSAIDs, DMARDs, etc. AND (3) Tried/failed/intolerance to Enbrel and Humira AND (4) Had a negative tuberculosis test or received treatment if tested positive AND (5) Has an absolute neutrophil count (ANC) greater than 2000/mm3 AND (6) Platelet count must be greater than 100,000/ mm3 AND (8) ALT and AST must not be 1.5 times the upper limit of normal |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | RA, GCA= 18 years of age or older, SJIA, PJIA, Cytokine Release Syndrome = 2 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by a Rheumatologist, |
| **Coverage Duration** | 12 months |
| **Other Criteria** | D. CYTOKINE RELEASE SYNDROME (1) Prescriber attests patient has a diagnosis of Cytokine Release Syndrome AND (2) Prescriber attests that patient has a documented diagnosis of having received CAR T-cell therapy within the past 28 days and must be administered by IV infusion AND (3) Had a negative tuberculosis test or received treatment if tested positive AND (4) Has an absolute neutrophil count (ANC) greater than 2000/mm3 AND (5) Platelet count must be greater than 100,000/ mm3 AND (6) ALT and AST must not be 1.5 times the upper limit of normal. RENEWAL FOR ALL INDICATIONS (1) Prescriber attests that patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patients condition AND (2) Prescriber attests that the patient has disease stabilization or improvement as defined by standard monitoring for the patients condition |

# ACTHAR HP NON FORMULARY

## Products Affected

- ACTHAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Infantile Spasm, Multiple Sclerosis-acute exacerbation, Nephrotic Syndrome, Dermatomyositis/Polymyositis, Systemic Lupus Erythematosus, Rheumatoid Arthritis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Concomitant use of live or live attenuated vaccines when receiving immunosuppressive corticotropin dose, Congenital infection in infants, Congestive heart failure, Hypertension, uncontrolled, Intravenous administration, Ocular herpes simplex infection, Osteoporosis, Peptic ulcers, history or presence of, Primary adrenocortical insufficiency or adrenocortical hyperactivity, Scleroderma, Sensitivity to porcine protein, Surgery, recent, Systemic fungal infection |
| **Required Medical Information** | A. INFANTILE SPASM (IS) (1) Prescriber attests patient has a definitive diagnosis of IS as evidenced by hypoarrythymia made by electroencephalogram. B. MULTIPLE SCLEROSIS, ACUTE EXACERBATION: (1) Prescriber must rule out pseudo-exacerbation from other precipitating factors (e.g., infection, pain, stress, premenstrual syndrome) with symptoms of acute exacerbation lasting at least 24 hours AND (2) Currently stable within the last 30 days on an immunomodulator agent (e.g., dimethyl fumarate, glatiramer, interferon beta 1a, interferon beta 1b, fingolimod, natalizumab, teriflunomide) (unless contraindicated) AND (3) History of inadequate response to, or an intolerance to an IV corticosteroid for current or previous acute exacerbation. C. NEPHROTIC SYNDROME: (1) History of inadequate response to or intolerance to an IV corticosteroid AND an immunosuppressant. D. DERMATOMYOSITIS/POLYMYOSITIS: (1) History of inadequate response to or an intolerance to an IV corticosteroid AND a non-biologic disease modifying anti-rheumatic drug. E. SYSTEMIC LUPUS ERYTHEMATOSUS: (1) Meets American College of Rheumatology diagnostic criteria for SLE AND (2) History of inadequate response to or intolerance to an IV corticosteroid AND hydroxychloroquine OR belimumab OR an immunosuppressant (e.g., azathioprine, cyclophosphamide, cyclosporine, mycophenolate). F. RHEUMATOID ARTHRITIS: (1) History of inadequate response to or intolerance to an IV corticosteroid AND (2) Prior treatment with a non-biologic disease-modifying anti-rheumatic drug AND at least two biologic disease-modifying anti-rheumatic drugs. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | Infantile Spasm=must be less than 24 months of age. MS-Acute Exacerbation, Dermatomyositis/Polymyositis, Rheumatoid Arthritis=18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Infantile Spasm=6 months, All other indications=1 month |
| **Other Criteria** | G. FOR ALL OTHER INDICATIONS: (1) Documented trial and failure of IV corticosteroid, or documented medical reason for why the patient cannot use an IV corticosteroid. AND (2) Documentation was provided that ALL other standard therapies have been used to treat the members condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care guidelines OR there is a documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other standard therapies could not be used to treat the members condition AND Must be prescribed by, or in consultation with, a specialist in the condition they are treating. RENEWAL 1. Prescriber attests to clinical improvement in patients condition and that patient is tolerating treatment |

# ACTIMMUNE

## Products Affected

- ACTIMMUNE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Granulomatous Disease, Severe malignant osteoporosis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC GRANULOMATOUS DISEASE (1) Prescriber attests patient has a diagnosis of Chronic Granulomatous Disease , OR B. SEVERE MALIGNANT OSTEOPOROSIS (1) Prescriber attests patient has a diagnosis of Severe malignant osteoporosis, and (2) Confirmed diagnosis by radiological evidence. FOR REAUTHORIZATION: Prescriber attests that patient has had a clinical response to medication |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | CGD=must be prescribed by or in consultation with an Immunologist, Hematologist, or Infectious disease physician. SMO=must be prescribed by or in consultation with an orthopedic surgeon, hematologist, or endocrinologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ACTIQ NON FORMULARY

## Products Affected

- ACTIQ
- *fentanyl citrate buccal*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis (including any applicable labs and /or tests) of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy (at least: 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer) for underlying persistent cancer pain, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BREAKTHROUGH CANCER PAIN (1) Prescriber attests patient has a diagnosis (including any applicable labs and /or tests) of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy (at least: 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer) for underlying persistent cancer pain AND (2)Must be on an adequate dose of a long-acting (maintenance, around-the-clock) opioid AND (3) An inadequate response, intolerance, or contraindication to at least a 2-week trial of immediate-release morphine at maximum tolerated dose for breakthrough pain AND (4) An inadequate response, intolerance, or contraindication to at least a 2-week trial of immediate-release oxycodone at maximum tolerated dose for breakthrough pain AND (5) Must be able to comply with instructions to keep medication out of the reach of children and to discard open units properly |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by oncologist or pain specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ADCIRCA

## Products Affected

- ADCIRCA
- ALYQ
- *tadalafil (pah)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Hypertension WHO group I, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Patients receiving organic nitrates in any form, either regularly or intermittently due to potentiation of the hypotensive effects of nitrates. Hypersensitivity reaction to Adcirca or Cialis. |
| **Required Medical Information** | A. PULMONARY HYPERTENSION WHO GROUP 1 (1) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records AND (2) greater than or equal to 18 years of age AND (3) Clinical diagnosis of pulmonary hypertension WHO group I (defined by pulmonary artery pressure greater than 25mm Hg at rest or greater than 30mm Hg with exertion) AND (4) Patients with NYHA class II-IV AND (5) Must have tried and failed or intolerant to sildenafil AND Letairis AND (6) Not on current nitrate therapy AND must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test AND (7) Patient has been evaluated for retinitis pigmentosa and completed counseling on the risk of ocular disturbances, non-arteric anterior ischemic optic neuropathy (NAION), and potential for blindness. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Must be prescribed by a cardiologist or pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ADEMPAS

## Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Arterial Hypertension (PAH) (WHO Group 1), NYHA functional class II-IV, Persistent/recurrent chronic thromboembolic pulmonary hypertension, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Not taking concurrent therapy with any nitrates (in any form) such as isosorbide dinitrate [Dilatrate,Isordil], isosorbide dinitrate/hydralazine [BiDil], isosorbide mononitrate [Imdur, Ismo], nitroglycerin. Not taking concurrent therapy with nitric oxide donors (i.e. amyl nitrate). Not taking concurrent therapy with any phosphodiesterase (PDE-5) inhibitors (i.e. sildenafil [Viagra, Revatio], tadalafil [Cialis, Adcirca], vardenafil [Levitra, Staxyn], dipyridamole or theophylline). |
| **Required Medical Information** | A. PULMONARY ARTERIAL HYPERTENSION (PAH WHO Group 1) (1) Prescriber attests patient has a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1), AND NYHA functional class II-IV AND (2) Not taking concurrent therapy with nitric oxide donors (i.e. amyl nitrate)AND (3) Not taking concurrent therapy with any phosphodiesterase (PDE-5) inhibitors (i.e. sildenafil [Viagra, Revatio], tadalafil [Cialis, Adcirca], vardenafil [Levitra, Staxyn] dipyridamole or theophylline). AND (4) Creatinine clearance is greater than 15 ml/min AND (5) Patient is not on dialysis AND (6) Patient does not have severe hepatic impairment (Child Pugh C)AND (7) Females of childbearing potential should have pregnancy excluded before the initiation of treatment B. PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO Group 4 (1) Prescriber attests patient has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) WHO Group 4 after surgical treatment or inoperable CTEPH, AND ALL of the following (2) Not taking concurrent therapy with any nitrates (in any form) such as isosorbide dinitrate [Dilatrate,Isordil], isosorbide dinitrate/hydralazine [BiDil], isosorbide mononitrate [Imdur, Ismo], nitroglycerin. AND (3) Not taking concurrent therapy with nitric oxide donors (i.e. amyl nitrate) AND (4) Not taking concurrent therapy with any phosphodiesterase (PDE-5) inhibitors (i.e. sildenafil [Viagra, Revatio], tadalafil [Cialis, Adcirca], vardenafil [Levitra, Staxyn] dipyridamole or theophylline). AND (5) Creatinine clearance is greater than 15 ml/min AND |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | None |
| **Prescriber Restrictions** | PAH=must be prescribed by cardiologist or pulmonologist |
| **Coverage Duration** | Initial=12 months, Renewal=1 year increments |
| **Other Criteria** | (6) Patient is not on dialysis AND (7) Patient does not have severe hepatic impairment (Child Pugh C) AND (8) Females of childbearing potential should have pregnancy excluded before the initiation of treatment. |

# AFINITOR

## Products Affected

- AFINITOR
- *everolimus*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postmenopausal women with clinically diagnosed advanced HR+ breast cancer, progressive neuroendocrine tumors of pancreatic origin, advanced renal cell carcinoma, renal angiomyolipoma and tuberous sclerosis complex, sub-ependymal giant cell astrocytoma (SEGA) tumors associated with tuberous sclerosis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Hypersensitivity to everolimus, to other rapamycin derivatives, or to any of the excipients. |
| **Required Medical Information** | A. COVERAGE OF ORAL ANTINEOPLASTICS IS RECOMMENDED IN THOSE WHO MEET THE FOLLOWING CRITERIA (1) Regimen is to be initiated by an oncologist/hematologist (2) Reviewed for appropriate FDA labeled indication and dosing (3) Reviewed for appropriate use of NCCN Guidelines and non-FDA labeled indications (4) Review of member clinical profile and treatment plan by pharmacist and/or medical director (5) Determine appropriate number of doses to be dispensed based on clinical treatment plan (not to exceed 30 days) (6) Obtain opinion of oncologist to review regimen(s) for appropriateness, if indicated. B. MEDICALLY ACCEPTED INDICATIONS (1)The indicated diagnosis (including any applicable labs and /or tests) and medication usage (2) Must be initially prescribed by an oncologist or hematologist (3) Postmenopausal women with clinically diagnosed advanced HR+ breast cancer and(3a)Must be used in combination with exemastane (3b)Must have failed treatment with letrozole or anastrozole OR C. PROGRESSIVE NEUROENDOCRINE TUMORS OF PANCREATIC ORIGIN (1) Clinically diagnosed progressive neuroendocrine tumors of pancreatic origin and(2)Must be prescribed by an oncologist or hematologist (3)Disease must be unresectable, locally advanced or metastatic (4)Safety and effectiveness has not been established for patients with carcinoid tumors OR D. ADVANCED RENAL CARCINOMA (1) Clinically diagnosed advanced renal cell carcinoma and (2) Must have tried and failed or intolerant to Sutent (3) Must have tried and failed or intolerant to Nexavar OR E. RENAL ANGIOMYOLIPOMA AND TUBEROUS SCLEROSIS COMPLEX (1) Clinically diagnosed renal angiomyolipoma and tuberous sclerosis complex and (2)Does not require immediate surgery OR F. SUB-EPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) TUMORS (1)Clinically diagnosed sub-ependymal giant cell |

| PA Criteria | Criteria Details |
|---|---|
| | astrocytoma (SEGA) tumors associated with tuberous sclerosis and (2) Tumors must be inoperable. G. CONTINUATION OF THERAPY (1) Disease stable without tumor progression. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Regimen is to be initiated by an oncologist/hematologist |
| **Coverage Duration** | Initial=6 months, Renewal=1 year |
| **Other Criteria** | None |

# AKYNZEO

## Products Affected

- AKYNZEO ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Prevention of chemotherapy-induced nausea/vomiting (CINV) associated with highly-emetogenic chemotherapy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Contraindication to an emetic regimen that includes combination of a serotonin antagonist and dexamethasone. |
| **Required Medical Information** | A. CHEMOTHERAPY-INDUCED NAUSEA/VOMITING (1) Prescriber attests patient has a diagnosis of chemotherapy-induced nausea/vomiting (CINV) associated with highly-emetogenic chemotherapy. Highly emetic chemotherapy classified as therapy with the following agents (AC: cyclophosphamide + anthracycline (doxorubicin, epirubicin), dacarbazine (DTIC), ifosfamide greater than or equal to 2g/m2 /dose, carmustine greater than 250 mg/m2, doxorubicin greater than or equal to 60 mg/m2, mechlorethamine, cisplatin, epirubicin greater than 90 mg/m2, Streptozocin, cyclophosphamide greater than 1,500 mg/m2. (2) Tried and failed, intolerance or contraindication to an emetic regimen that includes combination of a serotonin antagonist and dexamethasone AND (3) Must be administered with dexamethasone |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |

# ALBENZA

## Products Affected

- *albendazole oral*
- ALBENZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm. Cystic hydatid disease of the liver, lung, and peritoneum caused by larval form of the dog tapeworm. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. Prescriber attests that patient has a confirmed diagnosis of one of the following (1) Parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm (Taenia solium) (2) Cystic hydatid disease of the liver, lung, and peritoneum caused by larval form of the dog tapeworm (Echinococcus granulosus). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Infectious Disease specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ALDARA NON FORMULARY

## Products Affected

- ALDARA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Actinic Keratosis (AK), Superficial Basal Cell Carcinoma (sBCC), External Genital Warts (EGW). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACTINIC KERATOSIS/SUPERFICIAL BASAL CELL CARCINOMA (1) A diagnosis of Actinic Keratosis (AK) or Superficial Basal Cell Carcinoma (sBCC) AND (2) An inadequate response or intolerance to office-based treatments OR have been considered and ruled out as options due to the nature/number of lesions or limited resources to provide such treatments AND (3) An inadequate response to a full treatment course or intolerance/contraindication to a trial of 5-fluorouracil OR B. EXTERNAL GENITAL WARTS (1) A diagnosis of External Genital Warts (EGW) AND (2) An inadequate response or intolerance to office-based treatments OR have been considered and ruled out as options due to the nature/number of lesions or limited resources to provide such treatments AND (3) An inadequate response to a full treatment course or intolerance/contraindication to a trial of podofilox. |
| **Age Restrictions** | AK or sBCC=18 years of age and older. EGW=12 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Duration max 16 weeks, maximum quantity 48 units per 16 weeks |
| **Other Criteria** | None |

# ALINIA

## Products Affected

- ALINIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diarrhea caused by Giardia lamblia, cryptosporidiosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. GIARDIASIS (1) Prescriber attests patient has a diagnosis of diarrhea caused by Giardia lamblia (giardiasis) AND (2) Patient is immunocompetent and is not infected with HIV, AND (3) Patient has had a trial and failure, contraindication, or intolerance to metronidazole. B. CRYPTOSPORIDIOSIS (1) Prescriber attests patient has a diagnosis of diarrhea caused by Cryptosporidium parvum (cryptosporidiosis) AND (2)Patient is immunocompetent and not infected with HIV |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Giardiasis or Cryptosporidiosis=3 days |
| **Other Criteria** | None |

# ALOCRIL

## Products Affected

- ALOCRIL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of itching related to allergic ocular disorders such as allergic conjunctivitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TREATMENT OF ITCHING RELATED TO ALLERGIC OCULAR DISORDERS (1) Being used in the treatment of itching related to allergic ocular disorders such as allergic conjunctivitis, AND (2) Patient has had a clinical trial and failure, intolerance, or contraindication to two of the following (2a) Azelastine ophthalmic solution (2b) Cromolyn sodium ophthalmic solution (2c) Epinastine ophthalmic solution (2d) Olopatadine 0.1% ophthalmic solution |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ALOMIDE

## Products Affected

- ALOMIDE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of oculary inflammatory states. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. OCULARY INFLAMATORY STATES (1) Being used in the treatment of oculary inflammatory states, and (2) Patient is at least 2 years of age or older, and (3) Patient has had a clinical trial and failure, intolerance, or contraindication to two of the following (3a) Azelastine ophthalmic solution (3b) Cromolyn sodium ophthalmic solution (3c) Epinastine ophthalmic solution (3d) Olopatadine 0.1% ophthalmic solution |
| **Age Restrictions** | Oculary inflammatory states=2 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | None |

# AMPYRA

## Products Affected

- AMPYRA
- *dalfampridine er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Indication of walking difficulty with a diagnosis of MS. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Ampyra will not be covered in patients with any of the following exclusion criteria (1) The patient has a seizure disorder, OR (2) The patient has moderate renal impairment (defined as a creatinine clearance (CrCl) of 30-50 mL/min) or severe renal impairment (defined as a CrCl less than or equal to 50 mL/min), OR (3) The patient is unable to walk 25 feet in 8-60 seconds with walking aids if needed, OR (4) The patient has minimal or no impairment of ambulation (corresponding to an EDSS of less than 4.5*), OR (5) The patient has severe impairment of ambulation and is essentially restricted to a wheelchair (corresponding to an EDSS of 7* or higher) OR (6) Contraindications to prescribing. |
| **Required Medical Information** | A. WALKING DIFFICULTY WITH A DIAGNOSIS OF MS (1) Indication of walking difficulty with a diagnosis of MS (supported by documentation from the patients chart notes/medical records/brain MRI), AND (2) Prescribed by a neurologist AND (3) Medical records/chart notes from neurology consultation documenting the deterioration of walking ability confirmed by gait assessment (e.g. MS Walking Scale 12 (MSWS-12), Timed 25-foot Walk (T25FW), 6-minute Walk Test, Expanded Disability Status Scale (EDSS), AND Documentation of past or current physical therapy AND (4) History of or current treatment with immune modulating therapies for MS AND (5) No history of seizure and no diagnosis of moderate to severe renal impairment. B. CONTINUATION OF THERAPY (1) Medical records/chart notes from neurology consultation documenting the improvement of walking ability confirmed by gait assessment. NOTE- The Expanded Disability Status Score (EDSS) quantifies disability in eight functional systems: pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral, and other. EDSS scores 1.0 to 4.5 refer to people with multiple sclerosis who are fully ambulatory. EDSS scores 5.0 to 9.5 are defined by increasing impairment to ambulation. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a neurologist |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# AMRIX NON FORMULARY

## Products Affected

- AMRIX
- *cyclobenzaprine hcl er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of muscle spasm associated with acute painful musculoskeletal condition. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MUSCLE SPASM (1) Prescriber attests patient has a diagnosis of muscle spasm associated with acute painful musculoskeletal condition, AND (2) Documentation of a failed trial of cyclobenzaprine immediate release AND (3) Prescriber must indicate clinical reasoning why extended release product is expected to work when immediate release product has failed, AND (4) Clinical trial and failure of at least two (2) other covered generic skeletal muscle relaxants |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# Anadrol

## Products Affected

- ANADROL-50

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Anemia caused by deficient red cell production including acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs, anemia associated with chronic renal failure. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ANEMIA CAUSED BY DEFICIENT RED CELL PRODUCTION, INCLUDING ACQUIRED APLASTIC ANEMIA, CONGENITAL APLASTIC ANEMIA, MYELOFIBROSIS AND THE HYPOPLASTIC ANEMIAS DUE TO THE ADMINISTRATION OF MYELOTOXIC DRUGS (1) Prescriber attests patient has diagnosis of anemia caused by deficient red cell production, including acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs (2) Patient has a hematocrit (HCT) value less than 30% (3) One of the following: (i) patient is not currently treated with another androgen or anabolic steroid within the past 90 days (ii) if on current androgen or anabolic steroid, it will be discontinued before start of the requested agent (iii) prescriber will submit documentation in support of therapy with more than one agent which has been reviewed and approved. B. ANEMIA ASSOCIATED WITH CHRONIC RENAL FAILURE: (1) Prescriber attests patient has diagnosis of anemia associated with chronic renal failure and one of the following (i) patient has previously utilized an Erythropoiesis stimulating agent (ESA) (ii) patient has an intolerance or contraindication to use of an ESA. (2) Patient has a hematocrit (HCT) value less than 30% (3) One of the following: (i) patient is not currently treated with another androgen or anabolic steroid within the past 90 days (ii) if on current androgen or anabolic steroid, it will be discontinued before start of the requested agent (iii) prescriber will submit documentation in support of therapy with more than one agent which has been reviewed and approved. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ANA-LEX KIT NON FORMULARY

## Products Affected

- ANA-LEX
- *lidocaine-hydrocortisone ace rectal kit 2-2 %*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Itching, pain, soreness, and discomfort due to hemorrhoids, anal fissure, pruritus ani, or similar conditions of the anal area. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ITCHING, PAIN, SORENESS, AND DISCOMFORT DUE TO HEMORRHOIDS, ANAL FISSURE, PRURITUS ANI, OR SIMILAR CONDITIONS OF THE ANAL AREA (1) Prescriber attests patient has diagnosis of itching, pain, soreness, or discomfort due to hemorrhoids, anal fissure, pruritus ani, or similar condition of the anal area (2) Clinical trial and failure of ALL of the following: (i) PramCort Cream (ii) lidocaine/hydrocortisone cream (generic Anamantle HC cream) (2) Clinical reason why the kit would be more effective than the cream. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ANCOBON (FLUCYTOSINE)

## Products Affected

- ANCOBON
- *flucytosine oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cryptococcal Meningitis, Candida Endocarditis, Cryptococcal Pulmonary infection, Candida Septicemia, Candiduria. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CRYPTOCOCCAL MENINGITIS B. CANDIDA ENDOCARDITIS C. CRYPTOCOCCAL PULMONARY INFECTION (1) Prescriber attests patient has diagnosis of Cryptococcal meningitis B, Candida endocarditis, or Cryptococcal pulmonary infection (2) Documentation of clinical inappropriateness of treatment with at least one first-line agent (e.g. fluconazole, itraconazole, or voriconazole) D. CANDIDA SEPTICEMIA (1) Prescriber attests patient has diagnosis of Candida septicemia (2) Documentation of clinical inappropriateness of treatment with first-line agent (e.g. fluconazole, voriconazole, amphotericin B, or an echinocandin) E. CANDIDURIA (1) Prescriber attests patient has diagnosis of Candiduria (2) Documentation of clinical inappropriateness of treatment with fluconazole AND amphotericin B monotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ANDROGEL

## Products Affected

- ANDROGEL
- ANDROGEL PUMP
- FORTESTA
- NATESTO
- TESTIM
- *testosterone transdermal gel*
- VOGELXO
- VOGELXO PUMP

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary or Secondary Hypogonadism, Gender Dysphoria in female-to-male transgender. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | History of prostate or male breast carcinoma |
| **Required Medical Information** | A. PRIMARY OR SECONDARY HYPOGONADISM (1) Prescriber attests patient has diagnosis of primary or secondary hypogonadism (2) Patient does not have a history of prostate or male breast carcinoma (3) Prescriber must submit at least TWO separate serum testosterone levels (each drawn in the morning) that indicate level is below normal range (300-1,000 ng/dL within the past 6 months. B. CONTINUATION OF THERAPY (1) Prescriber attests that patient has been compliant with treatment based on refill history (2) Prescriber has submitted a serum testosterone level within normal range within past 12 months B. GENDER DYSPHORIA (1) Prescriber attests the drug is being prescribed for female-to-male gender reassignment in a patient who is 14 years of age or older and able to make informed, mature decision to engage in therapy |
| **Age Restrictions** | Gender dysphoria: 14 years of age and older, All other indications: 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# APIDRA

## Products Affected

- APIDRA
- APIDRA SOLOSTAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diabetes Mellitus. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. DIABETES MELLITUS (1) Prescriber attests patient has diagnosis of Diabetes Mellitus (2) Patient has had a previous trial and failure, intolerance, or contraindication to all of the following: (i) Novolin (ii) Novolog (iii) Fiasp |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# APLENZIN NON FORMULARY

## Products Affected

- APLENZIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Major Depressive Disorder or Seasonal Affective Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MAJOR DEPRESSIVE DISORDER OR SEASONAL AFFECTIVE DISORDER (1) Prescriber attests patient has diagnosis of Major Depressive Disorder or Seasonal Affective Disorder (2) Trial and failure or intolerance to a 30 day trial of EACH OF THE FOLLOWING: (i) generic bupropion hydrochloride ER tablets (ii) bupropion XL tablets (iii) fluoxetine (iv) paroxetine (v) sertraline (vi) citalopram (vii) venlafaxine (medication usage must be supported by documentation from the patients chart notes/medical records) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# APOKYN

## Products Affected

- APOKYN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced Parkinsons Disease with acute, intermittent hypomobility (off) episodes. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Concomitant use with 5HT2 antagonists, including antiemetics (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron). Hypersensitivity to sodium metabisulfite. |
| **Required Medical Information** | A. ADVANCED PARKINSONS DISEASE WITH ACUTE, INTERMITTENT HYPOMOBILITY (OFF) EPISODES (1) Prescriber attests patient has diagnosis of Advanced Parkinsons Disease with acute, intermittent hypomobility (off) episodes (2) Patient is 18 years of age or older (3) Prescribed by, or in conjunction with, a neurologist (4) Prescriber attests that medication will be used in combination with a levodopa containing product AND another anti-Parkinsons agent (i.e. dopamine agonist or COMT inhibitor) (5) Prescriber attests that the patient has received a test dose with no clinically significant orthostatic hypotension. B CONTINUATION OF THERAPY (1) Prescriber attests that the patient continues to meet initial criteria (2) Prescriber attests that the patient has experienced a reduction in hypomobility (off) episodes |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# APTIOM

## Products Affected

- APTIOM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Partial-Onset Seizures. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Hypersensitivity to eslicarbazepine acetate or hypersensitivity to oxcarbazepine |
| **Required Medical Information** | A. PARTIAL-ONSET SEIZURES (1) Prescriber attests patient has diagnosis of Partial-Onset Seizures (2) Trial and failure of immediate release oxcarbazepine as an adjunctive treatment (3) Trial and failure of or an intolerance to at least one other adjunctive treatment (4) Prescribed by, or in consultation with a neurologist (5) Patient is 4 years of age or older. B CONTINUATION OF THERAPY (1) Patient is tolerating and responding to the medication and there continues to be a medical need for the medication. |
| **Age Restrictions** | 4 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | CAUTION: (1) Suicidal behavior and ideation (2) Serious dermatologic reactions (3) Drug reaction with eosinophilia and systemic symptoms/multiorgan hypersensitivity (4) Hyponatremia (5) Neurological adverse reactions (6) Drug induced liver injury (7) Abnormal thyroid function tests. MONITORING: (1) Renal function - dose reduction is recommended for moderate-severe impairment (2) Serum sodium chloride levels NOT APPROVED IF: (1) Does not meet above criteria (2) Has any contraindication to treatment SPECIAL CONSIDERATIONS: (1) Eslicarbezepine is the active metabolite of oxcarbazepine (2) No comparative trials are available to evaluate the potential differences in efficacy or safety between eslicarbazepine acetate and oxcarbazepine (3) Published trials showed that Aptiom 800 mg or 1200 mg daily reduced the seizure frequency compared to placebo. An unpublished trial demonstrated a reduced seizure frequency with Aptiom 1200 mg daily. |

| PA Criteria | Criteria Details |
|---|---|
| | The seizure reduction with the 800 mg was not statistically significant (4)<br>Drug interactions: inhibits CYP2C19 and induces CYP3A4 |

# ARANESP NON FORMULARY

## Products Affected

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION PREFILLED SYRINGE 10 MCG/0.4ML, 100 MCG/0.5ML, 150 MCG/0.3ML, 200 MCG/0.4ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Kidney Disease (with or without dialysis), Chemotherapy-Induced Anemia in Cancer Patients, Hepatitis C Patients with Anemia Secondary to Combination Ribavirin and interferon-alfa therapy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Anemia in patients with cancer who are not receiving chemotherapy (2) Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers (3) Anemia associated with radiotherapy (as monotherapy) in cancer (4) To enhance athletic performance (5) Substitute for red blood cell transfusions in patients who require immediate correction of anemia (i.e acute blood loss) |
| **Required Medical Information** | A. CHRONIC KIDNEY DISEASE (WITH OR WITHOUT DIALYSIS) (INITIAL OR CONTINUATION) (1) Prescriber attests patient has diagnosis of anemia associated Chronic Kidney Disease (with or without dialysis) (2) Submission of lab findings confirming hemoglobin level is less than 10 g/dL within the past 30 days (3) Submission of lab findings confirming serum ferritin greater than/= 100 ng/mL or transferrin saturation of greater than/= 20% within the past 90 days (4) Rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion (5) Goal is to reduce risk of alloimmunization and/or other RBC transfusion related risks B. CHEMOTHERAPY-INDUCED ANEMIA IN CANCER PATIENTS (INITIAL OR CONTINUATION) (1) Prescriber attests patient has diagnosis of anemia due to chemotherapy for a non-myeloid malignancy (2) Submission of lab findings confirming hemoglobin level is less than 10 g/dL within the past 30 days (3) Submission of lab findings confirming serum ferritin greater than/= 100 ng/mL or transferrin saturation of greater than/= 20% within the past 90 days (4) Patient is being concurrently treated with chemotherapy, with or without radiation (5) There is a minimum of two additional months of planned chemotherapy C. HEPATITIS C PATIENTS WITH ANEMIA SECONDARY TO COMBINATION RIBAVIRIN AND INTERFERON-ALFA THERAPY (INITIAL) (1) Prescriber attests patient has diagnosis of Hepatitis C with anemia and concurrent use of ribavirin and interferon-alfa therapy confirmed by review of prescription claims (2) Submission of lab findings confirming hemoglobin level is less than 10 g/dL within the |

| PA Criteria | Criteria Details |
|---|---|
| | past 30 days (3) Submission of lab findings confirming serum ferritin greater than/= 100 ng/mL or transferrin saturation of greater than/= 20% within the past 90 days |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial 3 months, Renewal 3 months |
| **Other Criteria** | D. HEPATITIS C PATIENTS WITH ANEMIA SECONDARY TO COMBINATION RIBAVIRIN AND INTERFERON-ALFA THERAPY (CONTINUATION) (1) Submission of lab findings confirming HgB level less than/= 12 g/dL (2) Submission of lab findings confirming serum ferritin greater than/= 100 ng/mL or transferrin saturation of greater than/= 20% (3) Documentation that previous ribavirin dose did not require reduction due to symptomatic anemia (4) Documentation that the member Hgb levels have increased by at least 1 g/dL from pretreatment baseline |

# ARCALYST

## Products Affected

- ARCALYST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cryopyrin-Associated Periodic Syndromes (CAPS) disorder: Familial Cold Auto inflammatory Syndrome or Muckle-Wells Syndrome. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Diagnosed with the following CAPS disorders: Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA) |
| **Required Medical Information** | A. FAMILIAL COLD AUTOINFLAMMATORY SYNDROME AND MUCKLE-WELL SYNDROME (1) Prescriber attests patient has diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) disorder: Familial Cold Auto inflammatory Syndrome or Muckle-Wells Syndrome (2) Prescribed by a Rheumatologist or Immunologist (3) greater than/= 12 years of age |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by a Rheumatologist or Immunologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ARCAPTA

## Products Affected

- ARCAPTA NEOHALER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to Severe COPD |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MODERATE TO SEVERE COPD (1) Prescriber attests patient has diagnosis of moderate to severe COPD (2) The patient has had at least two COPD exacerbations in the past year as evidenced by chart notes (3) Trial and failure, intolerance or contraindication to the formulary alternatives: Striverdi, Breo Ellipta, and/or Atrovent HFA (medication usage must be supported by documentation from the patients chart notes/medical records/ electronic claims history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ASACOL HD / LIALDA NON FORMULARY

## Products Affected

- ASACOL HD
- LIALDA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mild to Moderate Ulcerative Colitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MILD TO MODERATE ULCERATIVE COLITIS (1) Prescriber attests patient has diagnosis of mild to moderate ulcerative colitis (supported by documentation from the patients chart notes/medical records) (2) Patient is 18 years of age or older (3) Prescribed by, or in conjunction with a Gastroenterologist (4) Tried and failed, intolerance, or contraindication to a 30-day trial of all of the following: (i) sulfasalazine (immediate-release/delayed-release) (ii) balsalazide (iii) mesalamine delayed release (iv) Apriso (maintenance of remission) (v) Delzicol |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with a gastroenterologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# AUBAGIO

## Products Affected

- AUBAGIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing-Remitting Multiple Sclerosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Severe Hepatic Impairment, Women who are pregnant or women of childbearing potential who are not using effective contraception, Leflunomide treatment |
| **Required Medical Information** | A. RELAPSING-REMITTING MULTIPLE SCLEROSIS INITIAL (1) Prescriber attests patient has a diagnosis of relapsing-remitting MS supported by documentation from the patients medical records/most recent brain MRI (Note: Relapsing forms of MS include relapsing-remitting, secondary progressive with relapses, clinically isolated syndrome and progressive relapsing) (2) Must be 18 years of age or older (3) Prescribed by a neurologist (4) The patient has tried and failed or has a contraindication to Betaseron OR Avonex OR Glatiramer (an exception to this criteria is provided for a patient who is unable to administer injections due to dexterity issues or visual impairment) (Note: If the patient has tried natalizumab (Tysabri), then he/she is not required to try an interferon beta product or glatiramer acetate) B. CONTINUATION OF THERAPY (1) Medical records/chart notes from neurology consultation documenting the improvement of the relapsing rate or that the patients clinical condition is stabilized with the current therapy with no significant adverse effects |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# AUGMENTIN

## Products Affected

- AUGMENTIN ORAL SUSPENSION RECONSTITUTED 125-31.25 MG/5ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Community-Acquired Pneumonia, Cystitis, Impetigo, Lower Respiratory Tract Infection, Otitis Media, Pneumonia, Sinusitis, Skin/Skin Structure Infections, Urinary Tract Infection, Other Infection Caused by Susceptible Organism. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. COMMUNITY-ACQUIRED PNEUMONIA, CYSTITIS, IMPETIGO, LOWER RESPIRATORY TRACT INFECTION, OTITIS MEDIA, PNEUMONIA, SINUSITIS, SKIN/SKIN STRUCTURE INFECTIONS, URINARY TRACT INFECTION OTHER INFECTION CAUSED BY SUSCEPTIBLE ORGANISM (1) Prescriber attests patient has diagnosis of Community-Acquired Pneumonia, Cystitis, Impetigo, Lower Respiratory Tract Infection, Otitis Media, Pneumonia, Sinusitis, Skin/Skin Structure Infections, Urinary Tract Infection, or Other Infection Caused by Susceptible Organism (2) There has been a clinical trial and failure, or intolerance to, one of the preferred generic products (amoxicillin/clavulanic tablet or suspension) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# AUSTEDO NON FORMULARY

## Products Affected

- AUSTEDO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Huntingtons Disease (Huntingtons Chorea) or Tardive Dyskinesia |
| **Exclusion Criteria** | (1) History of depression, suicide attempts, and/or suicidal ideation (2) Using concomitantly with tetrabenazine (3) Severe hepatic impairment (4) Using concomitantly with and MAOI (5) Using concomitantly with reserpine |
| **Required Medical Information** | A. HUNTINGTONS DISEASE (HUNTINGTONS CHOREA) OR TARDIVE DYSKINESIA (1) Prescriber attests patient has diagnosis of Huntingtons Disease (Huntingtons Chorea) or Tardive Dyskinesia (2) Patient has a documented trial and failure, intolerance to, or contraindication to tetrabenazine B. CONTINUATION OF THERAPY (1) Patient must have documentation of treatment response, as verified per progress notes |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or a psychiatrist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Quantity/Partial Fill Restrictions: Maximum of 240-6 mg tablets per 30 day period, 150-9 mg tablets per 30 day period, 120-12 mg tablets per 30 day period, any combination of available tablets that does not exceed 48 mg/day |

# AVONEX

## Products Affected

- AVONEX PEN
- AVONEX PREFILLED

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing-Remitting Multiple Sclerosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Concurrent use of interferon beta-1a (intramuscular) with interferon beta-1a (subcutaneous) (Rebif), interferon beta-1b (Betaseron, Extavia), or glatiramer acetate (Copaxone) is not recommended. These agents are not indicated for use in combination and studies that are currently under progress will determine the efficacy of these agents concurrently. Only limited data documents the use of these therapies in combination. Additional studies are needed to determine if combination therapy is effective and safe (2) Patient is receiving natalizumab (Tysabri) which is indicated as monotherapy for MS patients with relapsing forms of the disease (3) Patient is concurrently receiving fingolimod. Use of interferon beta-1a IM QW with fingolimod has not been studied or established |
| **Required Medical Information** | A. RELAPSING-REMITTING MULTIPLE SCLEROSIS INITIAL (1) Prescriber attests patient has a diagnosis of relapsing-remitting MS supported by documentation from the patients medical records/most recent brain MRI (Note: Relapsing forms of MS include relapsing-remitting, secondary progressive with relapses, clinically isolated syndrome and progressive relapsing) or that the patient has experienced an attack and is at risk of MS (2) Prescribed by a neurologist B. CONTINUATION OF THERAPY (1) Medical records/chart notes from neurology consultation documenting the improvement of the relapsing rate or that the patients clinical condition is stabilized with the current therapy with no significant adverse effects |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# AZASAN

## Products Affected

- AZASAN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Atopic Dermatitis, Autoimmune Hepatitis, Behcets Syndrome, Crohns Disease, Dermatomyositis, Idiopathic Thrombocytopenic Purpura (ITP), Kidney Transplant Rejection Prophylaxis, Lupus Nephritis, Myasthenia Gravis, Polymyositis, Psoriasis, Pulmonary Fibrosis, Rheumatoid Arthritis, Systemic Lupus Erythematosus (SLE), Ulcerative Colitis, or Wegeners Granulomatosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ATOPIC DERMATITIS, AUTOIMMUNE HEPATITIS, BEHCETS SYNDROME, CROHNS DISEASE, DERMATOMYOSITIS, IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP), KIDNEY TRANSPLANT REJECTION PROPHYLAXIS, LUPUS NEPHRITIS, MYASTHENIA GRAVIS, PLYMYOSITIS, PSORIASIS, PULMONARY FIBROSIS, RHEUMATOID ARTHRITIS, SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), ULCERATIVE COLITIS, WEGENERS GRANULOMATOSIS (1) Prescriber attests patient has diagnosis of Atopic Dermatitis, Autoimmune Hepatitis, Behcets Syndrome, Crohns Disease, Dermatomyositis, Idiopathic Thrombocytopenic Purpura (ITP), Kidney Transplant Rejection Prophylaxis, Lupus Nephritis, Myasthenia Gravis, Polymyositis, Psoriasis, Pulmonary Fibrosis, Rheumatoid Arthritis, Systemic Lupus Erythematosus (SLE), Ulcerative Colitis, or Wegeners Granulomatosis (2) Patient has had a clinical trial and failure to azathioprine tablet |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# AZASITE

## Products Affected

- AZASITE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Bacterial Conjunctivitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BACTERIAL CONJUNCTIVITIS (1) Prescriber attests patient has diagnosis of Bacterial Conjunctivitis (2) An inadequate response or intolerance or contraindication to a trial of two of the following: (i) ciprofloxacin ophthalmic (ii) sulfacetamide solution 10% ophthalmic solution (iii) Polymyxin B sul-trimethoprim |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# AZELEX CREAM NON FORMULARY

## Products Affected

- AZELEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acne Vulgaris. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACNE VULGARIS (1) Prescriber attests patient has diagnosis of Acne Vulgaris (2) An inadequate response or intolerance to a trial of ALL of the following: (i) benzoyl peroxide (ii) topical clindamycin (iii) topical erythromycin (iv) tretinoin |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BARACLUDE

## Products Affected

- BARACLUDE ORAL SOLUTION
- *entecavir*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic hepatitis B, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. FOR CHRONIC HEPATITIS B: INITIAL: (1) Prescriber attest to a documented diagnosis of chronic hepatitis B AND (2) Patient is HBsAg-positive for at least 6 months AND (3a) For HBeAg-positive patients, serum HBV DNA greater than 20,000 IU/mL (105 copies per mL) OR (3b) For HBeAg-negative patients, serum HBV DNA greater than 2,000 IU/mL (104 copies/mL) AND (4) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) at least 2 times the upper limit of normal or histologically active disease (i.e. necroinflammation on biopsy) AND (5) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection. RENEWAL: (1) Must be HBeAg negative and have not had HBsAg clearance OR HBeAg positive and have detectable HBV DNA and have not been anti-Hbe for at least 6 months. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BEPREVE

## Products Affected

- BEPREVE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ocular pruritus associated with the signs and symptoms of allergic conjunctivitis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. OCULAR PRURITUS ASSOCIATED WITH SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCITIVITS: (1) Prescriber attests the product is being used in the treatment of ocular pruritus associated with signs and symptoms of allergic conjunctivitis AND (2) Documentation of an inadequate response or intolerance to trials of both of the following: OTC ketotifen AND either azelastine or epinastine. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BETASERON

## Products Affected

- BETASERON

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing multiple sclerosis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Coverage of interferon beta-1b is not recommended in the following circumstances: Concurrent use of interferon beta-1b with interferon beta-1a (Avonex, Rebif) or glatiramer acetate (Copaxone) is not recommended. These agents are not indicated for use in combination and studies that are currently under progress will determine the efficacy of these agents concurrently, Patient is receiving natalizumab (Tysabri). Natalizumab is indicated as monotherapy for MS patients with relapsing forms of the disease, Patient is concurrently receiving fingolimod. Use of interferon beta-1b SC with fingolimod has not been studied or established. |
| **Required Medical Information** | A. RELAPSING MULTIPLE SCLEROSIS: INITIAL: (1) Prescriber documentation that the member has a diagnosis of relapsing multiple sclerosis, supported by documentation from the patients medical records or most recent brain MRI (Note: Relapsing forms of MS include relapsing-remitting, secondary progressive with relapses, clinically isolated syndrome and progressive relapsing) or have experienced an attack and who are at risk of MS. RENEWAL: (1) Medical records or chart notes from neurology consultation documenting the improvement of the relapsing rate or that the patients clinical condition is stabilized with the current therapy with no significant adverse effects. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BETOPTIC-S

## Products Affected

- BETOPTIC-S

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic open-angle glaucoma and ocular hypertension, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC OPEN-ANGLE GLAUCOMA AND OCULAR HYPERTENSION: (1) Prescriber attests to a diagnosis of chronic open-angle glaucoma and ocular hypertension AND (2) Patient has had a clinical trial and failure, intolerance, or contraindication to betaxolol 0.5% (generic). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BOSULIF

## Products Affected

- BOSULIF ORAL TABLET 100 MG, 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Myelogenous Leukemia (CML), Acute Lymphoblastic Leukemia (ALL), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: A. CHRONIC MYELOGENOUS LEUKEMIA (CML): (1) Prescriber attests to a diagnosis of Chronic Myelogenous Leukemia (CML) AND (2) Disease is confirmed by either a Philadelphia chromosome-positive (Ph positive) or BCR-ABL1 positive laboratory test AND (3a) Patient has chronic or accelerated blast phase disease and is resistant, intolerant, or had an inadequate response to Imatinib OR (3b) Patient has newly diagnosed chronic phase disease. B. ACUTE LYMPHOBLASTIC LEUKEMIA (ALL): (1) Prescriber attests to a diagnosis of Acute Lymphoblastic Leukemia (ALL) AND (2) Patients disease is Philadelphia chromosome-positive (Ph positive) AND (3) Requested medication is being used for relapsed or refractory disease AND (4a) Being used as a single agent OR (4b) Used in combination with an induction therapy not previously used OR (4c) Used in patients with any of the following mutations: E255K/V, F317L/V/I/C, F359V/C/I, T315A, or Y253H. RENEWAL: A. FOR CHRONIC MYELOGENOUS LEUKEMIA (CML): (1) Patient continues to meet initial criteria AND (2) Prescriber attests that patient has had treatment response as indicated by one of the following BCR-ABL1 transcript levels: Less than or equal to 10 percent at 3 months, or Less than or equal to 10 percent at 6 months, or Less than or equal to 1 percent at 12 months, or Less than 0.1 percent beyond 12 months. B. FOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL): (1) Patient continues to meet initial criteria AND (2) Prescriber attests patient has had a treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenetic analysis, QPCR, or FISH. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a Hematologist or Oncologist |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |

# BRISDELLE NON FORMULARY

## Products Affected

- BRISDELLE
- *paroxetine mesylate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Vasomotor symptoms associated with menopause, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE: (1) Prescriber attests to a diagnosis of vasomotor symptoms associated with menopause AND (2) Patient has tried and failed, been intolerant to or has contraindication to estrogen therapy (medication usage must be supported by documentation from the patients chart notes/medical records) AND (3) Patient has tried and failed or been intolerant to a trial of paroxetine, as well as all other generic formulary SSRIs (i.e., fluoxetine, citalopram, escitalopram and sertraline). Medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BROVANA

## Products Affected

- BROVANA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic obstructive pulmonary disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): (1) Prescriber attests to a documented diagnosis of chronic obstructive pulmonary disease AND (2) Trial and failure, contraindication or intolerance to therapy with all of the following: Serevent, Spiriva and if on formulary, Stiolto. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BUPRENORPHINE PAIN

## Products Affected

- *buprenorphine hcl injection*
- *buprenorphine transdermal*
- BUTRANS TRANSDERMAL PATCH WEEKLY 10 MCG/HR, 15 MCG/HR, 20 MCG/HR, 5 MCG/HR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe chronic pain, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | PRODUCTS AFFECTED: BUPRENEX (buprenorphine) injection and BUTRANS (buprenorphine) transdermal. A. MODERATE TO SEVERE CHRONIC PAIN: INITIAL: (1) Prescriber attests to diagnosis of moderate to severe chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate AND (2) Must have a documented diagnosis chronic pain requiring daily, around the clock opioid treatment and for which alternative treatment options are inadequate AND (3) Does not have significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected gastrointestinal obstruction, including paralytic ileus. RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria. |
| **Age Restrictions** | 18 years of age or older prior to approval of Butrans and 2 years of age or older prior to approval of Buprenex |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# BYDUREON

## Products Affected

- BYDUREON
- BYDUREON BCISE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Type 2 Diabetes Mellitus, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TYPE 2 DIABETES MELLITUS: (1) Prescriber attests to a diagnosis of Type 2 Diabetes Mellitus AND (2a) Trial and failure of metformin in combination with a sulfonylurea, insulin, or a thiazolidinedione [TZD] OR (2b) Tried and failed, intolerance or contraindication to metformin and one of the following: A contraindication to, or a clinical condition precluding use of all of the following: sulfonylurea, insulin and thiazolidinedione (TZD) OR An inadequate response or persistent adverse effect to one of the following: sulfonylurea, insulin or thiazolidinedione (TZD) AND (3) Trial and failure, intolerance, or contraindication to all of the following: Byetta AND Trulicity AND (4) Must have copies of recent Hgba1c labs that illustrate levels between 7.0 and 10.0. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CANASA

## Products Affected

- CANASA
- *mesalamine rectal suppository*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ulcerative Colitis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. Ulcerative Colitis: (1) Prescriber attests to a diagnosis of Ulcerative Colitis AND (2) Patient has had a trial and failure of all of the following: Mesalamine 1.2gm DR, Mesalamine 800mg DR and Mesalamine 4gm Enema. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CAPRELSA

## Products Affected

- CAPRELSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Follicular/Hurthle Cell/Papillary Carcinoma, Progressive and/or symptomatic medullary carcinoma that is unresectable, locally advanced or metastatic, Non-Small Cell Lung Cancer, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Prescriber attests that patient does not have any electrolyte abnormalities |
| **Required Medical Information** | INITIAL: A. FOLLICULAR/HURTHLE CELL/PAPILLARY CARCINOMA: (1) Prescriber attests to a diagnosis of Follicular/Hurthle Cell/Papillary Carcinoma AND (2) Patients disease is one of the following: metastatic, unresectable, recurrent, and/or persistent locoregional AND (3) Patients disease is progressive and/or symptomatic iodine refractory AND (4) Systemic therapy is not available/appropriate. B. PROGRESSIVE AND/OR SYMPTOMATIC MEDULLARY CARCINOMA: (1) Prescriber attests to a diagnosis of Progressive and/or symptomatic medullary carcinoma that is unresectable, locally advanced or metastatic. C. NON-SMALL LUNG CANCER: (1) Prescriber attests to a diagnosis of Non-Small Cell Lung Cancer AND (2) Patients tumor is confirmed to have RET gene rearrangements. RENEWAL FOR ALL INDICATIONS: (1) Patient continues to meet initial approval criteria AND (2) Prescriber attests to tumor response with stabilization of disease or decrease in size of tumor or tumor spread. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Oncologist. |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |

# CARAFATE SUSPENSION

## Products Affected

- CARAFATE ORAL SUSPENSION
- *sucralfate oral suspension*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Active duodenal ulcer disease, Gastritis, Gastric ulcer, Stress ulcer prophylaxis, Palliative treatment of aphthous ulcer, Palliative treatment of stomatitis due to chemotherapy or radiation, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACTIVE DUODENAL ULCER DISEASE, GASTRITIS, GASTRIC ULCER, STRESS ULCER PROPHYLAXIS: (1) Prescriber attests to a diagnosis of one (1) of the following: Active duodenal ulcer disease, Gastritis, Gastric Ulcer or Stress Ulcer prophylaxis AND (2) Trial and failure, intolerance, or contraindication to Sucralfate Tablet. B. PALLIATIVE TREATMENT OF APHTHOUS ULCER, PALLIATIVE TREATMENT OF STOMATITIS DUE TO CHEMOTHERAPY OR RADIATION: (1) Prescriber attests to a diagnosis of Palliative treatment of aphthous ulcer or Palliative treatment of stomatitis due to chemotherapy or radiation. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CEPROTIN SODIUM NON FORMULARY

## Products Affected

- CEPROTIN INTRAVENOUS SOLUTION RECONSTITUTED 1000 UNIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Congenital Protein C Deficiency, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CONGENITAL PROTEIN C DEFICIENCY: INITIAL: (1) Prescriber attests to a diagnosis of congenital protein C deficiency AND (2a) Prescribed for use in an acute setting OR (2b) Lab result confirming low protein C activity (due to low protein C levels or function or both). RENEWAL: (1) Prescriber attests that member is responding positively to therapy AND (2) If not previously determined, lab result confirms low protein C activity (due to low protein C levels or function or both). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or physician with expertise in inherited thrombophilias. |
| **Coverage Duration** | Initial: 6 months Renewal: 12 months |
| **Other Criteria** | None |

# CHENODAL NON FORMULARY

## Products Affected

- CHENODAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cerebrotendinous xanthomatosis (CTX), Radiolucent Gallstone, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CEREBROTENDINOUS XANTHOMATOSIS (CTX), RADIOLUCENT GALLSTONE: (1) Prescriber attests to a diagnosis of Cerebrotendinous xanthomatosis (CTX) or Radiolucent Gallstone AND (2) Tried/failed/intolerance to ursodiol. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CIALIS

## Products Affected

- CIALIS ORAL TABLET 2.5 MG, 5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Benign prostatic hypertrophy |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BENIGN PROSTATIC HYPERTROPHY: (1) Prescriber attests to a diagnosis of benign prostatic hypertrophy AND (2) Patient is NOT on nitrates AND (3) Tried/failed/intolerance to (6 month trial of ALL the following): Doxazosin or terazosin, Tamsulosin AND Finasteride AND (4) Prescribed for 2.5mg or 5mg tablets (ONLY Cialis 5mg is FDA approved for BPH, 2.5mg is also permissible per the package insert). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a urologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CIMZIA

## Products Affected

- CIMZIA
- CIMZIA PREFILLED
- CIMZIA STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Crohns Disease/Fistulizing Crohns disease, Rheumatoid Arthritis, Ankylosing Spondylitis (AS), Plaque psoriasis, moderate to severe, Psoriatic Arthritis (PsA), Non-Radiographic Axial Spondyloarthritis (nraxSpA), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections OR Individuals who have not had a tuberculin skin (TST), or a CDC-recommended equivalent, to evaluate for latent tuberculosis OR Using in combination with other TNF antagonists OR Using in combination with the following non-TNF immunomodulatory drugs: abatacept (Orencia), anakinra (Kineret), natalizumab (Tysabri), or rituximab (Rituxan). |
| **Required Medical Information** | INITIAL A. CROHNS DISEASE/FISTULIZING CROHNS DISEASE: (1) Prescriber attests to a diagnosis of Crohns disease AND (2) Failed/intolerant to at least one corticosteroid AND (3) Failed/intolerant to Humira AND (4) Failed/intolerant to at least one of the following: sulfasalazine (Azulfidine) or mesalazine (Asacol, Pentasa). B. RHEUMATOID ARTHRITIS: (1) Prescriber attests to a diagnosis of rheumatoid arthritis AND (2) Failed/intolerant to Enbrel and Humira AND (3) Failed/intolerant to at least one of the following: azathioprine (Imuran), 6-mercaptopurine (Purinethol), or methotrexate. C. ANKYLOSING SPONDYLITIS (AS): (1) Prescriber attests to a diagnosis of Ankylosing Spondylitis (AS) AND (2) Individual has failed to respond to, is intolerant of, or has medical contraindication to conventional therapy (such as NSAIDs or non-biologic DMARDs) AND (3) Failed/intolerant to Enbrel and Humira in the previous 180 days. D. PLAQUE PSORIASIS: (1) Prescriber attests to a documented diagnosis of plaque psoriasis AND (2a) Plaque psoriasis must involve greater than or equal to 5 percent of the body surface area (BSA) OR Patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (2b) Three of the following (i) Patient has had an inadequate response to 3-month trial of either topical therapy or localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA]) for psoriasis OR (ii) Patient has had an inadequate response to a 3-month trial of systemic therapy (i.e. MTX, cyclosporine, acitretin [Soriatane]) OR (iii) Patient has significant disability or impairment in |

| PA Criteria | Criteria Details |
|---|---|
| | physical or mental functioning, according to the treating physician AND (3) Failed/intolerant to Enbrel and Humira in the previous 180 days. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a specialist in the condition they are treating. RA: prescribed by or in consultation with a rheumatologist. CD: prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | E. PSORIATIC ARTHRITIS (PsA): (1) Prescriber attests to a diagnosis of active Psoriatic arthritis (PsA) AND (2) Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as non-biologic DMARDs) AND (3) Failed/intolerant to Enbrel and Humira in the previous 180 days. F. NON-RADIOGRAPHRIC AXIAL SPONDYLOARTHRITIS (nraxSpA): (1) Prescriber attests to a diagnosis of active non-radiographic axial spondyloarthritis AND (2) Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as NSAIDs or nonbiological DMARDs such as sulfasalazine) AND (3) Individual has had an inadequate response to, is intolerant of, or has a contraindication to Humira. RENEWAL FOR ALL INDICATIONS: (1) Achievement of clinical response. |

# CIPRO HC

## Products Affected

- CIPRO HC

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute Otitis Externa, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACUTE OTITIS EXTERNA (1) Prescriber attests patient has acute otitis externa AND (2) Patient has tried and failed two of the following (a) Neomycin-Polymyxin-HC otic suspension or otic solution (b) Ofloxacin otic solution (c.) Ciprofloxacin 0.2% otic solution |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# COMETRIQ

## Products Affected

- COMETRIQ (60 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Progressive, metastatic medullary thyroid cancer. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PROGRESSIVE, METASTATIC MEDULLARY THYROID CANCER (1) Prescriber attests patient has a diagnosis of progressive, metastatic medullary thyroid cancer |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CONDYLOX

## Products Affected

- CONDYLOX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Condyloma acuminatum, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CONDYLOMA ACUMINATUM (1) Prescriber attests patient has diagnosis of condyloma acuminatum AND (2) Patient has had a trial and failure to Podofilox 5% solution |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# COPAXONE

## Products Affected

- *glatiramer acetate*
- GLATOPA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 20 MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing-remitting Multiple Sclerosis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Concurrent use of glatiramer acetate with interferon beta-1a (Avonex, Rebif) ,interferon beta-1b (Betaseron, Extavia) or natalizumab (Tysabri) |
| **Required Medical Information** | A. RELAPSING-REMITTING MULTIPLE SCLEROSIS INITIAL (1) Prescriber attests patient has a diagnosis of relapsing-remitting MS (Note: Relapsing forms of MS include relapsing-remitting, secondary progressive with relapses, and progressive relapsing or clinically isolated MS) (2) Copaxone 40mg/mL requests: (2a) Must be started and stabilized on Glatiramer 20mg AND (2b) Must have valid medical reason why the 20mg daily dose cannot be used (i.e. clinically significant and intolerable post-injection reaction, individual requires assistance by caregiver to administer injections and caregiver is unable to administer injections on daily basis, etc. Convenience/preference is excluded.) B. CONTINUATION OF THERAPY (1) Medical records/chart notes from neurology consultation documenting the improvement of the relapsing rate or that the patients clinical condition is stabilized with the current therapy with no significant adverse effects. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a Neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CORDRAN

## Products Affected

- *flurandrenolide external cream*
- *flurandrenolide external lotion*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Corticosteroid responsive dermatoses, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CORTICOSTEROID RESPONSIVE DERMATOSES (1) Prescriber attests patient has diagnosis of corticosteroid responsive dermatoses AND (2) Trial, failure or intolerance to ALL of the formulary preferred topical steroids of similar potency (Medium potency alternatives) (2a) If preferred medium potency alternative trials are completed and do not yield adequate relief, the member must also provide a clinical reason for requesting a non-preferred alternative in the same potency instead of trying a high potency. (Medium potency: betamethasone valerate 0.1% cream and lotion, desoximetasone 0.05% cream, fluocinolone 0.025% cream and ointment, fluticasone 0.05% cream, hydrocortisone butyrate 0.1% solution, ointment, mometasone 0.1% cream and ointment and triamcinolone 0.1% cream, lotion and ointment. Medium to High potency: betamethasone diprop 0.05% cream and fluticasone 0.05% ointment.High potency: betamethasone diprop 0.05% ointment, betamethasone valerate 0.1% ointment, desoximetasone 0.025% cream and ointment, desoximetasone 0.05% gel, diflorasone 0.05% cream, fluocinonide 0.05% gel, ointment and cream and triamcinolone 0.5% cream and ointment. Ultra High potency: betamethasone dipropionate AUG 0.05% cream, gel, lotion and ointment, clobetasol 0.05% solution, gel and cream, diflorasone 0.05% ointment and halobetasol 0.05% cream and ointment) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CORLANOR

## Products Affected

- CORLANOR ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Stable, symptomatic heart failure (NYHA II-IV), Symptomatic NYHA class II-IV heart failure due to dilated cardiomyopathy, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Acute decompensated heart failure, Blood pressure less than 90/50 mm Hg, Sick sinus syndrome, sinoatrial block, or third-degree atrioventricular (AV) block (unless a functioning demand pacemaker is present), Resting heart rate less than 60 bpm prior to treatment, Severe hepatic impairment, Pacemaker dependence (heart rate maintained exclusively by the pacemaker), Concomitant use with strong CYP3A4 inhibitors |
| **Required Medical Information** | A. STABLE, SYMPTOMATIC HEART FAILURE (NYHA II-IV) (1) Prescriber attests patient has diagnosis of stable, symptomatic heart failure (NYHA II-IV) AND (2) Left ventricular ejection fraction less than or equal to 35% AND (3) In sinus rhythm AND (4) Resting heart rate greater than or equal to 70 beats per minute AND (5) Have symptoms despite maximal beta-blocker therapy or have documented contraindication to beta-blocker use AND (6) Trial, failure, or contraindication to ACE-inhibitor or ARB therapy AND (7) Have blood pressure greater than 90/50 mmHg AND (8) Must not be dependent on a pacemaker B. SYMPTOMATIC NYHA CLASS II-IV HEART FAILURE DUE TO DILATED CARDIOMYOPATHY (1) Prescriber attests patient has diagnosis of symptomatic NYHA class II-IV heart failure due to dilated cardiomyopathy AND (2) Prescriber attests to a resting heart rate of greater than or equal to 70 beats per minute AND (3) In sinus rhythm C. RENEWAL CRITERIA (1) Prescriber attests that patient continues to meet initial criteria AND (2) Prescriber attests that patient has experienced disease stabilization or improvement with medication. |
| **Age Restrictions** | Stable, symptomatic heart failure (NYHA II-IV)= 18 years of age or older, Symptomatic NYHA class II-IV heart failure due to dilated cardiomyopathy =6 months of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | None |

# CORTIFOAM NON-FORMULARY

## Products Affected

- CORTIFOAM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Adjunctive rectal treatment of chronic ulcerative colitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADJUNCTIVE RECTAL TREATMENT OF CHRONIC ULCERATIVE COLITIS (1) Prescriber attests that requested medication is being used as adjunctive rectal treatment of chronic ulcerative colitis, notably disease limited to the distal portion of the rectum (ulcerative proctitis), AND (2) Patient has documented inability to retain corticosteroid enema (COLOCORT ENEMA) Dosage: 1 applicatorful rectally (80mg hydrocortisone) 1-2 times daily for 2-3 weeks. Then every other day. Discontinue if no improvement within 2-3 weeks. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# COSENTYX NON-FORMULARY

## Products Affected

- COSENTYX
- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SENSOREADY PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Active non-radiographic axial spondyloarthritis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MODERATE TO SEVERE PLAQUE PSORIASIS (1) Prescriber attests patient has a diagnosis of moderate to severe plaque psoriasis, with documentation of disease severity and BSA coverage AND (2) Must have documentation of a negative TB test within the previous 12 months AND (3) 5. Must have failed or intolerance to a 3-month course of at least 1 conventional or non-biologic disease modifying therapy, such as methotrexate, cyclosporine, PUVA or UVB AND (4) Must have failed or have intolerance to Enbrel and Humira B. PSORIATIC ARTHRITIS (1) Prescriber attests patient has a diagnosis of psoriatic arthritis AND (2) Must have documentation of a negative TB test within the previous 12 months AND (3) Must have failed or intolerance to a non-biologic DMARD therapy AND (4) Must have failed or have intolerance to Enbrel and Humira C. ANDKYLOSING SPONDYLITIS (1) Prescriber attests patient has a diagnosis of ankylosing spondylitis AND (2) Must have documentation of a negative TB test within the previous 12 months AND (3) Must have failed or intolerance to two different NSAIDs AND (4) Must have failed or have intolerance to Enbrel and Humira |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Moderate to severe Plaque Psoriasis =Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | D. ACTIVE NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (1) Prescriber attests to diagnosis of Active non-radiographic axial spondyloarthritis AND (2) Patient has objective signs of inflammation with a C-reactive protein AND (3) Patient has ALL of the following (3a) |

| PA Criteria | Criteria Details |
|---|---|
| | active disease as defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of 4 or greater AND (3b) a visual analog scale (VAS) for total back pain of 40 or higher on a 100-point scale despite NSAID therapy AND (3c) no evidence of radiographic changes in the sacroiliac joints that would meet criteria for ankylosing spondylitis |

# CRESEMBA

## Products Affected

- CRESEMBA ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Invasive aspergillosis species or other filamentous fungi, Invasive mucormycosis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Coadministration with strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir, Coadministration with strong CYP3A4 inducers, such as rifampin, carbamazepine, St. Johns wort, or long acting barbiturates ,Use in patients with familial short QT syndrome |
| **Required Medical Information** | A. INVASIVE ASPERGILLOSIS SPECIES OR OTHER FILAMENTOUS FUNGI (1) Prescriber attests to diagnosis of invasive aspergillosis species or other filamentous fungi that is susceptible to the requested medication AND (2) Patient has had a clinical trial and failure, intolerance, or contraindication to therapy with voriconazole B. INVASIVE MUCOMYCOSIS (1) Prescriber attests to diagnosis of invasive mucormycosis AND (2) All of the following have been completed before initiation of treatment: (2a) Liver enzyme test AND (2b) Fungal culture report showing sensitivity to requested medication CAUTION: Hepatic Adverse Drug Reactions, Infusion-related reactions, Serious hypersensitivity and skin reactions (i.e.- anaphylaxis or Stevens Johnson syndrome) , Embryo-Fetal Toxicity, Insoluble drug particulates may form following reconstitution, Drug interactions |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Infectious Disease specialist |
| **Coverage Duration** | Initial 3 months, Renewal 3 months |
| **Other Criteria** | None |

# CRINONE GEL

## Products Affected

- CRINONE
- ENDOMETRIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Secondary Amenorrhea, Supplementation or replacement as part of an Assisted Reproductive Technology (ART) , Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL THERAPY A. ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT (1) Request is for Crinone 8% or Endometrin AND (3) Must meet one of the following (3a) Use as ART treatment for infertile women with progesterone deficiency OR (3b) Use in ART treatment in patients with partial or complete ovarian failure OR (3c) For support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an ART treatment program for infertile women B. LUTEAL PHASE SUPPORT (I.E. HISTORY OF SPONTANEOUS ABORTIONS) (1) Prescriber attests to this being used in luteal phase support AND (2) Request is for Crinone 8% or Endometrin C. SECONDARY AMENORRHEA (1) Prescriber attests to diagnosis of secondary amenorrhea AND (2) Request is for Crinone 4% or 8% AND (3) Clinical trial and failure to one alternative progestin (e.g., medroxyprogesterone, norethindrone) unless contraindicated or clinically significant adverse effects are experienced D.PREVENTION OF PRETERM BIRTH (1) Prescriber attests that this is used in prevention of preterm birth AND (2) Documentation of one of the following (2a) short cervix OR (2b) Singleton pregnancy and a history of spontaneous preterm birth |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial 12 months , Renewal 12 months |
| **Other Criteria** | CONTINUED THERAPY A. ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT (1) Currently receiving medication via health plan benefit or member has previously met initial |

| PA Criteria | Criteria Details |
| --- | --- |
| | approval criteria AND (2) Request is for Crinone 8% or Endometrin AND (3) Prescriber attests to a positive response to therapy B. LUTEAL PHASE SUPPORT (I.E. HISTORY OF SPONTANEOUS ABORTIONS) (1) Currently receiving medication via health plan benefit or member has previously met initial approval criteria AND (2) Request is for Crinone 8% or Endometrin AND (3) Prescriber attests to a positive response to therapy C. SECONDARY AMENORRHEA (1) Currently receiving medication via health plan benefit or member has previously met initial approval criteria AND (2) Prescriber attests to a positive response to therapy D. PREVENTION OF PRETERM BIRTH (1) Currently receiving medication via health plan benefit or member has previously met initial approval criteria AND (2) Prescriber attests to a positive response to therapy |

# CUPRIMINE NON FORMULARY

## Products Affected

- CUPRIMINE
- *penicillamine oral capsule*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Wilsons Disease, Cystinuria, Severe, active RA, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Pregnancy (except in Wilsons disease), Breastfeeding , Hypersensitivity to penicillamine, Rheumatoid arthritis patients with present or history of renal insufficiency |
| **Required Medical Information** | A. WILSONS DISEASE (1) Prescribers attests to diagnosis of Wilsons Disease AND (2) Has had trial and failure, or intolerance to Depen Titra Tab as documented by medical records or recent paid claim history AND (3) Confirmation of diagnosis through genetic testing OR presence of three of the following diagnostic features (3a) Presence of Kayser-Fleischer rings OR (3b) Serum ceruloplasmin (CPN) less than20 mg/Dl OR (3c) 24-hour urine Copper greater than 40 mcg OR (3d) Liver biopsy with copper dry weight greater than 250 mcg/g B.CYSTINURIA (1) Prescriber attests to diagnosis of cystinuria AND (2) Failure to respond (or contraindication) to urinary alkalization therapy with potassium citrate in the last 180 days C. SEVERE, ACTIVE RHEUMATOID ARTHRITIS (1) Prescribers attests to diagnosis of severe, active Rheumatoid arthritis AND (2) Failure to respond (or contraindication) to at least two of the following non-biologic disease modifying anti-rheumatic drugs (2a) Hydroxychloroquine OR (2b) Leflunomide OR (2c) Methotrexate OR (2d) Sulfasalazine AND (3) Failure to respond (or contraindication) to each of the following biologic therapies (3a) Enbrel (prior authorization required) AND (3b) Humira (prior authorization required) AND (4) Failure to respond (or contraindication) to at least two of the following biologic therapies (PA required for all): (4a) Actemra, Cimzia, Orencia, Kineret, Remicade, Rituxan |
| **Age Restrictions** | Wilsons Disease= 5 years of age or older, Cystinuria= 1 year of age or older, Severe, Active Rheumatoid arthritis= 18 years of age or older |
| **Prescriber Restrictions** | Severe, Active Rheumatoid arthritis= Prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | WD: Initial-6 months, Renewal- 1 year, Cystinuria, RA: Initial-3 months, Renewal- 6 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | None |

# CYSTADANE

## Products Affected

- CYSTADANE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Homocystinuria,  Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HOMOCYSTINURIA INITIAL  (1) Prescriber attests to diagnosis of homocystinuria, including deficiencies or defects in cystathionine beta-synthase (CBS), 5,10-methylenetetrahydrofolate reductase (MTHFR), and cobalamin factor metabolism (CBL) B. RENEWAL (1) Continue to meet initial therapy criteria and (2) Prescriber attests to positive response |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a physician specializing in metabolic disorders and genetics |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# CYSTAGON

## Products Affected

- CYSTAGON

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Nephropathic cystinosis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Contraindicated in patients who have developed hypersensitivity to Cystagon or to cysteamine or penicillamine. |
| **Required Medical Information** | A. NEPHROPATHIC CYSTINOSIS (1) Prescriber attests to diagnosis of nephropathic cystinosis AND (2) Condition confirmed by one of the following (2a) By leukocyte cystine measurements greater than normal (nl range normal values are less than0.2 nmol half-cystine/mg protein) OR (2b) By DNA testing (two mutations in the CTNS gene, the only gene) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# DANAZOL

## Products Affected

- *danazol oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Endometriosis amenable to hormonal management, Fibrocystic breast disease, Hereditary angioedema, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ENDOMETRIOSIS AMENABLE TO HORMONE MANAGEMENT (1) Prescriber attests to diagnosis of Endometriosis amenable to hormonal management AND (2) Must have a diagnosis of endometriosis confirmed by laparoscopy (2a) If the diagnosis is not confirmed by surgery, then chart documentation of an adequate work-up and the clinical rationale for the diagnosis must be provided AND (3) Must have had an adequate trial of oral contraceptives and/or progestins with an inadequate response or significant side effects or must have a contraindication to these therapies AND (4) Must not have abnormal genital bleeding, impaired hepatic, renal, or cardiac function, or porphyria AND (5) Must have a confirmed negative pregnancy test prior to starting therapy and must not be breastfeeding OR must be post-menopausal AND (6) Must not have an Androgen-dependent tumor AND (7) Must not have active thrombosis or thromboembolic disease and history of such events B. FIBROSYSTIC BREAST DISEASE (1) Prescriber attests to diagnosis of Fibrocystic breast disease AND (2) Must have symptomatic disease (such as pain, tenderness, discomfort) AND (3) Must have had an adequate trial of at least one non-pharmacologic therapy (such as padded brassieres) with inadequate response AND at least one analgesic therapy with an inadequate response or significant side effects /toxicity or must have a contraindication to all analgesic therapies AND (4) Must not have abnormal genital bleeding, impaired hepatic, renal, or cardiac function, or porphyria AND (5) Must have a confirmed negative pregnancy test prior to starting therapy and must not be breastfeeding OR must be post-menopausal AND (6) Must not have an Androgen-dependent tumor AND (7) Must not have active thrombosis or thromboembolic disease and history of such events |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a gynecologist =endometriosis amenable to hormonal management, fibrocystic breast disease. Prescribed by or in consultation with an allergist/immunologist= Hereditary angioedema |
| **Coverage Duration** | 12 months |
| **Other Criteria** | C. HEREDITARY ANGIOEDEMA (1) Prescriber attests to diagnosis of Hereditary angioedema AND (2) Must be used as prophylactic therapy for the prevention of hereditary angioedema attacks AND (3) Must not have abnormal genital bleeding, impaired hepatic, renal, or cardiac function, or porphyria AND (4) Must have a confirmed negative pregnancy test prior to starting therapy and must not be breastfeeding OR must be post-menopausal AND (5) Must not have an Androgen-dependent tumor AND (6) Must not have active thrombosis or thromboembolic disease and history of such events RENEWAL FOR ALL INDICATIONS (1) Initial criteria continues to be met AND (2) Prescriber attests to positive clinical response |

# DARAPRIM

## Products Affected

- DARAPRIM
- *pyrimethamine oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Toxoplasmosis, Pneumocystis Pneumonia Prophylaxis, Isosporiasis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Pneumocystis pneumonia treatment, Use of drug in patients with documented megaloblastic anemia due to folate deficiency |
| **Required Medical Information** | A. TOXOPLASMOSIS (1) Prescriber attests to diagnosis of toxoplasmosis AND (2) Primary prophylaxis must meet all (2a) Must be Toxoplasma-seropositive (IgG labs must be submitted) AND (2b) CD4 count less than 200 cells/mm3 AND (2c) Must have trial, failure, or contraindication to TMP-SMX AND (2d) Prescriber has informed patient importance of, and will monitor, adherence to antiretroviral therapy AND (2e) (For renewals only): Indications for discontinuation of prophylaxis have been evaluated, including= CD4 count greater than 200 cells/mm3 for at least 3 months OR (3) Acute Treatment must meet all (3a) Must be Toxoplasma-seropositive (IgG labs must be submitted) AND (3b) Will not be used as monotherapy OR (4) Secondary prophylaxis (maintenance treatment) must meet all (4a) Must have completed initial treatment regimen AND (4b) CD4 count less than 200 cells/mm3 AND (4c) Prescriber has informed patient importance of, and will monitor, adherence to antiretroviral therapy AND (4d) (For renewals only): Indications for discontinuation of prophylaxis have been evaluated, including: Remain asymptomatic AND CD4 count greater than 200 cells/mm3 for at least 6 months B. PNEUMOCYSTIS PNEUMONIA PROPHYLAXIS (1) Prescriber attests to diagnosis of pneumocystis pneumonia prophylaxis AND (2) Must meet ONE of the following (2a) CD4 count less than 200 cells/mm3 OR (2b) Oropharyngeal candidiasis OR (2c) CD4% less than 14% OR (2d) History of AIDS-defining illness OR (2e) CD4 count greater than 200 but less than 250 cells/mm3 and if CD4 cell count monitoring (e.g. every 3 months) is not possible OR (2f) Prior PCP infection AND (3) Must have trial, failure, or contraindication to ALL of the following (3a) TMP-SMX, Dapsone, Pentamidine and Atovaquone AND (4) (For renewals only): Indications for discontinuation of prophylaxis have been evaluated, including= CD4 count greater than 200 cells/mm3 for at least 3 months |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Primary prophylaxis= 6months, Treatment and secondary prophylaxis= 12 months |
| **Other Criteria** | C. ISOSPORIASIS (1) Prescriber attests to a current or previous diagnosis of Isosporiasis AND (2) Must have trial, failure, or contraindication to TMP-SMX AND (3) (For renewals only) Indications for discontinuation of prophylaxis have been evaluated, including= Remain asymptomatic AND CD4 count greater than 200 cells/mm3 for at least 6 months |

# DAYTRANA NON FORMULARY

## Products Affected

- DAYTRANA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Attention deficit hyperactivity disorder, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADHD (1) Prescriber attests to diagnosis of ADHD (supported by documentation from the patients chart notes/medical records) AND (2) Tried and failed, intolerance or contraindication to at least a 30-day trial of ALL of the following (medication usage must be supported by documentation from the patients chart notes/medical records/ electronic claim history) (2a) Amphetamine IR AND dextroamphetamine ER AND Long-acting and regular strength methylphenidate AND Amphetamine ER AND Focalin XR and Vyvanse OR (3) Clinical inability to swallow a tablet or capsule (verified by reviewing electronic claim history) and unable to use opened capsules due to a clinical reasons (supported by documentation from the patients chart notes/medical records) |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# DDAVP (DESMOPRESSIN) SOLUTION

## Products Affected

- *desmopressin acetate injection*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Central Cranial Diabetes Insipidus, Hemophilia A, von Willebrands disease (Type I) , Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CENTRAL CRANIAL DIABETES INSIPIDUS (1) Prescriber attests to diagnosis of Central Cranial Diabetes Insipidus B. HEMOPHILIA A, VON WILLEBRANDS DISEASE (TYPE 1) (1) Prescriber attests to diagnosis of Hemophilia A, von Willebrands disease (Type I) RENEWAL (1) Member continues to meet initial therapy criteria AND (2) Prescriber attests that patient is positively responding to therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# DENAVIR

## Products Affected

- DENAVIR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Herpes Labialis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HERPES LABIALIS (1) Prescriber attests to diagnosis of Herpes Labialis AND (2) Patient has tried and failed or has a documented intolerance to OTC Abreva 10% cream |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# DIBENZYLINE (PHENOXYBENZAMINE)

## Products Affected

- DIBENZYLINE
- *phenoxybenzamine hcl oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pheochromocytoma, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PHEOCHROMOCYTOMA (1) Prescriber attests to diagnosis of pheochromocytoma AND (2) Patient must have surgery planned, have a contraindication to surgery, or have malignant pheochromocytoma |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an endocrinologist or an endocrine surgeon, |
| **Coverage Duration** | Initial - 3 months, Renewal- 12 months |
| **Other Criteria** | None |

# DIFICID

## Products Affected

- DIFICID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Clostridium difficile-associated diarrhea, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CLOSTRIDIUM DIFFICILE- ASSOCIATED DIARRHEA (CDAD) (1) Prescriber attests to diagnosis of Clostridium difficile-associated diarrhea (CDAD) confirmed by a positive stool assay AND (2) The patient has any ONE of the following: (2a) High risk of Clostridium difficile Infection (CDI) recurrence OR (2b) Recurrent infection with Clostridium difficile after previous antibiotic therapy OR (2c) Requires additional medication to complete a 10 day course of Dificid therapy that was initiated in the hospital OR (3) The patient has experienced inadequate treatment response to metronidazole after a trial of at least 10 days OR has intolerance, contraindication to or is not a candidate for treatment with metronidazole (e.g., severe Clostridium difficile Infection [CDI], second recurrence) AND (4) The patient has experienced inadequate treatment response to FIRST-Vancomycin (vancomycin hydrochloride) after a trial of at least 7 days, OR has intolerance or contraindication to FIRST-Vancomycin (vancomycin hydrochloride) QTY LIMIT 20 per 10 day supply |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# DIPENTUM

## Products Affected

- DIPENTUM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mild to Moderate Ulcerative Colitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MILD TO MODERATE ULCERATIVE COLITIS (1) Prescriber attests to diagnosis of mild to moderate ulcerative colitis AND (2) Tried and failed, intolerance, or contraindication to ALL of the following (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) (2a) sulfasalazine (immediate-release/delayed-release), balsalazide, Apriso (maintenance of remission), Delzicol, Pentasa |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a Gastroenterologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# DUPIXENT NON FORMULARY

## Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe atopic dermatitis, Moderate to severe asthma with an eosinophilic phenotype OR with oral corticosteroid dependent asthma, Chronic Rhinosinusitis with Nasal Polyposis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MODERATE TO SEVERE ATOPIC DERMATITIS (1) Prescriber attests to diagnosis of moderate to severe atopic dermatitis with a baseline EASI (Eczema Area and Severity Index) score of 25 AND (2) Must have moderate to severe atopic dermatitis which has not responded to ALL of the following therapies or cannot use the products due to side-effects: (2a) TWO High potency topical steroids (i.e. Halobetasol propionate, Augmented betamethasone dipropionate) AND (2b) Elidel Ointment OR topical tacrolimus AND (2C) Eucrisa RENEWAL (1) Continuation of therapy will be allowed for patients who meet the following (1a) Reduction in EASI scores AND (1b) Decrease in pruritus AND (1c) Decrease in affected body area by 50% B. CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP): INITIAL: (1) Prescriber attests that patient has a diagnosis of CRSwNP with the presence of nasal polyps AND (2) Prescriber attests that patient has two or more of the following symptoms for greater than or equal to 12 weeks a. mucopurulent discharge OR b. nasal obstruction and congestion OR c. decreased or absent sense of smell OR d. facial pressure or pain (3) Prescriber attests that patient is unable to achieve symptom relief after trial of 2 intranasal corticosteroids for at least 3 months AND a trial and failure of a systemic corticosteroid AND (4) Prescriber attests that patient will continue to use Dupixent in combination with intranasal corticosteroid therapy RENEWAL (1) Prescriber attests patient has positive response to treatment |
| **Age Restrictions** | 6 years of age and older - AD, 12 years of age or older - Asthma , 18 years of age or older- Rhinosinusitis |
| **Prescriber Restrictions** | Must be prescribed by a dermatologist, an allergist, pulmonologist or an immunologist |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial- 6 months, Renewal- 12 months |
| **Other Criteria** | C. MODERATE TO SEVERE ASTHMA WITH AN EOSINOPHILIC PHENOTYPE OR WITH ORAL CORTICOSTERIOD DEPENDENT ASTHMA (1) Prescriber attests to diagnosis of moderate to severe asthma with an eosinophilic phenotype OR with oral corticosteroid dependent asthma AND (2) Member has experienced at least 2 exacerbations, within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., high dose inhaled corticosteroid (ICS) plus either a long acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindicated/intolerance) (2a) Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid) OR (2b) Urgent care visit or hospital admission OR (2c) Intubation OR (3) For patients without oral corticosteroid dependent asthma Eosinophilic phenotype defined as EITHER of the following (3a) Blood eosinophils greater than or equal to 150 cells/mcl within the previous 6 weeks OR (3b) History of blood eosinophils greater than or equal to 300 cells/mcl AND (3c) Continued use of an inhaled corticosteroid AND another controller therapy (for example, long-acting beta-agonist, leukotriene receptor) AND (4) Will not be used in combination with Xolair, Nucala, Cinqair or Fasenra RENEWAL (1) Patient has experienced an improvement in symptoms (reduction in exacerbation, reduction in oral glucocorticoids, improvement in FEV1) AND (2) Patient continues to tolerate treatment FOR ALL INDICATIONS Quantity/Partial Fill Restrictions = Maximum of 2 cartons (4 syringes) per 28 days (initial), 1 carton (2 syringes) per 28 days maintenance |

# DYSPORT

## Products Affected

- DYSPORT INTRAMUSCULAR SOLUTION RECONSTITUTED 300 UNIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cervical dystonia, Spasmodic torticollis, treatment of upper or lower limb spasticity, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CERVICAL DYSTONIA OR SPASMODIC TORTICOLLIS (1) Prescriber attests to diagnosis of Cervical dystonia or Spasmodic torticollis AND (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records AND (3) Have no contraindications including (3a) pregnancy OR (3b) sensitivity or allergic reaction to other botulinum toxins OR (3c) allergy to cows milk protein OR (3d) Not being used for treatment of moderate to severe glabellar lines B. LOWER OR UPPER LIMB SPASTICITY (1) Prescriber attests is being used for the treatment of lower limb spasticity OR the treatment of upper limb spasticity AND (2) Patient does not have spasticity caused by cerebral palsy AND (3) No contraindications including (3a) pregnancy OR (3b) sensitivity or allergic reaction to other botulinum toxins OR (3c) allergy to cows milk protein OR (3d) Not being used for treatment of moderate to severe glabellar lines CAUTION (1) Potency of units between different preparations of botulinum toxin products is not interchangeable AND (2) Spread of toxin effects may cause swallowing and breathing difficulties AND (3) Re-treatment should not occur in intervals of less than 12 weeks |
| **Age Restrictions** | 18 years of age or older- Cervical dystonia, Spasmodic torticollis, 2 years of age or older- lower or upper limb spasticity |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial - 6 months, Renewal- 6 months |
| **Other Criteria** | None |

# EDARBI NON FORMULARY

## Products Affected

- EDARBI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypertension, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPERTENSION (1) Prescriber attests to diagnosis of hypertension AND (2) Trial and failure, intolerance, or contraindication to at least one (1) of the following= Benazepril, Lisinopril, Enalapril, Quinapril, Moexipril, Fosinopril, Captopril, AND (3) Trial and failure, intolerance, or contraindication to at least two (2) of the following= Losartan, Candesartan, Irbesartan, Olmesartan, Telmisartan |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ELAPRASE NON FORMULARY

## Products Affected

- ELAPRASE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Hunter syndrome (mucopolysaccharidosis II), Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HUNTER SYNDROME (1) Prescriber attests to a documented diagnosis of MPS II (Hunter Syndrome) confirmed by iduronate-2-sulfatase (I2S) activity OR genetic testing confirming mutations in the IDS gene AND (2) The patient must have TWO of the following symptoms a. A decline in developmental skills ( usually between ages 18 months and 3 years), Coarse facial features, including thickening of the lips, protruding tongue and nostrils and a broad nose , Carpal tunnel syndrome, Claw-like hands, Diarrhea, Bone deformities, Hepatosplenomegaly, Recurrent otitis media, Macrocephaly, Recurrent sinopulmonary infections, Sleep apnea, Cardiac abnormalities and valvular disease, Impaired vision , Skin lesions on the back and upper arms, Impaired hearing, Aggressive behavior, Short stature (usually after age 4 or 5), Joint stiffness and reduced range of motion, Reduced pulmonary function AND (3) Provider attest to baseline urinary glycosaminoglycan (uGAG) AND (4) Baseline 6-minute walk test (6-MWT) and/or forced vital capacity (FVC) RENEWAL (1) 1. Prescriber attests to a clinical response to both of the following (1a) a. Improvement in walking capacity with greater than 30 meter or 29% increase in 6-minute walk test (6MWT) is required AND (1b) Decrease in urinary glycosaminoglycan (GAG) from baseline. |
| **Age Restrictions** | 16 months of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician specializing in metabolic disorders or genetics |
| **Coverage Duration** | Initial 12 months, Renewal 12 months |
| **Other Criteria** | None |

# ELIDEL

## Products Affected

- ELIDEL
- *pimecrolimus*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Atopic Dermatitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ATOPIC DERMATITIS (1) Prescriber attests to a diagnosis of atopic dermatitis AND (2) the patient has a history of one prescription strength topical corticosteroid AND (3) Trial and failure, intolerance, or contraindication to therapy with Tacrolimus ointment |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ELIGARD

## Products Affected

- ELIGARD

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Endometriosis, Advanced prostate cancer, Uterine Leiomyoma (uterine fibroids), Central precocious puberty, Polycystic ovarian disease/syndrome (PCOD/PCOS), Dysfunctional or excessive uterine bleeding, Testicular cancer, Vascular Cancer, Breast Cancer, Ovarian Cancer, Premenstrual syndrome, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ENDOMETRIOSIS (1) Prescriber attests to a diagnosis of endometriosis AND (2) Tried/failed/intolerance to at least two of the following = oral contraceptive, medroxyprogesterone, danazol B. ADVANCED PROSTATE CANCER (1) Prescriber attests to diagnosis of advanced prostate cancer C. UTERINE LEIOMYOMA (UTERINE FIBROIDS) (1) Prescriber attests to diagnosis of Uterine Leiomyoma (uterine fibroids) D. CENTRAL PRECOCIOUS PUBERTY (1) Prescriber attests to diagnosis of Central precocious puberty E. POLYSYSTIC OVARIAN DISEASE/SYNDROME (PCOD/PCOS) (1) Prescriber attests to diagnosis of Polycystic ovarian disease/syndrome (PCOD/PCOS) F. DYSFUNCTIONAL OR EXCESSIVE UTERINE BLEEDING (1) Prescriber attests to diagnosis of dysfunctional or excessive uterine bleeding AND (2) Tried/failed/intolerance to oral contraceptive G. CANCER (1) Prescriber attests to diagnosis of testicular cancer OR (2) Prescriber attests to diagnosis of vascular cancer OR (3) Prescriber attests to diagnosis of breast cancer OR (4) Prescriber attests to diagnosis of ovarian cancer H. PREMENSTRUAL SYNDROME (1) Prescriber attests to diagnosis of premenstrual syndrome |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ELMIRON

## Products Affected

- ELMIRON

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Interstitial cystitis,  Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL THERAPY A. INTERSTITIAL CYSTITIS (1)  Prescriber attests a diagnosis of interstitial cystitis with lab results including (1a) Negative urinalysis AND (1b) Negative urine culture RENEWAL (1) Prescriber attests a diagnosis of interstitial cystitis AND (2) Chart notes/medical records document improvement in symptoms (i.e., decrease in bladder pain, etc.) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a Urologist |
| **Coverage Duration** | Initial 3 months, Renewal 3 months |
| **Other Criteria** | None |

# EMFLAZA NON FORMULARY

## Products Affected

- EMFLAZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Duchenne muscular dystrophy,  Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Hypersensitivity to deflazacort or any component of the formulation |
| **Required Medical Information** | A. DUCHENNE MUSCULAR DYSTROPHY (1) Prescriber attests a diagnosis of Duchenne muscular dystrophy AND (2) The diagnosis has been confirmed by documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene AND (3) Serum creatinine kinase activity greater than or equal to 10 times the Upper Limit of Normal (ULN) prior to initiating therapy AND (4) The patient has tried and failed, have an intolerance to, or a contraindication to greater than or equal to a 6 month trial of prednisone or prednisolone (Requires claim history or medical history documentation) RENEWAL (1) Physician has attested that the patient has had a positive clinical response to Emflaza therapy |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders |
| **Coverage Duration** | Initial 3 months, Renewal 6 months |
| **Other Criteria** | None |

# ENBREL

## Products Affected

- ENBREL
- ENBREL SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Plaque psoriasis (Ps), Polyarticular juvenile idiopathic arthritis (JIA), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Used in combination with biological DMARDs |
| **Required Medical Information** | A. PLAQUE PSORIASIS (1) Prescriber attests to a documented diagnosis of plaque psoriasis AND (2) Plaque psoriasis must involve greater than or equal to 5% of the body surface area (BSA) OR (3) Patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (4) Three of the following (4a) Patient has had an inadequate response to 3-month trial of either topical therapy OR (4b) localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA]) for psoriasis OR (4c) Patient has had an inadequate response to a 3- month trial of systemic therapy (i.e. MTX, cyclosporine, acitretin [Soriatane]) OR (4d) Patient has significant disability or impairment in physical or mental functioning, according to the treating physician AND (5) Patient must have a negative tuberculosis test or receive treatment if tested positive B. ALL OTHER INDICATIONS INITIAL (1) Prescriber attests to a documented diagnosis of a FDA-approved indication AND (2) 2. Prescriber attests that the member has tried and failed one conventional therapy indicated for the diagnosis, including but not limited to, azathioprine, methotrexate, NSAIDs, DMARDs, etc. AND (3) Prescriber attests that patient has a negative tuberculosis test or receive treatment if tested positive. RENEWAL FOR ALL INDICATIONS (1) Prescriber attests that the patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patients condition AND (2) Prescriber attests that the patient has disease stabilization or improvement as defined by standard monitoring for the patients condition |
| **Age Restrictions** | Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older, Plaque Psoriasis (Ps) in patients 4 years or older, Rheumatoid Arthritis, Ankylosing Spondylitis, and Psoriatic Arthritis in patients 18 years and older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a specialist in the field of diagnosis. RA, PsA, AS, JIA: prescribed by or in consultation with a rheumatologist. Ps: prescribed by or in consultation with dermatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | QUANTITY RESTRICTION, 25 mg syringe - 16 syringes per 28 days for initial 12 weeks, then 8 syringes per 28 days thereafter, 50 mg syringe - 8 syringes per 28 days for initial 12 weeks, then 4 syringes per 28 days thereafter. |

# ENOXAPARIN (GENERIC LOVENOX)

## Products Affected

- *enoxaparin sodium*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute DVT/PE or prevention of DVT/PE in hip/knee replacement or abdominal surgery, Miscellaneous thrombin disorder, non-Q wave myocardial infarction or unstable angina, thrombophilia in patients who are pregnant, acute ST-segment elevation myocardial infarction (STEMI), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. Prescriber attests to diagnosis of hip/knee replacement or abdominal surgery OR B. Prescriber attests to a diagnosis of acute DVT/PE or prevention of DVT/PE OR C. Prescriber attests to a diagnosis of miscellaneous thrombin disorder in which the member has a demonstrated inability or previous failure with Coumadin and either Eliquis or Xarelto OR D. Prescriber attests to diagnosis of non-Q wave myocardial infarction or unstable angina where LMWH used to reduce serious cardiac events OR E. Prescriber attests to a diagnosis of thrombophilia in patients who are pregnant OR F. Prescriber attests to diagnosis of acute ST-segment elevation myocardial infarction (STEMI) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ENTRESTO

## Products Affected

- ENTRESTO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Stable, chronic heart failure (NYHA II-IV), Symptomatic heart failure with systemic left ventricular systolic dysfunction, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Hypersensitivity to sacubitril, valsartan, or any component of the formulation, History of angioedema related to previous ACE inhibitor or ARB therapy, Concomitant use or use within 36 hours of ACE inhibitors, Concomitant use of aliskiren in patients with diabetes. Pregnancy or breastfeeding. |
| **Required Medical Information** | A. STABLE, CHRONIC HEART FAILURE (NYHA II-IV) (1) Prescriber attests to a diagnosis of stable, chronic heart failure (NYHA II-IV) AND (2) Left ventricular ejection fraction is less than 40% B. SYMPTOMATIC HEART FAILURE WITH SYSTEMIC LEFT VENTRICULAR SYSTOLIC DYSFUNCTION (1) Prescriber attests to a diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction RENEWAL: (1) Prescriber attests that the Entresto dose has been titrated to a dose of 97/103mg twice daily or to a maximum dose as tolerated by the patient AND (2) Prescriber attests to positive clinical response to therapy. |
| **Age Restrictions** | 1 year of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ENTYVIO NON FORMULARY

## Products Affected

- ENTYVIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Crohns disease, ulcerative colitis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Serious or severe hypersensitivity to vedolizumab or any component of the formulation. Used in combination with biological DMARDs. |
| **Required Medical Information** | A. FOR ALL INDICATIONS: INITIAL: (1a) Prescriber attests to a documented diagnosis of moderate to severely active Crohns disease OR (1b) Prescriber attests a documented diagnosis of moderate to severely active Ulcerative Colitis AND (2a) Prescriber attests to a documented inadequate response or intolerance to tumor necrosis factor (TNF) blocker OR (2b) Prescriber attests to a documented inadequate response or intolerance to an immunomodulator OR (2c) Prescriber attests to a documented inadequate response, intolerance, or dependence to corticosteroids. RENEWAL FOR ALL INDICATIONS: (1) Prescriber attests that patient continues to meet initial criteria AND (2) Prescriber attests that the patient is experiencing a decrease in severity or frequency of symptoms while on therapy. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | None |

# EPCLUSA

## Products Affected

- *sofosbuvir-velpatasvir*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Hepatitis C (GT 1, 2, 3, 4, 5, and 6), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | If sofosbuvir/velpatasvir is administered with ribavirin, the contraindications to ribavirin also apply |
| **Required Medical Information** | A. CHRONIC HEPATITIS C (1) Prescriber attests to a documented diagnosis of Chronic Hepatitis C infection genotype (GT) 1, 2, 3, 4, 5 or 6. AND (2) Must provide HCV RNA level dated within last 6 months AND (3) Must provide the following lab values dated within 12 weeks of initiating therapy, CBC with Platelets, AST / ALT, Total Bilirubin, Serum Albumin, PT / INR, Serum Creatinine and GFR. AND (4) The member does not have end stage renal disease requiring dialysis or a glomerular filtration rate less than 30 mL/min/m2 AND (5) The member does not have evidence or known diagnosis of malignancy of any body organ diagnosed within the last 12 months, or currently receiving or planning to receive chemotherapy or radiation therapy (exceptions will be made for hepatocellular carcinoma if the member is on a liver transplant waiting list) AND (6) The member is not currently enrolled in hospice AND (7) The member has not been denied Hepatitis C treatment by another insurance carrier for an acceptable cause. If approved for coverage by another carrier, Envision will only approve coverage as a secondary payer after the primary payer has paid AND (8) If female of childbearing age, prescriber attests to discussion of risk vs. benefit of treatment due to lack of safety and efficacy data if patient becomes pregnant prior or during treatment. AND (9) Prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection and monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent |
| **Age Restrictions** | 6 years of age or older or weighing at least 17 kilograms |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, a Gastroenterologist, Hepatologist, or Infections Disease Specialist |
| **Coverage Duration** | See Other Criteria |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Patient population, Without cirrhosis or with compensated cirrhosis (Child- Pugh class A) - 1 tablet once daily for 12 weeks, Decompensated cirrhosis (Child-Pugh class B or C) - 1 tablet once daily for 12 weeks in combination WITH ribavirin, decompensated cirrhosis (Child-Pugh class B or C) 24 weeks for ribavirin INELIGIBLE. |

# EPOETIN ALPHA

## Products Affected

- PROCRIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Kidney Disease, Chemotherapy-induced anemia in cancer, Hepatitis C Patients with anemia secondary to combination ribavirin and interferon-alfa therapy, HIV Patients with anemia secondary to zidovudine, Myelodysplastic disease, Anemia of chronic disease-Rheumatoid Arthritis, Crohns Disease, Ulcerative Colitis, Presurgery, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Anemia in patients with cancer who are not receiving chemotherapy, Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers, Anemia associated with radiotherapy (as monotherapy) in cancer, To enhance athletic performance, Substitute for red blood cell transfusions in patients who require immediate correction of anemia (i.e. acute blood loss). |
| **Required Medical Information** | A. CHRONIC KIDNEY DISEASE (WITH OR WITHOUT DIALYSIS) (1) Prescriber attests to a diagnosis of anemia associated with chronic renal failure AND (2) Submission of lab findings confirming hemoglobin level less than 10 g/dL within the past 30 days AND (3) Submission of lab findings confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation of greater than or equal to 20% within the past 90 days AND (4) Rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND (5) Goal is to reduce risk of alloimmunization and/or other RBC transfusion related risks B. CHEMOTHERAPY INDUCED ANEMIA IN CANCER (1) Prescriber attests to a diagnosis of anemia due to chemotherapy for a non-myeloid malignancy AND (2) Submission of lab findings confirming hemoglobin level less than 10 g/dL within the past 30 days AND (3) Submission of lab findings confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation of greater than or equal to 20% within the past 90 days AND (4) Patient is being concurrently treated with chemotherapy, with or without radiation AND (5) There is a minimum of two additional months of planned chemotherapy C. HEPATITIS C PATIENTS WITH ANEMIA SECONDARY TO COMBINATION RIBAVIRIN AND INTERFERON-ALFA THERAPY , INTIAL (1) Prescriber attests to a diagnosis of anemia and concurrent use of ribavirin and interferon-alfa therapy confirmed by review of prescription claims AND (2) Submission of lab findings confirming HgB level less than 10 g/dL within the past 30 days AND (3) Submission of lab findings confirming serum ferritin |

| PA Criteria | Criteria Details |
|---|---|
| | greater than or equal to 100 ng/mL or transferrin saturation of greater than or equal to 20% within the past 90 days CONTINUATION (1) Submission of lab findings confirming HgB level less than or equal to 12 g/dL AND (2) Submission of lab findings confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation of greater than or equal to 20% AND |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial-3 months, Renewal- 3 months |
| **Other Criteria** | (3) Documentation that previous ribavirin dose did not require reduction due to symptomatic anemia AND (4) Documentation that the member HgB levels have increased by at least 1 g/dL from pretreatment baseline D. HIV PATIENTS WITH ANEMIA SECONDARY TO ZIDOVUDINE INTIAL (1) Documentation of HIV diagnosis and concurrent use of zidovudine as part of an appropriate highly-active anti-retroviral therapy regimen confirmed by review of prescription claims AND (2) Submission of lab findings confirming HgB level less than 10 g/dL within the past 30 days AND (3) Submission of lab findings confirming serum ferritin greater than or equal to 100 ng/mL or transferrin saturation of greater than or equal to 20% within the past 90 days CONTINUATION (1) Submission of lab findings confirming HgB level less than or equal to 12 g/dL AND (2) Submission of lab findings confirming serum ferritin greater than or equal to100 ng/mL or transferrin saturation of greater than or equal to20% AND (3) Documentation that the member HgB levels have increased by at least 1 g/dL from pretreatment baseline E. MYELODYSPLASTIC DISEASE INITIAL (1) Prescriber attests to a diagnosis of myelodysplastic disease AND (2) Submission of lab findings confirming HgB level less than 10 g/dL within the past 30 days AND (3) Submission of lab findings confirming serum ferritin greater than or equal to100 ng/mL or transferrin saturation greater than or equal to 20% within the past 90 days F. ANEMIA OF CHRONIC DISEASE INITIAL (1) Prescriber attests to a diagnosis of underlying chronic disease (Rheumatoid Arthritis, Crohns Disease, Ulcerative Colitis) AND (2) Submission of lab findings confirming HgB level less than 10 g/dL within the past 30 days AND (3) Serum ferritin greater than or equal to100 ng/mL or transferrin saturation greater than or equal to20% within the past 90 days CONTINUATION (1) Submission of lab findings confirming HgB level less than or equal to 12 g/dL AND (2) Submission of lab findings confirming serum ferritin greater than or equal to100 ng/mL or |

| PA Criteria | Criteria Details |
|---|---|
| | transferrin saturation of greater than or equal to20% AND (3) Documentation that the member HgB levels have increased by at least 1 g/dL from pretreatment baseline G. PRE-SURGERY INTIAL (1) Requested agent is being prescribed to reduce the possibility of allogenic blood transfusion in a surgery patient AND (2) Documentation of intended high-risk surgery (must be elective, non-cardiac, and non-vascular) AND (3) Patients hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL within the previous 30 days AND (4) Serum ferritin greater than or equal to100 ng/mL or transferrin saturation greater than or equal to20% within the previous 90 days AND (5) Patient is not willing to donate autologous blood preoperatively |

# ERIVEDGE NON FORMULARY

## Products Affected

- ERIVEDGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Metastatic Basal Cell Carcinoma (mBCC), locally advanced Basal Cell Carcinoma (LaBCC), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. METASTATIC BASAL CELL CARCINOMA (mBCC) (1) Prescriber attests to diagnosis of Metastatic Basal Cell Carcinoma (mBCC) AND (2) Patients mBCC has recurred following surgery or the patient is not a candidate for surgery AND (3) Prescriber attests that patient is not a candidate for radiation therapy B. LOCALLY ADVANCED BASAL CELL CARCINOMA (1) Prescriber attests to diagnosis of locally advanced Basal Cell Carcinoma (LaBCC) AND (2) Patients mBCC has recurred following surgery or the patient is not a candidate for surgery AND (3) Prescriber attests that patient is not a candidate for radiation therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ESBRIET

## Products Affected

- ESBRIET ORAL CAPSULE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Idiopathic pulmonary fibrosis (IPF), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Concurrent use of Ofev (nintedanib) or fluvoxamine, end-stage renal disease (ESRD), severe hepatic impairment (child pugh class C) or end-stage liver disease |
| **Required Medical Information** | A. IDIOPATHIC PULMONARY FIBROSIS (IPF) INITIAL (1) Prescriber attests to diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by the presence of usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) and/or surgical lung biopsy AND (2) Other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity have been excluded AND (3) Documented pulmonary function tests within the past 60 days with baseline percent predicted forced vital capacity (FVC) is between greater than or equal to 50% AND (4) The baseline percent predicted diffusing capacity of the lung for carbon monoxide (DLCO) is between 30-90% AND (5) There is clinical documentation that the patient is a nonsmoker or has been abstinent from smoking for at least six weeks AND (5) May be authorized in quantities of up to 270 capsules per month. RENEWAL (1) The medication is effective defined as improvement or maintenance (less than 10% decline in percent predicted FVC or less than 200mL decrease in FVC) of disease, and (2) There is clinical documentation that the member has remained tobacco-free |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, a pulmonologist |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |

# EUCRISA NON FORMULARY

## Products Affected

- EUCRISA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Atopic Dermatitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ATOPIC DERMATITIS (1) Prescriber attests to a diagnosis of atopic dermatitis AND (2) Trial and failure of a 2-week trial of two medium to very high potency topical corticosteroids (i.e. triamcinolone, halobetasol, mometasone, fluticasone, fluocinonide), unless contraindicated (i.e. areas involving the face, neck, or intertriginous areas) AND (3) Dose does not exceed 60 grams per 30 days |
| **Age Restrictions** | 3 months of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# EVOXAC

## Products Affected

- *cevimeline hcl*
- EVOXAC

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Sjogrens syndrome (xerostomia), Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SJOGRENS SYNDROME (1) Prescriber attests to diagnosis of Sjogrens syndrome (xerostomia) AND (2) Documented trial/failure or contraindication on a therapeutic course of pilocarpine tablets |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# EXALGO

## Products Affected

- *hydromorphone hcl er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Only approvable for patients who are already receiving and who are tolerant to opioid therapy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Contraindications are Impaired pulmonary function, Paralytic ileus, Narrowed or obstructed gastrointestinal tract, Contraindicated in opioid non-tolerant patients, Patients with known intolerance or hypersensitivity to any of its components or the drug hydromorphone hydrochloride and sulfites. Not approved if Patient has any contraindications to the use of hydromorphone, Patient does not meet above requirements, Patient has known past or current substance abuse potential, and Patient is being treated for substance abuse (including treatment with buprenorphine or buprenorphine-naloxone). |
| **Required Medical Information** | A. OPIOID-TOLERANT PATIENTS (1) Only approvable for patients who are already receiving and who are tolerant to opioid therapy (Patients considered opioid-tolerant are those who are taking at least 60 mg morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer.) AND (2) Must be 18 years of age or older AND (3) Must try and fail an adequate dose of a formulary long-acting narcotic such as morphine sulfate ER tablets, or fentanyl patches AND (4) For chronic non-cancer pain (4a) Must have functional impairment (4b) Must have clear treatment goals. B. CONTINUATION OF THERAPY (1) Patients pain has been recently re-assessed and there continues to be a medical need for the medication AND (2) Patient is tolerating and responding to medication AND (3) Patient has improved functioning and is meeting treatment goals AND (4) Patient is not exhibiting addictive behaviors and is not being treated for substance abuse. - - CAUTION - - Caution in patients with hepatic or renal impairment. The lowest possible dose should be used. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# EXJADE

## Products Affected

- *deferasirox oral tablet soluble*
- EXJADE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic iron overload due to blood transfusions (transfusional hemosiderosis), Diagnosis of myelodysplastic syndrome, or Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. (INITIAL) CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS (1) Prescriber attests patient has a diagnosis of Chronic iron overload due to blood transfusions (transfusional hemosiderosis) AND (2) Patient is 2 years of age or older AND (3) Patient has a baseline ferritin level more than 1,000 mcg/L AND (4) Patient has required the transfusion of at least 100 mL/kg packed red blood cells OR B. MYELODYSPLASTIC SYNDROME (1) Prescriber attests patient has a diagnosis of myelodysplastic syndrome AND (2) Patient has Low or Intermediate-1 disease or is a potential transplant patient AND (3) Patient has received more than 20 red blood cell transfusions. OR C. (RENEWAL) CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS (1) Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC) OR D. (INITIAL) CHRONIC IRON OVERLOAD DUE TO NON-TRANSFUSION-DEPENDENT THALASSEMIA (1) Prescriber attests patient has a diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) AND (2) Patient is 10 years of age or older AND (3) Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher AND (4) Serum ferritin level greater than 300 mcg/L E. (RENEWAL) CHRONIC IRON OVERLOAD DUE TO NON-TRANSFUSION-DEPENDENT THALASSEMIA (1) Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher AND (2) Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC) |
| **Age Restrictions** | Chronic iron overload due to blood transfusions=2 years of age and older, chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)=10 years of age and older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |

# FANAPT NON FORMULARY

## Products Affected

- FANAPT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Bipolar disorder, schizophrenia, or other psychotic disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BIPOLAR DISORDER, SCHIZOPHRENIA, OR OTHER PSYCHOTIC DISORDER (1) Prescriber attests patient has a diagnosis of bipolar disorder, schizophrenia, or other psychotic disorder AND (2) 18 years of age or older AND (3) Trial and failure, intolerance or contraindication of the formulary alternative risperidone (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) AND (4) Trial and failure, intolerance or contraindication of alternative quetiapine (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) AND (5) Trial and failure, intolerance or contraindication of olanzapine (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) AND (6) Trial and failure, intolerance or contraindication of ziprasidone (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FARESTON

## Products Affected

- FARESTON
- *toremifene citrate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of metastatic breast cancer with estrogen-receptor positive or unknown tumors. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL A. METASTATIC BREAST CANCER WITH ESTROGEN-RECEPTOR POSITIVE OR UNKNOWN TUMORS (1) Prescriber attests patient has a diagnosis of metastatic breast cancer with estrogen-receptor positive or unknown tumors, and (2) Patient is a postmenopausal female, and (3) Patient has had a clinical trial and failure, intolerance, or contraindication to both of the following (3a) Tamoxifen (3b) Anastrozole/Letrozole/Exemestane. RENEWAL (1) Patient continues to meet initial criteria, and (2) Prescriber attests that patient has had a positive response to therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FARYDAK

## Products Affected

- FARYDAK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Multiple myeloma. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MULTIPLE MYELOMA (1) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records. (2) Prescriber attests patient has a diagnosis of multiple myeloma AND (3) Must have tried and failed two previous therapies, including the following (3a) Revlimid, Thalomid or Pomalyst AND (3b) Velcade (4) Farydak must be taken in combination with Velcade AND dexamethasone (5) Must have an ECOG performance status between 0 and 2. ---ECOG PERFORMANCE STATUS-Grade -ECOG-0= Fully active, able to carry on all pre-disease performance without restriction. 1=Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work. 2=Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours. 3=Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours. 4= Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair. 5=Dead. - ADDITIONAL INFORMATION- If authorized, a maximum of 16 cycles of Farydak will be covered in a lifetime. Each fill is limited to 6 capsules. Request for any condition not listed as covered require evidence of current medical literature that substantiates drugs efficacy or that recognized oncology organizations generally accept the treatment for that condition. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FASENRA NON FORMULARY

## Products Affected

- FASENRA
- FASENRA PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe asthma with an eosinophilic phenotype. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Not for treatment of other eosinophilic conditions. Not for relief of acute bronchospasm or status asthmaticus. Known hypersensitivity to benralizumab or excipients |
| **Required Medical Information** | A. SEVERE ASTHMA WITH AN EOSINOPHILIC PHENOTYPE (1) Prescriber attests patient has a diagnosis of severe asthma with an eosinophilic phenotype AND (2) Must be 12 years of age or older AND (3) Must be prescribed by, or in conjunction with, an allergist, pulmonologist or immunologist AND (4) Must not be used for the relief of acute bronchospasm or status asthmaticus AND (5) Must have a baseline absolute blood eosinophil count greater than or equal to 150 cells/microL at initiation of therapy or greater than or equal to 300 cells/microL within the last 12 months AND (6) The member must still be symptomatic despite being compliant to a trial of a combination of at least a high dose inhaled corticosteroid with either a long acting beta agonist (LABA), leukotriene modifier, or theophylline, AND (7) Prescriber attests that Fasenra will not be used in conjunction with dupilumab (Dupixent), mepolizumab (Nucala), omalizumab (Xolair) or reslizumab (Cinqair). B. RENEWAL/CONTINUATION OF THERAPY (1) Must continue to meet initial criteria AND (2) Patient has responded to Fasenra therapy as determine by the prescriber (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations/emergency department visits, or decreased requirement for oral corticosteroid therapy). |
| **Age Restrictions** | Severe asthma with eosinophilic phenotype=12 years of age and older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, an allergist, pulmonologist or immunologist AND |
| **Coverage Duration** | Initial=12 months. Renewal=12months |
| **Other Criteria** | None |

# FASLODEX

## Products Affected

- FASLODEX
- *fulvestrant*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of breast cancer or uterine cancer. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL A. BREAST CANCER (1) Prescriber attests patient has a diagnosis of breast cancer AND (2) Patient is postmenopausal, or premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis AND (3) Patients disease is advanced, metastatic, or recurrent, AND (3a) Will be used in combination with palbociclib, or abemaciclib AND (3b) Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease, AND (3c) Patient has progressed on endocrine therapy, OR (3d) Patient has HR-positive, HER2-negative disease and has not previously received endocrine therapy, OR (3e) Patient has HR-positive disease and progressed on endocrine therapy, OR (3f) Patient has HR-positive, HER2-positive disease B. UTERINE CANCER (1) Prescriber attests patient has a diagnosis of Uterine Cancer AND (2) Requested medication is being used as a single agent, and (3) Patient has grade 1 or 2 endometrioid histology AND (4) Patient has a small tumor volume or indolent growth pace AND (5) Requested medication will be used as one of the following (5a) Primary treatment for metastatic or unresectable disease excluding patients with cervical involvement undergoing brachytherapy with or without external beam radiation therapy (EBRT), OR (5b) Adjuvant treatment for locally advanced or metastatic disease, OR (5c) Used as hormonal therapy for recurrent or disseminated metastatic disease. C. RENEWAL (1) Patient continues to meet the criteria for Initial Therapy, AND (2) Tumor response with stabilization of disease or decrease in size of tumor or tumor spread. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Oncologist |
| **Coverage Duration** | 12months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | None |

# FENOGLIDE NON FORMULARY

## Products Affected

- *fenofibrate oral tablet 120 mg, 40 mg*
- FENOGLIDE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary hypercholesterolemia, Mixed dyslipidemia, Hypertriglyceridemia, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRIMARY HYPERCHOLESTEROLEMIA, MIXED DYSLIPIDEMIA, HYPERTRIGLYCERIDEMIA (1) Prescriber attests to a diagnosis of primary hypercholesterolemia, mixed dyslipidemia OR Hypertriglyceridemia AND (2) Patient must already be on an appropriate lipid lowering diet and should continue during treatment AND (3) Trial and failure, intolerance or contraindication of both of the following- gemfibrozil, fenofibrate 67mg, 134mg or 200mg capsules or fenofibrate 54mg or 160mg tablets (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claims history) must be evidence of 90 day trials of each AND (4) Tried and failed, intolerance or contraindication to one of the following prior authorized alternatives - fenofibrate (generic Tricor) or Lipofen (medication usage must be supported by documentation from the patients chart notes/medical records/ electronic claims history) must be evidence of 90 day trials of each. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FENTANYL PATCH

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | For these and other diagnoses, please request alternative therapy with the covered alternatives Norco/Lortab, Morphine Sulfate ER, Dilaudid, Percocet, Methadone and Oxycodone IR (1)acute or postoperative pain- risk of life-threatening hypoventilation (2) bronchial asthma- acute or severe increased risk of life-threatening hypoventilation (transdermal) (3)hypersensitivity to fentanyl or any product or system components (4)mild or intermittent pain management- risk of life-threatening hypoventilation (transdermal) (5) opioid non-tolerant patients- increased risk of life-threatening hypoventilation (6) paralytic ileus, suspected or known (transdermal) (7) situations of significant respiratory depression, especially in unmonitored settings that lack resuscitative equipment- risk of life-threatening hypoventilation (transdermal)- possibly contraindicated with obstructive sleep apnea. (8) immediate post-surgical pain (9) use in patients who require opioid analgesia for a short period of time |
| **Required Medical Information** | A. CANCER PAIN (1) Around-the-clock cancer pain, in opioid-tolerant patients (supported by documentation from the patients chart notes/medical records/electronic claims history) AND (2) Tried and failed, intolerance or inability to utilize therapy with all of the following) (2a) Hydrocodone/APAP, THEN (2b) Morphine Sulfate ER Tablet. B. CHRONIC PAIN (1) Around-the-clock chronic pain, in opioid tolerant patients AND (2) Tried and failed, intolerance or inability to utilize therapy with all of the following) (2a) Hydrocodone/APAP, THEN (2b) Morphine Sulfate ER Tablet. C. POST-OPERATIVE PAIN (1) Short-term management of postoperative pain ONLY during hospitalization AND (2) Tried and failed, intolerance or inability to utilize therapy with all of the following) (2a) Hydrocodone/APAP, THEN (2b) Morphine Sulfate ER Tablet. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FERRIPROX

## Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of transfusional iron overload due to thalassemia syndrome. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL A. TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDRONE (1) Diagnosis of transfusional iron overload due to thalassemia syndrome, AND (2) One of the following (2a) History of failure, defined by a serum ferritin greater than 2,500 mcg/L, to Exjade (deferasIROX) or (2b) Patient has been intolerant to or experienced clinically significant adverse effects to Exjade (deferasirox), such as evidence of cardiac iron overload or iron-induced cardiac dysfunction. B. REAUTHORIZATION (1) Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline, AND (2) Absolute neutrophil count (ANC) greater than 1.5 x 10^9/L |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FETZIMA

## Products Affected

- FETZIMA
- FETZIMA TITRATION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Major Depressive Disorder, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Hypersensitivity to levomilnacipran, milnacipran HCl, or any excipient in the Fetzima formulation. Simultaneous use with or within 14 days of stopping a mono-amine oxidase inhibitor (MAOI). Use of MAOI within 7 days of stopping Fetzima. Starting Fetzima in an individual on Linezolid |
| **Required Medical Information** | INITIAL A. MAJOR DEPRESSIVE DISORDER (1) Prescriber attests patient has a diagnosis of Major Depressive Disorder (MDD) AND (2) Individual has failure, contraindication or intolerance to TWO preferred SSRI step therapy. Preferred SSRI step therapy agents include (2a) Citalopram (2b) Escitalopram (2c) Fluoxetine (2d) Fluvoxamine (2e) Paroxetine (2f) Sertraline AND (3) Individual has failure, contraindication or intolerance to TWO preferred SNRI step therapy agent. Preferred SNRI step therapy agents include (3a) Desvenlafaxine (Generic Pristiq) (3b) Duloxetine (3c) Venlafaxine HCl ER (Capsule) (3d) Venlafaxine HCl (4) There are NO contraindications. Contraindications include- Hypersensitivity to levomilnacipran, milnacipran HCl, or any excipient in the Fetzima formulation. Simultaneous use with or within 14 days of stopping a mono-amine oxidase inhibitor (MAOI). Use of MAOI within 7 days of stopping Fetzima. Starting Fetzima in an individual on Linezolid. B. RENEWAL (1) Individuals condition responded while on therapy. Response is defined as improved mood, behavior, interest in daily activities, sleep, energy, sense of worthiness, no thoughts of suicide and no attempts, no aggression or violent behavior, no hospitalizations. (2) Prescriber attests that the individual has been adherent with the medication |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FINACEA

## Products Affected

- *azelaic acid external*
- FINACEA EXTERNAL GEL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | A diagnosis of rosacea. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ROSACEA (1) A diagnosis of rosacea AND (2) Trial and failure or intolerant of generic topical metronidazole. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FIRMAGON NON FORMULARY

## Products Affected

- FIRMAGON

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of advanced prostate cancer. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL A. ADVANCED PROSTATE CANCER (1) Diagnosis of advanced prostate cancer, AND (2) Prescribed by, or in consultation with, an Oncologist. B. RENEWAL (1) Initial criteria continues to be met (2) Prescriber attests that patient has had clinical response to medication (i.e. stabilization of disease, decrease size in tumor) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FONDAPARINUX (GENERIC ARIXTRA)

## Products Affected

- *fondaparinux sodium*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute ST segment or Non-ST segment elevation myocardial infarction. Angioplasty, thrombosis of superficial vein of lower limb, treatment or prophylaxis of DVT following hip or knee replacement, or abdominal surgery, short-term treatment for DVT or PE with planned conversion to warfarin, treatment for DVT and warfarin is contraindicated, or prothrombic disorders requiring long term anticoagulation. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACUTE ST SEGMENT OR NON-ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (1) Prescriber attests patient has a diagnosis of Acute ST segment or Non-ST segment elevation myocardial infarction AND(2) Tried/failed warfarin (thrombolic event with therapeutic INR) OR B. ANGIOPLASTY (1) Angioplasty OR C. THROMBOSIS OF SUPERFICIAL VEIN OF LOWER LIMB (1) Prescriber attests patient has a diagnosis of Thrombosis of superficial vein of lower limb AND(2) Tried/failed warfarin (thrombolic event with therapeutic INR) OR D. PROPHYLAXIS OF DVT OR ABDOMINAL SURGERY (1) Treatment or prophylaxis of DVT following hip or knee replacement, or abdominal surgery AND (2) Tried/failed warfarin (thrombolic event with therapeutic INR) OR E. SHORT-TERM TREATMENT FOR DVT OR PE (1) Short-term treatment for DVT or PE with planned conversion to warfarin AND (2) Tried/failed warfarin (thrombolic event with therapeutic INR) OR F. TREATMENT FOR DVT AND WARFARIN IS CONTRAINDICATED (1) Treatment for DVT and warfarin is contraindicated AND (2) Tried/failed warfarin (thrombolic event with therapeutic INR) OR G. PROTHROMBIC DISORDERS (1) Prescriber attests patient has a diagnosis of Prothrombic disorders requiring long term anticoagulation and at least one of the following- (2a)Pregnancy or (2b) Cancer |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FORFIVO NON FORMULARY

## Products Affected

- *bupropion hcl er (xl) oral tablet extended release 24 hour 450 mg*
- FORFIVO XL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | A diagnosis of Major Depressive Disorder (MDD). Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MAJOR DEPRESSIVE DISORDER (1) A diagnosis of Major Depressive Disorder (MDD) AND (2) Trial and failure or intolerant to long-acting generic bupropion tablets (both bupropion SR and XL) AND one other formulary antidepressant (i.e. fluvoxamine, citalopram, escitalopram, paroxetine, sertraline) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FORTEO NON FORMULARY

## Products Affected

- FORTEO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary or hypogonadal Osteoporosis in men, Osteoporosis due to corticosteroid, Postmenopausal osteoporosis with a high risk for fracture. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Prevention of osteoporosis (women and men). |
| **Required Medical Information** | A. OSTEOPOROTIC FRACTURE, MULTIPLE RISK FACTORS FOR FRACTURE, OR PATIENTS WHO FAILED OR/ARE INTOLERANT TO OTHER OSTEOPOROSIS THERAPY, INCREASE OF BONE MASS IN MEN WITH PRIMARY OR HYPOGONADAL OSTEOPOROSIS AT HIGH RISK FOR FRACTURE, TREATMENT OF MEN AND WOMEN WITH OSTEOPOROSIS ASSOCIATED WITH SUSTAINED SYSTEMIC GLUCOCORTICOID THERAPY (1) Prescriber attests patient has a diagnosis of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy OR Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture OR Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture AND (2) Patient has a diagnosis of osteoporosis defined as a T-score that is -2.5 or lower (2.5 or more standard deviations below the mean bone mineral density (BMD) value for a young adult) AND ONE of the following- (2a) Patient has a very low BMD defined as a T-score that is -3.5 or lower OR (2b) Patient has a history of prevalent vertebral fracture(s) or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] OR (2c) Patients medication history includes a first-line agent (bisphosphonate or SERM for women, bisphosphonate for men) OR (2d) Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to SERM and bisphosphonate (bisphosphonate only if male) OR |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | (3) Patient has a history of prevalent vertebral fracture(s) or low trauma or fragility fracture(s) (without a diagnosis of osteoporosis) AND ONE of the following- (3a) Patients medication history includes a first-line agent (bisphosphonate or SERM for women, bisphosphonate for men) OR (3b) Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to SERM and bisphosphonate (bisphosphonate only if male) AND (4) Patient is not receiving concomitant bisphosphonate, SERM, or Prolia (denosumab) therapy AND (5) Total duration of treatment with Forteo has not exceeded 2 years. |

# FOSAMAX PLUS D

## Products Affected

- FOSAMAX PLUS D

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | A diagnosis of Osteoporosis. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. OSTEOPOROSIS (1) Diagnosis of Osteoporosis, OR (2) Pagets disease AND (3) Patient has had a clinical trial and failure to therapy with alendronate once weekly and vitamin D supplement taken concurrently as separate ingredients |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FOSRENOL NON FORMULARY

## Products Affected

- FOSRENOL ORAL TABLET CHEWABLE
- *lanthanum carbonate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | A diagnosis of hyperphosphatemia associated with chronic kidney disease, dialysis, end stage renal disease (ESRD), or renal failure. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPERPHOSPHATEMIA (1) A diagnosis of hyperphosphatemia associated with chronic kidney disease, dialysis, end stage renal disease (ESRD), or renal failure, AND (2) Patient is on a phosphate-restricted diet, AND (3) Patient has had a clinical trial and failure, contraindication, or intolerance to BOTH of the following-(3a) Sevelamer carbonate (generic Renvela) (3b) Calcium carbonate/Calcium Acetate |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a nephrologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# FRAGMIN

## Products Affected

- FRAGMIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Thrombosis/Thromboembolism, Anticoagulation in Pregnancy, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.THROMBOSIS/THROMBOEMBOLISM INITIAL (1) Prescriber attests to diagnosis of thrombosis/thromboembolism AND (2) Has any of the following indications (2a) Thrombosis or thromboembolism prevention associated with any of the following conditions= cancer, unstable angina or myocardial infarction, atrial fibrillation or prosthetic heart valve, major surgery- orthopedic and non-orthopedic, critical illness related to ICU admissions or events, restricted mobility associated with acute illnesses or conditions, implanted devices-vascular (e.g., central venous access device, umbilical venous catheter, devices/fistulas related to hemodialysis, ventricular assist devices) OR (2b) Thrombosis or thromboembolism treatment OR (2c) Short-term prophylaxis for transition to or from oral anticoagulation AND (3) Failure of a trial of enoxaparin unless (3a) Enoxaparin is contraindicated OR (3b) History of clinically significant adverse effects to enoxaparin OR (3c) The requested use is FDA labeled for dalteparin but not for enoxaparin (i.e., VTE treatment in patients with cancer) RENEWAL (1) Currently receiving medication or member has previously met initial approval criteria AND (2) Member is responding positively to therapy AND (3) Continued use is limited to any of the following indications (3a) Venous thrombosis prophylaxis or treatment in the presence of cancer OR (3b) Past history of failed anticoagulation therapy (clot development) on a nonLMWH* (e.g., failed therapy on heparin, fondaparinux, warfarin, apixaban, dabigatran, edoxaban, rivaroxaban) OR (3c) Any other indication in section I.A where bridging to warfarin is inappropriate or member has a contraindication to warfarin and extended (indefinite duration) anticoagulation therapy is required |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | B. ANTICOAGULATION IN PREGNANCY INITIAL (1) Prescriber attests to diagnosis of anticoagulation in Pregnancy: Ante- and Postpartum AND (2) Any of the following indications= Acute venous thrombosis during current pregnancy, prior venous thrombosis, receiving long-term therapy with a vitamin K antagonist (e.g., warfarin), prosthetic heart valve, inherited thrombophilia, antiphospholipid antibody syndrome, development of severe ovarian hyperstimulation syndrome post assisted reproduction, cesarean section - current pregnancy and request is for the postpartum period AND (2) Patient is pregnant or less than 6 months postpartum AND (3) Failure of a trial of enoxaparin unless contraindicated or clinically significant adverse effects are experienced. RENEWAL (1) Member has previously met initial approval criteria AND (2) Member is responding positively to therapy |

# FYCOMPA

## Products Affected

- FYCOMPA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Intractable (refractory) seizure, Partial-onset seizures, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. INTRACTABLE (REFRACTORY) SEIZURES (1) Prescriber attests to diagnosis of intractable (refractory) seizures B. PARTIAL ONSET SEIZURES (1) Prescriber attests to diagnosis of partial-onset seizures AND (2) Patient must have a history of trial and failure of (2a) at least 2 concomitant antiepileptic drugs OR (2b) at least 3 different antiepileptic drugs OR (2c) History Vagal Nerve Stimulator (VNS) implantation or lobectomy |
| **Age Restrictions** | Intractable (refractory) seizures= 12 years of age or older, Partial-onset seizures= 4 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# GAMUNEX/GAMUNEX C NON FORMULARY

## Products Affected

- GAMMAGARD
- GAMMAKED INJECTION SOLUTION 10 GM/100ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary immune deficiency, Kawasaki disease, Chronic lymphocytic leukemia-related IgG deficiency, Bone Marrow Transplant, HIV infection-related IgG deficiency, Guillain-Barre Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Dermatomyositis (including juvenile) or Polymyositis, Systemic Lupus Erythematosus (SLE), Relapsing-Remitting Multiple Sclerosis, Autoimmune hemolytic anemia, Autoimmune neutropenia, Cytomegalovirus infection, Dermatomyositis, Kidney disease, Myasthenia gravis, Toxic shock syndrome, Hemolytic disease of fetus OR newborn due to RhD isoimmunization, Prophylaxis, Motor neuropathy with multiple conduction block, Multiple myeloma, Polymyositis, Stiff-man syndrome, Thrombocytopenia, Antenatal and neonatal, Kidney transplant - Pretransplant desensitization, Neonatal jaundice, Pemphigus vulgaris, Renal Transplant rejection, Respiratory syncytial infection, Sepsis, Uveitis, Von Willebrand disorder, Idiopathic (immune) thrombocytopenic purpura, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRIMARY IMMUNE DEFICIENCY (1) Prescriber attests to diagnosis of Primary immune deficiency AND (2) This includes one of the following (2a) Common Variable Immunodeficiency (hypogammaglobulinemia) OR (2b) IgG deficiency (IgGless than400mg/dl and/or a significant inability to respond with IgG antibody production after antigenic challenge) OR (2c) Brutons or X-linked agammaglobulinemia OR (2d) Severe Combined Immunodeficiency (SCID) OR (2e) Wiskott-Aldrich Syndrome OR (2f) X-linked Hyper IgM Syndrome B. CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) (1) Prescriber attests to diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) AND (2) Tried/failed/intolerance of corticosteroids or plasma exchange C. DERMATOMYOSITIS OR POLYMYOSITIS (1) Prescriber attests to diagnosis of Dermatomyositis (including juvenile) or Polymyositis AND (2) Tried/failed/intolerance to corticosteroids and adjuvant therapy |

| PA Criteria | Criteria Details |
|---|---|
| | (methotrexate, hydroxychloroquine, cyclosporine, etc.) D. SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) (1) Prescriber attests to diagnosis of Systemic Lupus Erythematosus (SLE) AND (2) Tried/failed/intolerance of NSAIDs, corticosteroids and/or antimalarials) AND immunosuppressants E. RELAPSING-REMITTING MULTIPLE SCLEROSIS (1)Prescriber attests to diagnosis of Relapsing-Remitting Multiple Sclerosis AND (2) Tried/failed/intolerance to Avonex, Betaseron, Copaxone, and/or Rebif |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a specialist in the area of the patient diagnosis |
| **Coverage Duration** | 12 months |
| **Other Criteria** | F.OTHER DIAGNOSES (1) Prescriber attests to diagnosis of one of the following Kawasaki disease, Chronic lymphocytic leukemia-related IgG deficiency, Bone Marrow Transplant (prevention of graft-versus-host disease and/or infection), HIV infection-related IgG deficiency OR Guillain-Barre Syndrome, Autoimmune hemolytic anemia, Autoimmune neutropenia, Cytomegalovirus infection, Dermatomyositis, Kidney disease, Myasthenia gravis, Toxic shock syndrome, Hemolytic disease of fetus OR newborn due to RhD isoimmunization, Prophylaxis, Motor neuropathy with multiple conduction block, Multiple myeloma, Polymyositis, Stiff-man syndrome, Thrombocytopenia, Antenatal and neonatal, Kidney transplant - Pretransplant desensitization, Neonatal jaundice, Pemphigus vulgaris, Renal Transplant rejection, Respiratory syncytial infection, Sepsis, Uveitis, Von Willebrand disorder RENEWAL FOR ALL DIAGNOSES (1) Platelet count of at least 50,000/mm3) AND (2) Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding |

# GENOTROPIN

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Growth Hormone Deficiency in Children, Turner Syndrome, Short Stature Homeobox- containing gene (SHOX) deficiency, Growth Failure in chronic renal insufficiency, Prader Willi Syndrome, Noonan Syndrome, HIV associated wasting or cachexia, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Hypersensitivity to the requested medication or to any component of the formulation, Acute critical illness, Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment, Active Malignancy, Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy, Children with closed epiphyses, Used to improve functional status in elderly patients (i.e. antiaging), Used to enhance athletic ability, Bone marrow transplantation without total body irradiation, Patients with bony dysplasias (i.e. achondroplasia or hypochondroplasia), Use in children if burn injury, Use in central precocious puberty, Use in chronic fatigue syndrome, Use in congenital adrenal hyperplasia, Use in corticosteroid -induced short stature, Use in Crohns disease, Use in Cystic Fibrosis, Use in Dilate cardiomyopathy and heart failure, Use in Downs syndrome, Use in Familial dysautonomia, Use in fibromyalgia, Use in HIV-associated adipose redistribution syndrome (HARS), Use in infertility, Use in kidney or liver transplant patients, Use in multiple system atrophy (MSA), Use in persons with myelomeningocele, Use in obesity, Use in osteogenesis imperfecta or osteoporosis, Use in children with thalassemia, Use in X-linked hypophosphatemic rickets |
| **Required Medical Information** | STEP ALERT: GENOTROPIN IS THE PRIMARY PRODUCT. MUST HAVE A TRIAL AND FAILURE OF GENOTROPIN BEFORE A SECONDARY PRODUCT UNLESS OTHERWISE CONTRAINDICATED. A. GROWTH HORMONE DEFICIENCY IN CHILDREN (1) Prescriber attests to a diagnosis of growth hormone deficiency AND (2) Must have documentation of non-fused epiphyses AND (3) Must have a documented growth hormone deficiency as defined by a diminished serum growth hormone response to stimulation testing of less than 10 ng/mL for one of the following stimulation tests= Levodopa, Insulin-induced hypoglycemia, Arginine, Clonidine, Glucagon AND (4) The patients baseline height must be less than the 3rd percentile for age and gender (i.e., greater than 2 standard deviations [SD] below the mean for gender and age) AND (5) Children less than 3 years of age must have |

| PA Criteria | Criteria Details |
|---|---|
| | a pretreatment growth rate of less than 7 cm per year OR (6) Children greater than 3 years of age must have a pretreatment growth rate of less than 4 cm per year OR (7) Children of any age with a growth velocity less than 10th percentile for age and gender (based on the last 6 months of data) B. TURNER SYNDROME (1) Prescriber attests to a diagnosis of Turner Syndrome confirmed by chromosome analysis AND (2) Must have documentation of non-fused epiphyses C. SHORT STATURE HOMEOBOX-CONTAINING GENE (SHOX) DEFICIENCY (1) Prescriber attests to a diagnosis of SHOX deficiency confirmed by chromosome analysis AND (2) Must have documentation of non-fused epiphyses D.GROWTH FAILURE IN CHRONIC RENAL INSUFFICIENCY (CKD) (1) Prescriber attests to a diagnosis of chronic renal insufficiency AND (2) Must have documentation of non-fused epiphyses AND (3) Patient has not had a kidney transplant |
| **Age Restrictions** | 18 years of age and younger, over age 18 is excluded |
| **Prescriber Restrictions** | Prescribed by, or in conjunction, with an Endocrinologist. |
| **Coverage Duration** | Initial- 12 months, Renewal-12 months |
| **Other Criteria** | D. PRADER-WILLI SYNDROME (1) Prescriber attests to a diagnosis of Prader-Willi syndrome AND (2) Must have documentation of non-fused epiphyses E. NOONAN SYNDROME (1) Prescriber attests to a diagnosis of Noonan syndrome AND (2) Must have documentation of non-fused epiphyses AND (3) The patients baseline height must be less than the 3rd percentile for age and gender (i.e., greater than 2 standard deviations [SD] below the mean for gender and age) CONTINUING THERAPY (1) Growth rate must have increased significantly (height velocity at least doubles by the end of the first year) AND (2) The patients height velocity is greater than or equal to 2.5 cm/year |

# GILENYA

## Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing- remitting Multiple Sclerosis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Severe hepatic impairment, Pregnancy, leflunomide treatment, non-relapsing forms of MS, Concurrent use of interferon beta-1a IM (Avonex), interferon beta-1a SC (Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone), or natalizumab (Tysabri). |
| **Required Medical Information** | A. RELAPSING-REMITTING MULTIPLE SCLEROSIS INITIAL (1) Prescriber attests patient has a diagnosis of relapsing-remitting MS (Note: Relapsing forms of MS include relapsing-remitting, secondary progressive with relapses, and progressive relapsing or clinically isolated syndrome) RENEWAL (1) Medical records/chart notes from neurology consultation documenting the improvement of the relapsing rate or that the patients clinical condition is stabilized with the current therapy with no significant adverse effects. |
| **Age Restrictions** | 10 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or multiple sclerosis specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# GILOTRIF

## Products Affected

- GILOTRIF

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-Small Cell Lung Cancer (NSCLC) with known EGFR mutation, Non-Small Cell Lung Cancer (NSCLC)-Human Epidermal Growth Factor Receptor 2 (HER2) Mutation-Positive, Central Nervous System Cancers with metastases, Non-nasopharyngeal cancer, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NON-SMALL CELL LUNG CANCER (NSCLC) WITH KNOWN EGFR MUTATION (1) Prescriber attests to diagnosis of Non-Small Cell Lung Cancer (NSCLC) with known EGFR mutation AND (2) The patient has metastatic OR recurrent NSCLC AND (3) The patient has an EGFR mutation detected by an FDA-approved test AND (4) The patient meets ONE of the following conditions (4a) First line-therapy OR (4b) Subsequent therapy following disease progression on afatinib for asymptomatic disease, symptomatic brain lesions, or isolated symptomatic systemic lesions OR (4c) In combination with cetuximab as subsequent therapy for metastatic disease in patient who are T790M negative, have progressed on a tyrosine kinase inhibitor, and have multiple symptomatic systemic lesions. B. NON-SMALL CELL LUNG CANCER (NSCLC)-HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2) MUTATION-POSITIVE (1) Prescriber attests to diagnosis of Non-Small Cell Lung Cancer (NSCLC) Human Epidermal Growth Factor Receptor 2 (HER2) Mutation-Positive C. CENTRAL NERVOUS SYSTEM CANCERS (1) Prescriber attests to diagnosis of Central Nervous System Cancers with metastases AND (2) if afatinib is active against primary tumor D. NON-NASOPHARYNGEAL CANCER (1) Prescriber attests to diagnosis of Non-nasopharyngeal cancer AND (2) disease progression on or after platinum-containing chemotherapy E. OTHER MEDICALLY ACCEPTED INDICATIONS (1) 5Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber will provide specific diagnosis for documentation. |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# GLEEVEC

## Products Affected

- *imatinib mesylate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Philadelphia chromosome positive chronic myeloid leukemia, KIT (CD117) positive, resectable, unresectable, recurrent and/or metastatic malignant gastrointestinal stromal tumors (GIST), Adult patient with Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), Adult patient with Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), Pediatric patient with Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML ) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) ,Adult patient with hypereosinophilic syndrome (HES), Adult patient with chronic eosinophilic leukemia (CEL), Adult patient with aggressive systemic mastocytosis (ASM), Adult patient with myelodysplastic/ myeloproliferative disease (MDS/MPD), Adult patient with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP), Desmoid tumors, Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT),Adult patient with Chordoma, Adult patient with advanced or metastatic Melanoma with C-Kit mutated tumors, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADULT PATIENT (1) Patient is 18 years of age and older AND (2) Prescriber attests to ONE of these diagnoses: (2a) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase, in blast crisis, or in accelerated phase, OR (2b) Patient with molecular or cytogenetic relapse, or patients not in cytogenetic remission, after hematopoietic stem cell transplant (HSCT), or who are resistant to interferon-alpha therapy OR (2c) KIT (CD117) positive, resectable, unresectable, recurrent and/or metastatic malignant gastrointestinal stromal tumors (GIST) OR (2d) Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) AND (2e) hypereosinophilic syndrome (HES) OR (2f) chronic eosinophilic leukemia (CEL) OR (2g) aggressive systemic mastocytosis (ASM), and the patient does not have a D816V C-Kit mutation or the c-Kit mutation status is unknown OR (2h) myelodysplastic/ myeloproliferative disease (MDS/MPD), and the MDS/MPD is associated with PDGFR (platelet-derived growth factor receptor) gene re- arrangements OR (2i) unresectable, recurrent and/or |

| PA Criteria | Criteria Details |
|---|---|
| | metastatic dermatofibrosarcoma protuberans (DFSP) OR (1j) Chordoma OR (2k) advanced or metastatic Melanoma with C-Kit mutated tumors B.PEDIATRIC PATIENT (1) Prescriber attests to ONE of these diagnoses: (1a) Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML), And the pediatric patient is in a chronic phase or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy OR (1b) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in a newly diagnosed patient being used in combination with chemotherapy C. ADULT OR PEDIATRIC (1) Prescriber attests to ONE of these diagnoses: (1a) Desmoid tumors OR (1b) Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT) |
| **Age Restrictions** | 18 years of age or older= Chronic eosinophilic leukemia, DFSP,HSCT,KIT (CD117),ALL, HES, CEL, ASM,MDS/MPD, DFSP, Chordoma, advanced or metastatic Melanoma with C-Kit mutated tumors, 1 year of age and older = Pediatric CML, All other= None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a Hematologist or Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# GLEOSTINE

## Products Affected

- GLEOSTINE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Intracranial tumor, Relapsed or refractory Hodgkins disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRIMARY OR METASTATIC BRAIN TUMOR (1) Prescriber attests to diagnosis of primary or metastatic brain tumor AND (2) Individual has already received surgical and/or radiotherapeutic procedures B. REFRACTORY HODGKINS DISEASE (1) Prescriber attests to diagnosis of relapsed or refractory Hodgkins disease C. CENTRAL NERVOUS SYSTEM CANCER (1) Prescriber attests to diagnosis of one of the following (1a) Adult intracranial and spinal ependymoma (NCCN 2A) OR (1b) Adult low-grade infiltrative supratentorial astrocytoma/oligodendroglioma (NCCN 2A) OR (1c) Adult medulloblastoma OR (1d) Anaplastic gliomas (NCCN 2A) OR (1e) Glioblastoma (NCCN 2A) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# GLUMETZA NON FORMULARY

## Products Affected

- GLUMETZA
- *metformin hcl er (mod)*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Type 2 Diabetes, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.TYPE 2 DIABETES (1) Prescriber attests to diagnosis of Type 2 Diabetes AND (2) An allergic or adverse reaction to an excipient found in generic extended-release metformin (generic Glucophage XR) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic medical record) AND (3) Trial and failure of metformin ER (Fortamet) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# GRASTEK NON FORMULARY

## Products Affected

- GRASTEK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. GRASS POLLEN-INDUCED ALLERGIC RHINITIS (1) Prescriber attests to diagnosis of grass pollen-induced allergic rhinitis is confirmed by either a positive skin test response to a grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass) AND (2) Therapy is initiated 12 weeks prior to the expected onset of the grass pollen season or therapy is being dosed daily continuously for consecutive grass pollen seasons AND (3) Positive in vitro test (blood test for allergen-specific IgE antibodies) for a grass in the Pooideae subfamily of grasses AND (4) The member is NOT currently receiving subcutaneous allergen immunotherapy AND (5) If approved, members may obtain 30 sublingual Grastek tablets per 30 days |
| **Age Restrictions** | 5 to 65 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or ENT (ear, nose, throat) specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# HECTOROL (DOXERCALCIFEROL)

## Products Affected

- *doxercalciferol oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Secondary hyperparathyroidism, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SECONDARY HYPERPARATHYROIDISM (1) Prescriber attests to diagnosis of secondary hyperparathyroidism associated with one of the following diagnoses: (1a) Stage 3 or 4 chronic kidney disease not yet requiring dialysis (pre-dialysis) AND Patient has had a clinical trial and failure, intolerance, or contraindication to calcitriol OR (1b) Stage 5 chronic kidney disease requiring dialysis AND Patient has a serum intact parathyroid hormone (iPTH) level greater than 10 pg/mL |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# HEPSERA

## Products Affected

- *adefovir dipivoxil*
- HEPSERA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic hepatitis B, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC HEPATITIS B (1) Prescriber attests to diagnosis of chronic hepatitis B AND (2) Prescriber attests that patient has evidence of active viral replication AND (3) Prescriber attests that patient has elevated ALT or AST or histologically active disease AND (4) 6. Patient has had a clinical trial and failure, intolerance, or contraindication to therapy with Baraclude |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an infectious disease physician, gastroenterologist, hepatologist, or transplant physician |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# HEREDITARY ANGIOEDEMA POLICY

## Products Affected

- BERINERT
- CINRYZE
- FIRAZYR
- HAEGARDA
- *icatibant acetate*
- RUCONEST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary Angioedema, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | History of anaphylactic or life-threatening hypersensitivity reactions to human C1 inhibitor, icatibant, ecallantide or any component of the formulation. RUCONEST ONLY: known or suspected allergy to rabbits and rabbit derived products. |
| **Required Medical Information** | A. HAE: PROPHYLAXIS, CINRYZE OR HAEGARDA INITIAL (1) Prescriber attests to a documented history of greater than 1 abdominal or cutaneous HAE attack per month OR history of laryngeal attacks, OR emergency medical care related to HAE greater than 3 times per year AND (2) Prescriber attests HAE diagnosis is based on documentation of a low C4 level (less than 14 mg/dL) or below the lower limit of normal as defined by the laboratory performing the test AND (3) Prescriber attests to one of the following (3a) Low C1 inhibitor antigenic level (C1INH) (less than 19 mg/dL) or below the lower limit of normal as defined by the laboratory performing the test OR (3b) Normal C1INH (greater than or equal to 19 mg/dL) but a low C1INH functional level (functional C1INH less than 50% or below the lower limit of normal as defined by the laboratory performing the test) OR (3c) A known HAE causing mutation AND (4) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, and estrogens) AND (5) Member has tried and failed, intolerant to, or has a contraindication to 17-alpha alkylating androgens (i.e. danazol, stanozol) or fibrinolytic agents (i.e. tranexamic acid) for HAE prophylaxis AND (6) Prescriber attests that the patient and/or caregiver has been properly trained on self-administration technique. RENEWAL (1) Prescriber attests to a documented decrease in HAE attack frequency AND (2) Decrease in severity and duration of attacks |
| **Age Restrictions** | Cinryze: 6 years of age or older, Berinert, Ruconest: 13 years or older, Firazyr, Icatibant: 18 years or older, Haegarda: 12 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with medical geneticist, allergist, immunologist, or hematologist |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | B. HAE: ACUTE, BERINERT, FIRAZYR, ICATIBANT OR RUCONEST INITIAL (1) Prescriber attests to a documented diagnosis of HAE AND (2) Prescriber attests HAE diagnosis is based on documentation of a low C4 level (less than 14 mg/dL) or below the lower limit of normal as defined by the laboratory performing the test AND (3) Prescriber attests to one of the following (3a) Low C1INH (less than 19 mg/dL) or below the lower limit of normal as defined by the laboratory performing the test OR (3b) Normal C1INH (greater than or equal to 19 mg/dL) but a low C1INH functional level (functional C1INH less than 50% or below the lower limit of normal as defined by the laboratory) AND (4) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, estrogens) AND (5) Prescriber attests that patient is experiencing at least one (1) symptom of moderate to severe HAE attack (i.e. airway swelling, severe abdominal pain, facial swelling, nausea/vomiting, painful facial distortion) AND (6) Prescriber attests that patient is receiving only ONE agent indicated for treatment of acute HAE attack AND (7) ONE of the following: (7a) Dose is within the program quantity limit (allows for 2 acute attacks/month)OR (7b) Quantity requested is greater than the program quantity limit and prescriber has submitted documentation (e.g. frequency of attacks w/in the past 3 months has been greater than 2 attacks/month) in support of therapy with a higher quantity which has been reviewed and approved by the CD pharmacist AND (8) Prescriber attests that the patient/ caregiver has been properly trained on self-administration technique AND FOR BERINERT, FIRAZYR, OR RUCONEST (9) Member has tried and failed generic icatibant |

# HETLIOZ

## Products Affected

- HETLIOZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-24 hour sleep-wake cycle, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Severe hepatic impairment (Child-Pugh Class C) |
| **Required Medical Information** | A. NON-24 HOUR SLEEP-WAKE CYCLE (1) Prescriber attests to a diagnosis of non-24-hour sleep wake disorder (non-24 or N24) in completely blind members AND (2) Member must have tried OTC melatonin and failed to achieve an adequate response |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# HIZENTRA NON FORMULARY

## Products Affected

- CUVITRU
- HIZENTRA SUBCUTANEOUS SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary immune deficiency, Kawasaki disease, Chronic lymphocytic leukemia-related IgG deficiency, Bone Marrow Transplant, HIV infection-related IgG deficiency, Guillain-Barre Syndrome,Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Dermatomyositis (including juvenile) or Polymyositis, Systemic Lupus Erythematosus (SLE), Relapsing-Remitting Multiple Sclerosis, Autoimmune hemolytic anemia, Autoimmune neutropenia, Cytomegalovirus infection, Dermatomyositis, Kidney disease, Myasthenia gravis, Toxic shock syndrome, Hemolytic disease of fetus OR newborn due to RhD isoimmunization, Prophylaxis, Motor neuropathy with multiple conduction block, Multiple myeloma, Polymyositis, Stiff-man syndrome, Thrombocytopenia, Antenatal and neonatal, Kidney transplant - Pretransplant desensitization, Neonatal jaundice, Pemphigus vulgaris, Renal Transplant rejection, Respiratory syncytial infection, Sepsis, Uveitis, Von Willebrand disorder, Idiopathic (immune) thrombocytopenic purpura, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRIMARY IMMUNE DEFICIENCY (1) Prescriber attests to diagnosis of Primary immune deficiency AND (2) This includes one of the following (2a) Common Variable Immunodeficiency (hypogammaglobulinemia) OR (2b) IgG deficiency (IgGless than400mg/dl and/or a significant inability to respond with IgG antibody production after antigenic challenge) OR (2c) Brutons or X-linked agammaglobulinemia OR (2d) Severe Combined Immunodeficiency (SCID) OR (2e) Wiskott-Aldrich Syndrome OR (2f) X-linked Hyper IgM Syndrome B. CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP) (1) Prescriber attests to diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) AND (2) Tried/failed/intolerance of corticosteroids or plasma exchange C. DERMATOMYOSITIS OR POLYMYOSITIS (1) Prescriber attests to diagnosis of Dermatomyositis (including juvenile) or Polymyositis AND (2) Tried/failed/intolerance to corticosteroids and adjuvant therapy (methotrexate, hydroxychloroquine, cyclosporine, etc.) D. SYSTEMIC |

| PA Criteria | Criteria Details |
|---|---|
| | LUPUS ERYTHEMATOSUS (SLE) (1) Prescriber attests to diagnosis of Systemic Lupus Erythematosus (SLE) AND (2) Tried/failed/intolerance of NSAIDs, corticosteroids and/or antimalarials) AND immunosuppressants E. RELAPSING-REMITTING MULTIPLE SCLEROSIS (1)Prescriber attests to diagnosis of Relapsing-Remitting Multiple Sclerosis AND (2) Tried/failed/intolerance to Avonex, Betaseron, Copaxone, and/or Rebif |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a specialist in the area of the patient diagnosis |
| **Coverage Duration** | 12 months |
| **Other Criteria** | F.OTHER DIAGNOSES (1) Prescriber attests to diagnosis of one of the following Kawasaki disease, Chronic lymphocytic leukemia-related IgG deficiency, Bone Marrow Transplant (prevention of graft-versus-host disease and/or infection), HIV infection-related IgG deficiency OR Guillain-Barre Syndrome, Autoimmune hemolytic anemia, Autoimmune neutropenia, Cytomegalovirus infection, Dermatomyositis, Kidney disease, Myasthenia gravis, Toxic shock syndrome, Hemolytic disease of fetus OR newborn due to RhD isoimmunization, Prophylaxis, Motor neuropathy with multiple conduction block, Multiple myeloma, Polymyositis, Stiff-man syndrome, Thrombocytopenia, Antenatal and neonatal, Kidney transplant - Pretransplant desensitization, Neonatal jaundice, Pemphigus vulgaris, Renal Transplant rejection, Respiratory syncytial infection, Sepsis, Uveitis, Von Willebrand disorder RENEWAL FOR ALL DIAGNOSES (1) Platelet count of at least 50,000/mm3) AND (2) Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding |

# HUMATIN NON FORMULARY

## Products Affected

- *paromomycin sulfate oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Intestinal amebiasis (dientamoeba fragilis, or entamoeba histolytica), Adjunct treatment of hepatic coma or hepatic encephalopathy, Cryptosporidium parvum (cryptosporidiosis) in HIV-infected patient, Infection with Giardiasis, Tapeworm infestations (caused by: Diphyllobothrium latum, Dipylidium caninum, Taenia saginata, Taenia solium, Hymenolepis nana), Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. INTESTINAL AMEBIASIS, GIARDIASIS (1) Prescriber attests to diagnosis of Intestinal amebiasis (dientamoeba fragilis, or entamoeba histolytica) OR Infection with Giardiasis AND (2) the patient has had a clinical trial and failure with tinidazole B. HEPATIC COMA OR HEPATIC ENCEPHALOPATHY (1) Prescriber attests to diagnosis of adjunct treatment of hepatic coma or hepatic encephalopathy AND (2) patient has had a trial and failure of the following metronidazole AND neomycin C. CRYPTOSPORIDIUM PARVUM (1) Prescriber attests to diagnosis of Cryptosporidium parvum (cryptosporidiosis) in HIV-infected patient D. TAPEWORM INFESTATIONS (1) Prescriber attests to diagnosis of tapeworm infestations (caused by: Diphyllobothrium latum, Dipylidium caninum, Taenia saginata, Taenia solium, Hymenolepis nana) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# HUMIRA

## Products Affected

- HUMIRA PEN
- HUMIRA PEN-CD/UC/HS STARTER SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML
- HUMIRA PEN-PS/UV/ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.2ML, 20 MG/0.4ML, 40 MG/0.4ML, 40 MG/0.8ML

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Crohn disease (CD), Hidradenitis suppurativa (HS), Juvenile idiopathic arthritis (JIA), Plaque psoriasis (Ps), Psoriatic arthritis(PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC), Uveitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Used in combination with biological DMARDs |
| **Required Medical Information** | A. PLAQUE PSORIASIS (1) Prescriber attests to a documented diagnosis of plaque psoriasis AND (2) Plaque psoriasis must involve greater than or equal to 5% of the body surface area (BSA) OR (3) Patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (4) Three of the following (4a) Patient has had an inadequate response to 3-month trial of either topical therapy OR (4b) localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA]) for psoriasis OR (4c) Patient has had an inadequate response to a 3- month trial of systemic therapy (i.e. MTX, cyclosporine, acitretin [Soriatane]) OR (4d) Patient has significant disability or impairment in physical or mental functioning, according to the treating physician AND (5) Patient must have a negative tuberculosis test or receive treatment if tested positive B. ALL OTHER INDICATIONS INITIAL (1) Prescriber attests to a documented diagnosis of a FDA-approved indication AND (2) 2. Prescriber attests that the member has tried and failed one conventional therapy indicated for the diagnosis, including but not limited to, azathioprine, methotrexate, NSAIDs, DMARDs, corticosteroids, sulfasalazine, mesalamine, antibiotics etc. AND (3) Prescriber attests that patient has a negative tuberculosis test or receive treatment if tested positive. RENEWAL FOR ALL INDICATIONS (1) Prescriber attests that the patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patients condition AND (2) Prescriber attests that the |

| PA Criteria | Criteria Details |
|---|---|
| | patient has disease stabilization or improvement as defined by standard monitoring for the patients condition |
| **Age Restrictions** | Crohn Disease, 6 years of age or older. Juvenile idiopathic arthritis and Uveitis, 2 years of age or older. Hidradenitis Suppurativa, 12 years of age and older. |
| **Prescriber Restrictions** | AS, JIA, PsA, RA: Prescribed by or in consultation with a rheumatologist. HS, Ps: Prescribed by or in consultation with a dermatologist. UC, CD: prescribed by or in consultation with a gastroenterologist. UV: Prescribed by or in consultation with a uveitis specialist (e.g. ophthalmologist, ocular immunologist) |
| **Coverage Duration** | Initial: 12 months , Renewal: 12 months |
| **Other Criteria** | 40 mg syringe - One starter pack containing 6 syringes will initially be authorized for a 21-day supply, followed by 2 syringes per 28 days. Indication of Hidradenitis suppurativa will be allowed 4 syringes per 28 days. |

# HYDROXYPROGESTERONE NON FORMULARY

## Products Affected

- *hydroxyprogesterone caproate intramuscular solution*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced stage (stage III or IV) adenocarcinoma of the uterine corpus, Primary or secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in absence of organic pathology, For production on secretory endometrium and desquamation, To test for endogenous estrogen production, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADVANCED STAGE ADENOCARCINOMA OF UTERINE CORPUS: (1) Prescriber attests to a diagnosis of advanced stage (stage III or IV) adenocarcinoma of the uterine corpus. B. PRIMARY OR SECONDARY AMENORRHEA: (1) Prescriber attests to a diagnosis of primary or secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology (e.g. submucous fibroids or uterine cancer). C. PRODUCTION ON SECRETORY ENDOMETRIUM AND DESQUAMATION: (1) Prescriber attests to a product being used for production on secretory endometrium and desquamation. D. TEST FOR ENDOGENOUS ESTROGEN PRODUCTION: (1) Prescriber attest to a product being used as a test for endogenous estrogen production AND (2) Patient is a non-pregnant female. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# HYQVIA

## Products Affected

- HYQVIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary Humoral/Combined Immune Deficiencies, Common Variable Immunodeficiencies, Other Combined Immunodeficiencies, or Unspecified Hypogammaglobulinemia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRIMARY HUMORAL AND COMBINED IMMUNE DEFICIENCIES (INITIAL THERAPY) (1) Prescriber attests patient has diagnosis of one of the following Primary Humoral or Combined Immune Deficiencies (i) X-linked agammaglobulinemia (XLA) [Brutons agammaglobulinemia, congenital agammaglobulinemia] (ii) Severe combined immunodeficiencies (iii) Wiskott-Aldrich syndrome (iv) Hyper-Immunoglobulin M (IgM) syndrome, X-linked (CD40 L deficiency), or autosomal recessive (activation-induced cytidine deaminase, uracil-DNA glycosylase, CD40 deficiency) (2) Prescribed by or in consultation with one of the following: (i) allergist/immunologist (ii) immunologist (iii) otolaryngologist (ENT physician) (iv) pulmonologist (v) infectious diseases physician who treats patients with primary immune deficiencies B. COMMON VARIABLE IMMUNODEFICIENCIES (INITIAL THERAPY) (1) Prescriber attests patient has diagnosis of Common Variable Immunodeficiencies (CVID) (2) Prescribed by or in consultation with one of the following: (i) allergist/immunologist (ii) immunologist (iii) otolaryngologist (ENT physician) (iv) pulmonologist (v) infectious diseases physician who treats patients with primary immune deficiencies (3) Other disorders that may increase susceptibility to infection such as allergy or anatomic defects, have been sought out and treated aggressively if present according to the prescribing physician (4) The total serum IgG level is below the normal range (age-adjusted and according to the normal reference range for the reporting laboratory) measured on at least two occasions more than 3 weeks apart (5) The IgA or IgM serum level is lower than the normal range (age-adjusted and according to the normal reference range for the reporting laboratory) measured on at least two occasions more than 3 weeks apart (6) One of the following: |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following physician specialists: an allergist/immunologist, immunologist, otolaryngologist (ear nose and throat [ENT] physician), pulmonologist, or an infectious diseases physician who treats patients with primary immune deficiencies |
| **Coverage Duration** | 12 months |
| **Other Criteria** | (i) The patient has a markedly impaired antibody response to protein (e.g., tetanus, diphtheria) antigen (ii) antibody testing with a polysaccharide antigen (pneumococcus) (iii) according to the prescribing physician the delay caused by pre-vaccination and post-vaccination antibody measurement would be deleterious to the patients health. Note: In cases where impaired antibody testing would be deleterious to the patients health, all other criteria for CVID in this section must be met C. OTHER COMBINED IMMUNODEFICIENCIES (INITIAL THERAPY) (1) Prescriber attests patient has diagnosis of Other combined immunodeficiencies with significant hypogammaglobulinemia or antibody production defect (ataxia-telangiectasia, Hyper-Immunoglobulin E (IgE) syndrome, STAT (signal transducer and activator of transcription)-3 deficiency, 15 STAT-1 deficiency, 15 DiGeorge syndrome, or 24-25 nuclear factor KB essential modifier (NEMO) deficiency) (2) Prescribed by or in consultation with one of the following: (i) allergist/immunologist (ii) immunologist (iii) otolaryngologist (ENT physician) (iv) pulmonologist (v) infectious diseases physician who treats patients with primary immune deficiencies (3) Patient has frequent and severe infections according to the prescribing physician D. UNSPECIFIED HYPOGAMMAGLOBULINEMIA (INITIAL THERAPY) (1) Prescriber attests patient has diagnosis of Unspecified hypogammaglobulinemia (or unspecified IgG deficiency) (2) Prescribed by or in consultation with one of the following physician specialists: (i) allergist/immunologist (ii) immunologist (iii) otolaryngologist (ENT physician) (iv) pulmonologist (v) infectious diseases physician who treats patients with primary immune deficiencies (3) Other disorders that may increase susceptibility to infection such as allergy or anatomic defects, have been sought out and treated aggressively if present according to the prescribing physician (4) The total serum IgG level is below the normal range (age-adjusted and according to the normal reference range for the reporting laboratory) measured on at least two occasions more than 3 weeks apart (5) The IgA or IgM serum level is in the normal range or higher (age-adjusted and according to the normal reference range for the reporting laboratory) measured on at least two occasions more than 3 weeks apart (6) The patient has a markedly impaired antibody response to protein (e.g., tetanus, diphtheria) antigen OR antibody testing with a polysaccharide |

| PA Criteria | Criteria Details |
| --- | --- |
| | antigen (pneumococcus) E. CONTINUATION OF THEARPY: PATIENTS CURRENTLY RECEIVING SCIG (HYQVIA) (1) One of the following: (i) Patient has a diagnosis of CVID, other combined immunodeficiencies with significant hypogammaglobulinemia or antibody production defect, or unspecified hypogammaglobulinemia, and the frequency and/or severity of infections has decreased according to the prescribing physician (ii) Patient has a diagnosis of CLA, SCID, Wiskott-Aldrich syndrome, or hyper-IgM syndromes |

# HYSINGLA

## Products Affected

- HYSINGLA ER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Around-the-Clock Severe-Chronic Pain in Opioid Tolerant Patients. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Significant respiratory depression (2) Acute or severe bronchial asthma or hypercarbia (3) Patient has or is suspected of having paralytic ileus (4) Hypersensitivity to any components of Hysingla ER or the active ingredient, hydrocodone bitartrate |
| **Required Medical Information** | A. AROUND-THE-CLOCK SEVERE-CHRONIC PAIN IN OPIOID TOLERANT PATIENTS (1) Prescriber attests patient has diagnosis of Around-the-clock severe-chronic pain, in opioid-tolerant patients (2) The patient must be over the age of 18 years (3) The patient must have severe pain enough to require daily, around-the clock, long-term opioid treatment (4) Patient has had inadequate pain control or intolerance to a two week trial of at least 1 non-opioid and a 2 week trial of 1 short-acting opioid |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Hysingla ER is not indicated as an as-needed (PRN) analgesic |

# IBRANCE

## Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Estrogen Receptor-Positive, HER2-Negative Advanced or Metastatic Breast Cancer, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ESTROGEN RECEPTOR-POSITIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER (1) Prescriber attests patient has diagnosis of Estrogen Receptor-Positive, HER2-negative advanced or metastatic breast cancer (2) One of the following: (i) All of the following: (a) Patient has had no prior endocrine therapy for metastatic breast cancer (b) Given in combination with an aromatase inhibitor (c) Patient is a Postmenopausal female or adult male (ii) All of the following: (a) Patient has had disease progression following endocrine-based therapy (b) Given in combination with fulvestrant |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | When prior authorization is approved, up to 21 capsules may be authorized per 28 days. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective. |

# ICLUSIG

## Products Affected

- ICLUSIG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC MYELOID LEUKEMIA (CML) (1) Prescriber attests patient has diagnosis of Chronic Myeloid Leukemia (CML) Chronic Phase, Accelerated Phase, or Blast Phase (2) Prescribed by, or in consultation with, an Oncologist (3) All of the following: (i) Patient is an adult (ii) Patient meets ONE of the following conditions: (a) Patient is T315I-positive (b) Patients disease has not responded to 2 or more tyrosine kinase inhibitor therapies (c) According to the prescribing physician, no other tyrosine kinase inhibitor (TKI) therapy is indicated B. PHILADELPHIA CHROMOSOME POSITIVE (PH+0 ACUTE LYMPHOBLASTIC LEUKEMIA (1) Prescriber attests patient has diagnosis of Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) (2) Prescribed by, or in consultation with, an Oncologist (3) All of the following: (i) Patient is an adult (ii) Patient meets ONE of the following conditions: (a) Patient is T315I-positive (b) Is resistant to or progressive on multiple TKIs as a single agent (c) According to the prescribing physician, no other TKI therapy is indicated |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ILARIS NON FORMULARY

## Products Affected

- ILARIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Periodic Fever Syndromes or Systemic Juvenile Idiopathic Arthritis (SIJA). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PERIODIC FEVER SYNDROMES (INITIAL) (1) Prescriber attests patient has diagnosis of One of the following: (i) Cryopyrin-Associated Periodic Syndromes (CAPS) (ii) Familial Cold Autoinflammatory Syndrome (FACS (iii) Muckle-Wells Syndrome (MWS) (iv) Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) (v) Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (vi) Familial Mediterranean Fever (FMF) (2) For FMF DIAGNOSIS ONLY: Prescriber attests that patient has a history of failure, contraindication, or intolerance to colchicine B. PERIODIC FEVER SYNDROMES CONTINUATION OF THERAPY (1) Prescriber attests that member continues to meet initial criteria (2) Prescriber attests that member has had improvement or stabilization with therapy C. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) (1) Prescriber attests patient has diagnosis of SIJA (2) Prescriber attests that patient has tried and failed one conventional therapy indicated for the diagnosis, including but not limited to, azathioprine, methotrexate, NSAIDs, DMARDs D. SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) CONTINUATOIN OF THERAPY (1) Prescriber attests that patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patients condition (2) Prescriber attests that the patient has disease stabilization or improvement as defined by standard monitoring for the patients condition |
| **Age Restrictions** | CAPS, FACS, MWS: 4 years of age or older and weighing at least 15 kg, TRAPS, HIDS, MDS, FMF: 2 years of age or older, SJIA: 2 years of age or older and weighing at least 7.5 kg |
| **Prescriber Restrictions** | SJIA: Prescribed by or in consultation with a rheumatologist, Other: Prescribed by or in consultation with a provider with expertise in the treatment of the conditions |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# IMBRUVICA

## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mantle Cell Lymphoma, Waldenstroms Macroglobulinemia, Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia, Marginal Zone Lymphoma (MZL), Chronic Graft Versus Host Disease (cGVHD), Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC LYMPHOCYTIC LEUKEMIA/SMALL LYMPHOCYTIC LEUKEMIA (1) Prescriber attests patient has diagnosis of Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia (2) Patient is 18 years of age or older (3) Prescribed by an Oncologist or Hematologist B. MANTLE CELL LYMPHOMA (1) Prescriber attests patient has diagnosis of Mantle Cell Lymphoma (2) Patient is 18 years of age or older (3) Prescribed by an Oncologist or Hematologist (4) Member has received at least one (1) prior therapy (i.e. Revlimid) C. WALDENSTROMS MACROGLOBULINEMIA (1) Prescriber attests patient has diagnosis of Waldenstroms macroglobulinemia (2) Patient is 18 years of age or older (3) Prescribed by an Oncologist or Hematologist (4) Requested medication is being used as a single agent D. MARGINAL ZONE LYMPHOMA (MZL) (1) Prescriber attests patient has diagnosis of Marginal Zone Lymphoma (MZL) (2) Patient is 18 years of age or older (3) Prescribed by an Oncologist or Hematologist (4) Disease requires systemic therapy (5) Patient has received at least one prior Anti-CD 20 based therapy E. CHRONIC GRAFT VERSUS HOST DISEASE (CGVHD) (1) Prescriber attests patient has diagnosis of Chronic Graft Versus Host Disease (cGVHD) (2) Patient is 18 years of age or older (3) Prescribed by an Oncologist or Hematologist (4) Patient is post-allogeneic stem cell transplant (generally 3 or more months) (5) Patient has failed one or more previous lines of systemic therapy (i.e. corticosteroids or immunosuppressants such as cyclosporine) F. CONTINUATION OF THERAPY (1) For oncology indications, prescriber attests to tumor response with stabilization of disease or decrease in size of tumor or tumor spread (2) For cGVHD, prescriber attests to a response to therapy defined as at least one of the following: (i) Clinician assessment (e.g. NIH |

| PA Criteria | Criteria Details |
|---|---|
| | Skin score, upper GI Response Score, NIH Lung Symptom Score, etc.) (ii) Patient-reported symptoms (Lee Symptom Scale) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by an Oncologist or Hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# INCRELEX

## Products Affected

- INCRELEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe Primary Insulin-Like Growth Factor Deficiency (IGFD) or Growth Hormone Gene Deletions with GH Neutralizing Antibodies. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SEVERE PRIMARY INSULIN-LIKE GROWTH FACTOR DEFICIENCY (IGFD) AND GROWTH HORMONE GENE DELETIONS WITH GH NEUTRALIZING ANTIBODIES (1) Prescriber attests patient has diagnosis of severe primary insulin-like growth factor deficiency (IGFD) or patients with growth hormone gene deletion who have developed neutralizing antibodies to GH as defined by all of the following: (i) IGF-1 level that is considered low (less than -2 standard deviations below the mean) based on the labs reference range (ii) Lab results within 3 months of initial request (iii) Height standard deviation score less than or equal to -3.0 (iv) Normal or elevated growth hormone level, (except for growth hormone (GH) deletion), based on growth hormone stimulation test with peak greater than 10 ng/mL (2) Prescribed by a Pediatric Endocrinologist (3) The following indications of secondary IGF-1 have been ruled out: (i) Growth Hormone Deficiency (ii) Hypothyroidism (iii) Malnutrition (4) Open epiphyses (5) Patient is greater than/=2 and less than/= 20 years of age B. CONTINUATION OF THERAPY (1) Increase in height velocity greater than 2.5cm total growth in 1 year (2) No evidence of epiphyseal closure (3) Patient has not met their expected final adult height or targeted height based on min-parental height calculation or their current absolute height is less than/= the 25th percentile (defined as 68 inches in males and 63 inches in females) |
| **Age Restrictions** | greater than/=2 and less than/= 20 years of age |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# INFED NON FORMULARY

## Products Affected

- INFED

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Iron Deficiency. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. IRON DEFICIENCY (1) Prescriber attests patient has diagnosis of Iron Deficiency (2) One of the following: (i) Inadequate response or adverse reaction to one oral iron formulation (ii) Clinical rationale why oral iron therapy cannot be used |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# INFERTILITY

## Products Affected

- *clomiphene citrate oral*
- *ganirelix acetate*
- GONAL-F RFF REDIJECT
- PREGNYL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Infertility or Assisted Reproductive Technology. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. INFERTILITY AND ASSISTED REPRODUCTIVE TECHNOLOGY (1) Prescriber attests patient has diagnosis of Infertility or Assisted Reproductive Technology (ART) (2) Prescribed in accordance with FDA-approved labeling or a medically accepted indication (3) No exclusions to therapy (4) Prescribed by or in consultation with an infertility specialist or gynecologist for fertility/ART or endocrinologist for hypogonadism (5) Member 18 years of age or older B. ALL OTHER INDICATIONS (1) Prescribed in accordance with FDA-approved labeling or a medically accepted indication (2) No exclusions to therapy (3) Prescribed by or in consultation with an infertility specialist or gynecologist for fertility/ART or endocrinologist for hypogonadism |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infertility specialist or gynecologist for fertility/ART or endocrinologist for hypogonadism |
| **Coverage Duration** | See Other Criteria |
| **Other Criteria** | INITIAL AUTHORIZATION: (1) Cryptorchidism: 6 weeks (2) Hypogonadotropic hypogonadism: 9 months (3) Ovulation induction one treatment cycle (10-12 days) (4) CLOMIPHENE ONLY, Ovulatory failure: 1 cycles of 5 days (5) Hypogonadism: 90 days (6) All Other Indications/Medication Not Specified: 12 months RENEWAL: (1) Cryptorchidism - 6 weeks (2) Hypogonadotropic hypogonadism 12 months (3) Ovulation induction - check members benefits (4) CLOMIPHENE ONLY RENEWAL, Ovulatory failure renew for 3 more cycles if other cause of infertility have been ruled out for ovarian failure or 12 months if prescriber attest to improvement in condition for |

| PA Criteria | Criteria Details |
|---|---|
| | hypogonadism (5) ALL OTHER INDICATIONS/ MEDICATION NOT SPECIFIED: 12 months |

# INFLIXIMAB NON FORMULARY

## Products Affected

- INFLECTRA
- REMICADE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Crohns disease (CD), Plaque psoriasis (Ps), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Used in combination with a biologic DMARD |
| **Required Medical Information** | STEP ALERT: MUST HAVE A TRIAL AND FAILURE OF RENFLEXIS AND AVSOLA A. PLAQUE PSORIASIS: INITIAL: (1) Prescriber attests to a documented diagnosis of plaque psoriasis AND (2a) Patients with plaque psoriasis involving greater than or equal to 5% of the body surface area (BSA)OR (2b) Patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (2c) Three of the following, a. Patient has had an inadequate response to 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA]) for psoriasis AND b. Patient has had an inadequate response to a 3-month trial of systemic therapy (i.e. MTX, cyclosporine, acitretin [Soriatane]) AND c. Patient has significant disability or impairment in physical or mental functioning, according to the treating physician AND (3) patient must have a negative tuberculosis test or receive treatment if tested positive. See other criteria. |
| **Age Restrictions** | CD, greater than or equal to 6 years for age, UC greater than or equal to 6 years for age. AS, Ps, PsA, RA 18 years of age or older |
| **Prescriber Restrictions** | AS, PsA, RA: Prescribed by or in consultation with a rheumatologist PS: Prescribed by or in consultation with a dermatologist. UC, CD: Prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | B. FOR ALL OTHER INDICATIONS, (1) Prescriber attests to a documented diagnosis of a FDA-approved indication AND (2) Must have a tried and failed one conventional therapy indicated for the diagnosis, including but not limited to, azathioprine, methotrexate, NSAIDs, DMARDs, corticosteroids, sulfasalazine, mesalamine, etc. AND (3) |

| PA Criteria | Criteria Details |
| --- | --- |
| | patient must have a negative tuberculosis test or receive treatment if tested positive. Quantity Limit: 10 each per 14 days C. ADDITIONAL INFORMATION FOR ALL DIAGNOSES (1) Patient must try and fail Humira and Enbrel prior to approval of Infliximab for the following diagnoses: (1a) Rheumatoid Arthritis (1b) Crohns Disease (Humira only) (1c) Ankylosing Spondylitis (1d) Psoriatic Arthritis (1e) Plaque Psoriasis (1f) Ulcerative Colitis (Humira only) |

# INGREZZA NON FORMULARY

## Products Affected

- INGREZZA ORAL CAPSULE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Tardive Dyskinesia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Patients with unstable psychiatric symptoms |
| **Required Medical Information** | A. TARDIVE DYSKINESIA (1) Prescriber attests patient has diagnosis of Tardive Dyskinesia (2) One of the following: (i) If patient is being treated for schizophrenia, schizoaffective disorder or mood disorder, then prescriber must provide a rationale as to why a lower dose is not being used AND why switching to a 2nd generation antipsychotic if on a 1st generation is not available (ii) If being treated with metoclopramide, then prescriber must provide a rationale why discontinuation is not possible (3) Member is 18 years of age and older (4) Prescribed by or in consultation with a psychiatrist B. CONTINUATION OF THERAPY (1) Prescriber must show symptomatic improvement from baseline |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a psychiatrist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# INLYTA

## Products Affected

- INLYTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Renal Cell Carcinoma, Thyroid Carcinoma, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RENAL CELL CARCINOMA (1) Prescriber attests patient has diagnosis of Renal Cell Carcinoma AND (2) Must be used as a single agent with advanced disease after failure of one prior systemic therapy OR (3) Used in combination with avelumab or pembrolizumab for advanced disease AND (4) Patients disease must be relapsed or surgically unresectable stage IV and one of the following: (4a) Must be used as first-line or subsequent therapy for clear cell histology OR (4b) Patient has non-clear cell histology B. THYROID CARCINOMA (1) Prescriber attests patient has diagnosis of Thyroid Carcinoma (Follicular carcinoma/Hurthle cell carcinoma/Papillary carcinoma) AND (2) Patient has unresectable recurrent, persistent, or metastatic disease AND (3) Patient has progressive and/or symptomatic iodine-refractory disease AND (4) Other therapies are not available or appropriate C. CONTINUATION OF THERAPY (1) Tumor response with stabilization of disease or decrease in size of tumor or tumor spread (2) Absence of unacceptable toxicity from the drug |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | None |

# INTRON-A

## Products Affected

- INTRON A INJECTION SOLUTION 6000000 UNIT/ML
- INTRON A INJECTION SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hairy Cell Leukemia, Malignant Melanoma, Follicular Lymphoma, Condylomata Acuminata, AIDS-Related Kaposis Sarcoma, Chronic Hepatitis C, Chronic Hepatitis B, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Patients with: Autoimmune hepatitis, decompensated liver disease, Combination therapy with ribavirin in pregnant women or in men whose female partner are pregnant, patients with hemoglobinopathies (e.g., thalassemia major, sickle cell anemia), patients with creatinine clearance less than 50 mL/min |
| **Required Medical Information** | A. HAIRY CELL LEUKEMIA: (1) Prescriber attests patient has diagnosis of hairy cell leukemia B. MALIGNANT MELANOMA: (1) Prescriber attests patient has diagnosis of malignant melanoma (disease free but at high risk for systemic recurrence) (2) Will be used as adjuvant to surgical treatment (within 56 days of surgery) C. FOLLICULAR NON-HODGKINS LYMPHOMA: (1) Prescriber attests patient has diagnosis of clinically aggressive follicular Non-Hodgkin lymphoma (2) Will be used in conjunction with an anthracycline-containing chemotherapy regimen (3) Not being used in patients with low-grade, low-tumor burden follicular D. CONDYLOMATA ACUMINATA (1) Prescriber attests patient has diagnosis of condylomata acuminata involving external surfaces of the genital and perianal areas E. AIDS-RELATED KAPOSI SARCOMA: (1) Prescriber attests patient has diagnosis of AIDS-related Kaposi sarcoma F. CHRONIC HEPATITIS C: (1) Prescriber attests patient has diagnosis of chronic hepatitis C - genotype 1, 2, 3, 4, 5, 6 with detectable HCV RNA levels (2) Trial/failure/contraindication to all appropriate formulary direct acting anti-viral therapies (ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, glecaprevir/pibrentasvir) (3) No history of hepatic encephalopathy, variceal bleeding, ascites, or other clinical signs of decompensation (4) The following laboratory results have been provided (within 6 weeks of therapy): (i) HCV RNA (ii) HCV GT (iii) CBC with platelets (iv) AST/ALT (v) Total bilirubin (vi) Serum G. CHRONIC HEPATITIS B: (1) Prescriber attests patient has diagnosis of chronic hepatitis B with compensated liver disease confirmed by the detection of one of the |

| PA Criteria | Criteria Details |
|---|---|
| | following: (i) HBV viral RNA (ii) Hepatitis B surface antigen (HBsAG) (iii) Hepatitis Be antigen (HBeAG) (2) The following laboratory results have been provided (within 6 weeks of therapy): (i) HBV RNA (ii) HCV GT (iii) CBC with platelets (iv) AST/ALT (v) Total bilirubin (vi) Serum albumin (vii( PT/INR (viii) Serum creatinine and GFR |
| **Age Restrictions** | HAIRY CELL LEUKEMIA, MALIGNANT MELANOMA, FOLLICULAR LYMPHOMA, CONDYLOMATA ACUMINATA, AIDS RELATED KAPOSI SARCOMA: 18 years of age or older, CHRONIC HEPATITIS C: 3 years of age or older when treated with Rebetol, otherwise 18 years of age or older, CHRONIC HEPATITS B: 1 year of age or older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a Gastroenterologist, Hepatologist, Oncologist or Infectious Disease Specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# INVEGA

## Products Affected

- INVEGA
- INVEGA SUSTENNA
- *paliperidone er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Bipolar Disorder, Schizophrenia, Other Psychotic Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BIPOLAR DISORDER, SCHIZOPHRENIA, AND OTHER PSYCHOTIC DISORDER (1) Prescriber attests patient has diagnosis of bipolar disorder, schizophrenia, or other psychotic disorder (2) 12 years of age or older (3) Significant hepatic impairment or severe renal impairment (creatinine clearance less than or equal to 30 ml/min) One of the following: (i) Trial and failure, intolerance or contraindication of two of the following formulary alternatives: (a) Risperidone (b) Olanzapine (c) Ziprasidone (d) Quetiapine (e) Aripiprazole (ii) For Invega Sustenna, patient has documented issues with compliance and long acting injection is clinically necessary |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For Invega Sustenna, patient has documented issues with compliance and long acting injection is clinically necessary |

# JADENU NON FORMULARY

## Products Affected

- *deferasirox oral tablet 360 mg, 90 mg*
- JADENU

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Transfusional Iron Overload or Non-Transfusional Iron Overload. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Clinical trial and failure of Exjade is required prior to consideration of Jadenu (convenience, disliking the taste of Exjade, etc. are not considered failure) |
| **Required Medical Information** | A. TRANSFUSIONAL IRON OVERLOAD (INITIAL) (1) Prescriber attests patient has diagnosis of iron overload related to anemia found in patients medical conditions, progress notes, and/or discharge notes (2) Patient must be 2 years of age or older (3) Documentation in medical records (e.g., progress notes, discharge notes) of a recent history of frequent blood transfusions that has resulted in chronic iron overload (4) Serum ferritin must be consistently greater than1000 mcg/L as documented by lab results submitted and dated within the past month B. TRANSFUSIONAL IRON OVERLOAD (CONTINUATION) (1) Serum ferritin must have been measured within 30 days of continuation of therapy request (copy lab results must be submitted) (2) Ferritin levels must be greater than500mcg/L (3) Dose must not exceed 28mg/kg/day C. NON-TRANSFUSIONAL IRON OVERLOAD (INITIAL) (1) Prescriber attests patient has diagnosis of iron overload related to anemia found in patients medical conditions, progress notes, and/or discharge notes (2) Patient must be greater than 10 years of age (3) Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of initiation (copy of lab results must be submitted) (4) Serum ferritin levels must be greater than300mcg/L (5) Liver iron concentration (LIC) must be greater than5 mg Fe/g dried weight (dw) D. NON-TRANSFUSIONAL IRON OVERLOAD (CONTINUATION) (1) Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of continuation of therapy request (copy of lab results must be submitted) (2) Serum ferritin levels must be greater than300mcg/L (3) Liver iron concentration (LIC) must be greater than3 mg Fe/g dw (4) Dose must not exceed: 14mg/kg/day |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 3 months |
| **Other Criteria** | Transfusional Iron Overload: Starting dose is 14 mg/kg/day. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg) Non-Transfusional Iron Overload: Starting dose is 7mg/kg/day. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg) |

# JAKAFI

## Products Affected

- JAKAFI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary Myelofibrosis, Post-Polycythemia Vera Myelofibrosis, Post-Essential Thrombocythemia Myelofibrosis, Polycythemia Vera, or Steroid-Refractory Acute Graft-Versus-Host Disease. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS, AND POST-ESSENTIAL THROMBOCYTHEMIA MYELOFIBROSIS (1) Prescriber attests patient has diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis (2) Patient has intermediate or high risk disease as defined by possessing TWO or more of the following criteria: (i) Age greater than 65 (ii) Documented Hemoglobin less than 10g / dL (iii) Documented WBC greater than 25 x 109 / L (iv) Circulating Blasts greater than/= 1% (v) Presence of Constitutional Symptoms (weight loss greater than 10% from baseline or unexplained fever or excessive sweats persisting for more than 1 month) (3) Baseline complete blood count (CBC) with platelet count of at least 50 X 109 / L prior to initiating therapy (4) Patient will be using Jakafi (ruxolitinib) as monotherapy (excludes medically necessary supportive agents) B. POLYCYTHEMIA VERA (1) Prescriber attests patient has diagnosis of polycythemia vera (2)inadequate response to or intolerance to hydroxyurea C. STEROID-REFRACTORY ACUTE GRAFT-VERSUS-HOST DISEASE (1) Prescriber attests patient has diagnosis of steroid-refractory acute graft-versus-host disease (2) Patient is 12 years of age or older D. CONTINUATION OF THERAPY (1) One of the following: (i) Patient has achieved a reduction from pretreatment baseline of at least 50% in palpable spleen length or a 35% in spleen volume as measured by CT or MRI (ii) Patient has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF) |
| **Age Restrictions** | GVHD: 12 years of age or older |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 3 months, Renewal: 6 months |
| **Other Criteria** | None |

# JUXTAPID NON FORMULARY

## Products Affected

- JUXTAPID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Homozygous Familial Hypercholesterolemia |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (1) Prescriber attests patient has diagnosis of Homozygous Familial Hypercholesterolemia, confirmed by genetic testing documentation and liver enzyme test results (2) Patient must already be on an appropriate lipid lowering diet and should continue during treatment (3) Trial and failure, intolerance or contraindication of the maximum tolerated doses of ALL of the following (medication usage must be supported by documentation from the patients chart notes/medical records): (i) HMG CoA reductase inhibitors including atorvastatin and rosuvastatin (Crestor) (ii) Cholesterol absorption inhibitors, including ezetimibe (Zetia) (4) Tried and failed, intolerance or contraindication to Kynamro or the patient is concurrently receiving lipid apheresis (medication usage must be supported by documentation from the patients chart notes/medical records) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KALBITOR NON FORMULARY

## Products Affected

- KALBITOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of acute hereditary angioedema. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACUTE HEREDITARY ANGIOEDEMA (1) Diagnosis of acute hereditary angioedema AND (2) Age greater than 12 years of age AND (3) C4 level less than 14 mg/L AND (4) C1 INH (antigenic) level less than 19.9 mg/Dl OR (4) C1 INH (functional) level less than 72% of the reference range |
| **Age Restrictions** | Age greater than 12 years of age |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KALYDECO

## Products Affected

- KALYDECO ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Cystic fibrosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CYSTIC FIBROSIS (1) Diagnosis of Cystic fibrosis AND (2) Must have documentation of one of the following gating or residual function mutations in the CFTR gene (arrows have been replaced with dashes in mutations [note - if mutation given is not one of the following please verify package insert])- E56K, P67L, R74W, D110E, D110H, R117C, R117H, G178R, E193K, L206W, R347H, R352Q, A455E, S549N, S549R,G551D, G551S, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, G1244E, S1251N, S1255P, D1270N, G1349D, 2789+5G-A, 3272-26A-G, 3849+10kbC-T. AND (3) Medication is prescribed by an appropriate specialist such as pulmonologist or endocrinologist AND (4) Patient is not have homozygous for theF508del mutation in the CFTR gene AND (5) Member is 6 months of age or older |
| **Age Restrictions** | Member is 6 months of age or older |
| **Prescriber Restrictions** | Prescribed by an appropriate specialist such as pulmonologist or endocrinologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KEVZARA NON FORMULARY

## Products Affected

- KEVZARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of an FDA approved indication |
| **Exclusion Criteria** | (1) Known hypersensitivity to sarilumab or any component of the formulation. (2) Patients with active hepatic disease or hepatic impairment. (3) Patients with an ANC less than 2,000/mm3, a platelet count less than 150,000/mm3, or an ALT or AST greater than 1.5 times the upper limit of normal (ULN) |
| **Required Medical Information** | A. FDA APPROVED INDICATION (1) Must have a documented diagnosis of an FDA approved indication AND (2) Must have a tried and failed one conventional therapy indicated for the diagnosis, including but not limited to: azathioprine, hydroxychloroquine, leflunomide, methotrexate, NSAIDs, other DMARDs, corticosteroids, sulfasalazine, etc. AND (3) Must have a documented trial and failure or contraindication to Enbrel AND Humira AND (4) Prescriber must have a documented plan for lab monitoring 4-8 weeks post therapy initiation and every 3 months thereafter for platelet count, ANC, LFTs and every 6 months for lipid parameters AND (5) Prescribed by or in consultation with a rheumatologist AND (6) Patient is 18 years and older |
| **Age Restrictions** | Patient is 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KEYTRUDA NON FORMULARY

## Products Affected

- KEYTRUDA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of unresectable or metastatic malignant melanoma, metastatic NSCLC. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Any of the following adverse events that have occurred while on Keytruda therapy- (1a) Any life-threatening adverse reaction (excluding endocrinopathies controlled with hormone replacement therapy) (1b) Grade 3 or 4 pneumonitis or recurrent pneumonitis of Grade 2 severity (1c) Grade 3 or 4 nephritis (1d) AST or ALT greater than 5 times ULN or total bilirubin greater than 3 times ULN. (2) For patients with liver metastasis who begin treatment with Grade 2 AST or ALT, if AST or ALT increases by greater than or equal to 50% relative to baseline and lasts for at least 1 week (2a) Grade 3 or 4 infusion-related reactions (2b) Inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks (2c) Persistent Grade 2 or 3 adverse reactions (excluding endocrinopathies controlled with hormone replacement therapy) that do not recover to Grade 0-1 within 12 weeks after last dose of KEYTRUDA (2d) Any severe or Grade 3 treatment-related adverse reaction that recurs. (3) Hypersensitivity to Keytruda or any other component of the requested formulation |
| **Required Medical Information** | A. MELANOMA (1) Must have a documented diagnosis of unresectable or metastatic malignant melanoma AND (2) Must have tried and failed Yervoy (ipilimumab) AND (3) If the melanoma is BRAF V600 mutation positive, must also try a BRAF inhibitor (e.g. Tafinlar [dabrafenib], Mekinist [trametinib] or Zelboraf [vemurafenib]) B. NON-SMALL CELL LUNG CANCER(NSCLC) (1) Must have a documented diagnosis of metastatic NSCLC AND (2) Tumors must express PD-L1 AND (3) Must have tried and failed or have disease progression on or after platinum-containing chemotherapy AND (4) Patients with EGFR or ALK tumor aberrations should have disease progression on a FDA approved therapy before Keytruda OR C. MEDICALLY ACCEPTED INDICATION (1) Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. AND (2) Chart notes detailing the members current clinical status AND (3) Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | Melanoma/Non-small cell lung cancer=18 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KHEDEZLA NON FORMULARY

## Products Affected

- *desvenlafaxine er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Major Depressive Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MAJOR DEPRESSIVE DISORDER (1) A diagnosis of Major Depressive Disorder, AND (2) Trial and failure or intolerance to a 30 day trial of generic venlafaxine and bupropion XL tablets, fluoxetine, paroxetine, sertraline, citalopram, AND (3) Trial and failure, or contraindication or intolerance to Desvenlafaxine Succinate ER Tab (Pristiq). --NOTE-- Desvenlafaxine ER (Pristiq) is covered on the formulary. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KINERET

## Products Affected

- KINERET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cryopyrin-associated periodic syndromes (CAPS) - neonatal-onset multisystem inflammatory disease NOMID, Rheumatoid arthritis (RA), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Used in combination with biological DMARDs, Hypersensitivity to E. coli derived products. |
| **Required Medical Information** | A. FOR RHEUMATOID ARTHRITIS:INITIAL: (1) Prescriber attests to a documented diagnosis of a moderately or severely active RA AND (2) Prescriber attests that patient has tried and failed one conventional therapy indicated for the diagnosis, including but not limited to, azathioprine, methotrexate, NSAIDs, DMARDs AND (3) Prescriber attests that Patient must have a negative tuberculosis test or receive treatment if tested positive AND (4) RA STEP ALERT: TRIAL AND FAILURE OF ENBREL AND HUMIRA B. FOR CAPS (NOMID) INITIAL: (1) Prescriber attests that patient has a documented diagnosis of a (CAPS)/ neonatal-onset multisystem inflammatory disease (NOMID) AND (2) Prescriber attests that patient has a negative tuberculosis test or receive treatment if tested positive. RENEWAL FOR ALL INDICATIONS: (1) Prescriber attests that patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patients condition AND (2) Prescriber attests that patient has disease stabilization or improvement as defined by standard monitoring for the patients condition |
| **Age Restrictions** | RA - 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | Initial : 12 months, Renewal : 12 months |
| **Other Criteria** | None |

# KISQALI

## Products Affected

- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)
- KISQALI FEMARA(200 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of advanced, or metastatic hormone receptor positive (HR+), human epidermal growth factor receptor (HER2)-negative breast cancer. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADVANCED, OR METASTATIC HORMONE RECEPTOR POSITIVE (HR+), HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR (HER2) NEGATIVE BREAST CANCER (1) Diagnosis of advanced, or metastatic hormone receptor positive (HR+), human epidermal growth factor receptor (HER2)-negative breast cancer, AND (2) Patient meets one of the following-(2a) The patient is postmenopausal and Kisqali will be used as first-line endocrine therapy in combination with anastrozole, exemestane, letrozole OR tamoxifen, OR (2b) The patient is postmenopausal and Kisqali and fulvestrant will be used as first-line endocrine therapy, OR (2c) The patient is premenopausal or perimenopausal and meets the following conditions (2d and 2e). (2d) The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]), surgical bilateral oophorectomy, or ovarian irradiation, AND (2e) Kisqali will be used as first-line endocrine therapy in combination with anastrozole, exemestane, letrozole OR tamoxifen. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KRISTALOSE

## Products Affected

- KRISTALOSE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Constipation, Hepatic Encephalopathy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CONSTIPATION (1) Clinical diagnosis of Constipation AND (2) Clinical trial and failure, intolerance, or contraindication to formulary preferred Lactulose Solution OR B. HEPATIC ENCEPHALOPATHY (1) Clinical diagnosis of Hepatic Encephalopathy, AND (2) Clinical trial and failure, intolerance, or contraindication to formulary preferred Lactulose Solution |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KUVAN

## Products Affected

- KUVAN
- *sapropterin dihydrochloride oral tablet soluble*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hyperphenylalaninemia, medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPERPHENYLALANINEMIA (1) Hyperphenylalaninemia due to tetrahydropterin- (BH4-) responsive phenylketonuria AND (2) Tried/failed/intolerance to a phenylalanine restricted diet alone AND (3) Phe levels greater than 6 mg/Dl for less than 12 years of age OR (3) Phe levels greater than 15 mg/Dl on average for greater than 12 years of age. B. REAUTHORIZATION/CONTINUING THERAPY (1) Decrease in Phe levels by at least 30 percent within 60 days of initiation of therapy (indicating response to treatment) OR (1) Phe levels maintained below baseline levels AND (2) Dosage not greater than 20mg/kg/day |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# KYPROLIS

## Products Affected

- KYPROLIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Clinically diagnosed with Multiple Myeloma or diagnosis of Waldenstroms Macroglobulinemia/Lymphoplasmacytic Lymphoma. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MULTIPLE MYELOMA (1) Prescriber attests to diagnosis of multiple myeloma AND (2) Used as primary chemotherapy or for disease relapse after 6 months following primary chemotherapy with this same regimen in patients with active (symptomatic) disease AND (2a) Used in combination with lenalidomide and dexamethasone OR (2b) Used in combination with dexamethasone and cyclophosphamide in NON stem-cell transplant candidates OR (3) Used for previously treated myeloma for disease relapse or for progressive or refractory disease AND (3a) Used for previously treated myeloma for disease relapse or for progressive or refractory disease OR (3b) In combination with dexamethasone with or without lenalidomide OR (3c) In combinations with dexamethasone and cyclophosphamide OR (3d) In combination with panobinostat AND (3e) Patient has received at least 2 prior regimens, including bortezomib and an immunomodulatory agent OR (3f) In combination with pomalidomide and dexamethasone AND (3g) Patient has received at least 2 prior therapies, including a proteasome inhibitor and an immunomodulatory agent AND (3h) Patient has progressed on or within 60 days of completion of the last therapy |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | B. WALDENSTROMS MACRGLOBULINEMIA/LYMPHOPLASMACYTIC LYMPHOMA (1) Prescriber attests to diagnosis of Waldenstroms Macroglobulinemia/Lymphoplasmacytic Lymphoma AND (2) Requested |

| PA Criteria | Criteria Details |
| --- | --- |
| | medication will be used in combination with rituximab and dexamethasone AND (3) Used as primary therapy OR (4) Used for relapsed disease AND (4a) This regimen was used as primary therapy AND (4b) Patient achieved a response that lasted for at least 24 months RENEWAL (1) Stabilization of disease and/or absence of progression of disease AND (2) Absence of unacceptable toxicity from the drug. |

# LACRISERT NON FORMULARY

## Products Affected

- LACRISERT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Clinical diagnosis of Dry Eye Syndrome, Keratoconjunctivitis sicca, or acute Keratoconjunctivitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. DRY EYE SYNDROME, KERATOCONJUNCTIVITIS SICCA, ACUTE KERATOCONJUNCTIVITIS (1) Clinical diagnosis of Dry Eye Syndrome, Keratoconjunctivitis sicca, or acute Keratoconjunctivitis, AND (2) An inadequate response, adverse reaction, or contraindication to therapy with Restasis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LASTACAFT

## Products Affected

- LASTACAFT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of allergic conjunctivitis. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ALLERGIC CONJUNCTIVITIS (1) Prescriber attests patient has a diagnosis of allergic conjunctivitis, AND (2) Patient has had a clinical trial and failure, intolerance, or contraindication to TWO of the following- (2a) Azelastine 0.05% ophthalmic solution (2b) Cromolyn Sodium Solution 4% (2c) Epinastine 0.05% Ophthalmic solution (2d) Olopatadine 0.1% Ophthalmic solution |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LATUDA

## Products Affected

- LATUDA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of bipolar disorder, schizophrenia, or other psychotic disorder. Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BIPOLAR DISORDER, SCHIZOPHRENIA, OR OTHER PSYCHOTIC DISORDER (1) A diagnosis of bipolar disorder, schizophrenia, or other psychotic disorder AND (2) 18 years of age or older<br>OR (2) If patient is less than 18 years of age, medication is prescribed by or documented consultation with a psychiatrist, neurologist, or developmental/behavior pediatrician AND (3) Patient is participating in a behavioral management program (NOTE- Not applicable if a Psychiatrist) AND (4) Trial and failure, intolerance or contraindication THREE of the following formulary alternatives (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) (4a) Risperidone (4b) Quetiapine (c) Olanzapine (4d) Ziprasidone (4e) Aripiprazole |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LEMTRADA NON FORMULARY

## Products Affected

- LEMTRADA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | A definitive diagnosis of a relapsing form of multiple sclerosis(relapsing-remitting or secondary progressive multiple sclerosis). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RELAPSING FORM OF MULTIPLE SCLEROSIS (1) Prescriber attests patient has a diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting or secondary progressive multiple sclerosis) that has been established by a specialist in neurology or multiple sclerosis AND (2) Prescribed by, or in consultation with, a specialist in neurology or multiple sclerosis AND (3) Human immunodeficiency virus (HIV) negative AND (4) There is clinical documentation that at least three disease modifying therapies for multiple sclerosis were ineffective, contraindicated or not tolerated, as specified by criteria 1, 2, and 3- (4a) An interferon beta product (Avonex) (4b) Glatiramer acetate (Glatopa) (4c) Teriflunomide (Aubagio) (5) Ineffectiveness is defined as meeting at least two of the following three criteria (a, b, or c) during treatment with one of these medications- (5a) The patient continues to have clinical relapses (at least two relapses within the past 12 months). (5b) The patient continues to have CNS lesion progression as measured by MRI. (5c) The patient continues to have worsening disability. Examples of worsening disability include, but are not limited to, decreased mobility, decreased ability to perform activities of daily living due to disease progression, or EDSS greater than 3.5. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a specialist in neurology or multiple sclerosis |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LETAIRIS

## Products Affected

- *ambrisentan*
- LETAIRIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary hypertension WHO group I, WHO Class II or III. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PULMONARY HYPERTENSION WHO GROUP I-WHO CLASS II OR III (1) Prescribed by a Cardiologist, or Pulmonologist AND (2) Prescriber attests patient has a diagnosis of Pulmonary hypertension WHO group I, WHO Class II or III AND (3) Tried/failed/intolerance to Calcium channel blockers AND (4) Women of child bearing age must have a negative pregnancy test and must be using two reliable methods of contraception, an IUD or undergone tubal sterilization AND (5) ALT & AST less than 3 x the ULN at baseline |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a Cardiologist, or Pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LEUKINE

## Products Affected

- LEUKINE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute myeloid leukemia (AML) following induction chemotherapy, Autologous peripheral blood progenitor cell mobilization and collection, Autologous peripheral blood progenitor cell and bone marrow transplantation in patients with non-Hodgkins lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkins lymphoma (HL), Allogenic bone marrow transplantation from HLA-matched related donor, Allogenic or autologous bone marrow transplantation: treatment of delayed neutrophil recovery or graft failure, Acute exposure to myelosuppressive doses of radiation (H-ARS), medically accepted indications are considered for approval |
| **Exclusion Criteria** | Hypersensitivity to stimulating factor such as sargramostim, yeast-derived products, or any component of the product. When administering Leukine to neonates or infants reconstitute with sterile water to avoid exposure to benzyl alcohol exposure. LEUKINE should not be administered simultaneously with or within 24 hours preceding cytotoxic chemotherapy or radiotherapy or within 24 hours following chemotherapy. Treatment for afebrile neutropenia, unless below criteria are met |
| **Required Medical Information** | A. FOR ALL INDICATIONS: (1a) Prescriber attests that use is for: Primary prophylaxis of febrile neutropenia (FN) in individuals with a high risk for FN (greater than 20%) based on chemotherapy regimen OR (1b) Prescriber attests that use is for: Primary prophylaxis in individuals with an intermediate risk for FN (10%-20%) based on chemotherapy regimen and individuals have one or more of the following risk factors for FN: a.65 years of age or older b. Previous chemotherapy or radiation therapy c. Pre-existing neutropenia d. Bone marrow involvement with tumor e. Previous episodes of FN f. Infection/open wounds g. Recent surgery h. Poor performance status i. Poor renal function j. Liver dysfunction (i.e. elevated bilirubin) k. HIV-infected patient OR (1c) Prescriber attests that use is for: Secondary prophylaxis in individuals who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose or treatment delay may compromise treatment outcome OR (1d) Prescriber attests that use is for: In an individual receiving dose-dense therapy (treatment given more frequently, such as every 3 weeks instead of every 4 weeks) for breast cancer, lymphoma, or urothelial cancer OR (1e) Prescriber attests that use is for: patients with acute myeloid leukemia |

| PA Criteria | Criteria Details |
|---|---|
| | (AML) following induction or consolidation chemotherapy for individuals over 55 years of age OR (1f) Prescriber attests that use is for: After bone marrow transplantation to promote myeloid reconstitution or when engraftment is delayed or has failed for individuals older than 2 years of age OR (1g) Prescriber attests that use is for: For mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis for adults OR (1h) Prescriber attests that use is for: individuals acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation syndromes (H-ARS) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LIDOCAINE PATCH 5% (LIDODERM)

## Products Affected

- *lidocaine external patch 5 %*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postherpetic neuralgia, Diabetic peripheral neuropathy, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. POSTHERPETIC NEURALGIA (1) Prescriber attests to diagnosis of post-herpetic neuralgia (shingles or herpes zoster) AND (2) Tried and failed, intolerance, or contraindication to Xylocaine (Lidocaine 2.5% or 4.0% solution, Lidocaine 2.5% or 3% cream, Lidocaine 2% gel) OR Capsaicin 0.025%, 0.075%, 0.1% cream (medication usage must be supported by documentation from the patients chart notes/medical records) AND (3) Tried and failed, intolerance, or contraindication to gabapentin (medication usage must be supported by documentation from the patients chart notes/medical records) B. DIABETIC PERIPHERAL NEUROPATHY (1) Prescriber attests to diagnosis of diabetic peripheral neuropathy AND (2) Tried and failed, intolerance, or contraindication to Xylocaine (Lidocaine 2.5% or 4.0% solution, Lidocaine 2.5% or 3% cream, Lidocaine 2% gel) OR Capsaicin 0.025%, 0.075%, 0.1% cream (medication usage must be supported by documentation from the patients chart notes/medical records) AND (3) Tried and failed, intolerance, or contraindication to a one month trial of ALL of the following (medication usage must be supported by documentation from the patients chart notes/medical records): (3a) At least two tricyclic antidepressants (amitriptyline, desipramine, imipramine, and nortriptyline) AND (3b) traditional anticonvulsant (eg. Carbamazepine, sodium valproate) AND (3c) Venlafaxine AND (3d) duloxetine |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LOTRONEX

## Products Affected

- *alosetron hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Irritable Bowel Syndrome, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Constipation, History of chronic or severe constipation or with a history of sequelae from constipation, History of intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions, History of ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, Current or history of Crohns disease or ulcerative colitis, Active diverticulitis or a history of diverticulitis, Unable to understand or comply with the Patient-Physician Agreement, Known hypersensitivity to any component of the product |
| **Required Medical Information** | A. IRRITABLE BOWEL SYNDROME INITIAL: (1) Prescriber attests to diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) AND (2) Adult female AND (3) Only physicians who have enrolled in the Prometheus Prescribing Program for Lotronex should prescribe Lotronex AND (4) Must have diarrhea and one or more of the following: (4a) Frequent and severe abdominal pain/discomfort OR (4b) Frequent bowel urgency or fecal incontinence OR (4c) Disability or restriction of daily activities due to IBS AND (5) IBS symptoms are chronic (generally lasting 6 months or longer) AND (6) Other GI medical conditions that could explain the symptoms have been ruled out AND (7) Failed conventional therapy including: Dietary changes (including fiber), or stress reduction, or behavioral changes, Antidiarrheals (ie, loperamide, diphenoxylate and atropine), Antidepressants (ie, desipramine, imipramine), Antispasmodics (ie, dicyclomine, hyoscyamine) RENEWAL: (1) Prescriber attests to clinical notes demonstrating adequate control of IBS symptoms |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Duration of therapy: ONE MONTH. Renewal: 6 months |
| **Other Criteria** | None |

# LUPANETA

## Products Affected

- LUPANETA PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Endometriosis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Undiagnosed abnormal uterine bleeding, pregnancy or suspected pregnancy, women who are breastfeeding, known, suspected or history of breast or other hormone-sensitive cancer, thrombotic or thromboembolic disorders, liver tumors or liver disease. |
| **Required Medical Information** | A. ENDOMETRIOSIS INITIAL (1) Prescriber attests to a diagnosis of endometriosis AND (2) Prescriber attests to appropriate monitoring during drug therapy RENEWAL (1) Prescriber attests that patient has had stabilization or improvement in symptoms AND (2) Prescriber attests that patient continues to meet initial criteria AND (3) Prescriber attests to assessing bone density before retreatment begins |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a gynecologist |
| **Coverage Duration** | Initial: 6 months Renewal: 6 months |
| **Other Criteria** | Use is not recommended longer than a total of 12 months due to concerns about adverse impact on bone mineral density. |

# LUPRON (LEUPROLIDE)

## Products Affected

- *leuprolide acetate injection*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Central precocious puberty (Lupron Depot-Ped only), palliative treatment of advanced prostate cancer, endometriosis, uterine leiomyomata (fibroids), gender dysmorphia in female to male transgender and medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Pregnancy, lactation, undiagnosed abnormal vaginal bleeding |
| **Required Medical Information** | CENTRAL PRECOCIOUS PUBERTY: INITIAL: (1) Prescriber attests that patient has a documented diagnosis of central precocious puberty AND (2) Prescriber attests to appropriate lab monitoring (i.e. GnRH test or third- generation basal luteinizing hormone assay). AND (3a) Prescriber attests that member was less than 8 years of age at onset of symptoms if female (secondary sexual characteristics) OR (3b) Prescriber attests that member was less than 9 years of age at onset of symptoms if male (secondary sexual characteristics). RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria. B. PALLATIVE TREATMENT OF ADVANCED PROSTATE CANCER: INITIAL: (1) Prescriber attests to a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved or use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1, 2a, 2b only). AND (2) Documentation of dose and dates of all previous therapies and the resulting outcomes AND (3) Documentation that the proper succession of the therapies have been tried and failed (i.e. intolerance, contraindication, or progression) AND (4) Chart notes detailing the members current clinical status AND (5) Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment. RENEWAL: (1) Current chart notes detailing response and adherence to therapy AND (2) Documented clinically significant improvements in the disease state and stability on the medication |
| **Age Restrictions** | Central precocious puberty: less than or equal to 12 years of age (females), less than or equal to 13 years of age (males), use of Lupron Depot-PED in children under 2 years of age is not recommended. |

| PA Criteria | Criteria Details |
|---|---|
| | Endometriosis/Uterine Leiomyomata: females greater than or equal to 18 years of age. Gender dysphoria: 14 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with an endocrinologist, oncologist, or gynecologist |
| **Coverage Duration** | Based on indication. Please see Other Criteria section for Coverage Duration. |
| **Other Criteria** | C. ENDOMETRIOSIS INITIAL: (1) Prescriber attests that patient has a documented diagnosis of endometriosis (via ultrasound, laparoscopy etc) AND (2) Moderate to severe pain secondary to endometriosis AND (3) Inadequate response to at least (3) month trial of hormonal therapy (i.e. medroxyprogesterone acetate or oral contraceptives) OR (4) Documented contraindication to hormonal therapy RENEWAL: (1) Prescriber attests the member is still symptomatic with pain after initial (6) months of therapy AND (2) Member is taking with appropriate add-back therapy (unless contraindicated) D. UTERINE LEIOMYOMATA (FIBROIDS): (1) Prescriber attests that patient has a documented diagnosis of uterine leiomyomata (fibroids) AND (2) Prescriber attests patient will be receiving iron therapy as well. **this prior authorization does not apply to leuprolide acetate 1mg/0.2ml daily injection kits. E. GENDER DYSPHORIA (1) Prescriber attests the drug is being prescribed for female-to-male gender reassignment in a patient who is 14 years of age or older and able to make informed, mature decision to engage in therapy. COVERAGE DURATION: Endometriosis: initial/renewal: 6 months, recommended duration of continuous therapy is limited to a total of 12 months, Uterine leiomyomata (fibroids): up to 6 months total, All other indications: Initial/renewal: 12 months |

# LUXTURNA NON FORMULARY

## Products Affected

- LUXTURNA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of biallelic RPE65 mutation-associated retinal dystrophy, evidenced by the blueprint genetics retinal dystrophy panel. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BIALLELIC RPE65 MUTATION-ASSOCIATED RETINAL DYSTROPHY (1) Prescriber attests that patient has a diagnosis of biallelic RPE65 mutation-associated retinal dystrophy, evidenced by the blueprint genetics retinal dystrophy panel. AND (2) Prescriber must document patients have viable retinal cells. AND (3) Must be prescribed by an ophthalmologist trained by manufacturer with injection technique AND (4) Member must be greater than 12 months of age AND less than 65 years of age |
| **Age Restrictions** | Member must be greater than 12 months of age AND less than 65 years of age |
| **Prescriber Restrictions** | Must be prescribed by an ophthalmologist trained by manufacturer with injection technique |
| **Coverage Duration** | Once per lifetime per eye, claims for each eye must not be less than 6 days apart |
| **Other Criteria** | None |

# LUZU

## Products Affected

- LUZU

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Tinea pedis, Tinea cruris or Tinea corporis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TINEA PEDIS, TINEA CRURIS, TINEA CORPORIS (1) Prescriber attests that patient has a diagnosis of ONE of the following0- (1a) Tinea pedis and member is 12 years of age or older OR (1b) Tinea cruris and member is 12 years of age or older OR (1c) Tinea corporis and member is 2 years of age or older (2) Patient has had a clinical trial and failure, intolerance, or contraindication to at least TWO of the following-(2a) Clotrimazole topical (2b) Econazole topical (2c) Ketoconazole topical (2d) Miconazole topical (3) If requesting brand name Luzu, clinically documented allergic reaction to the generic luliconazole is required. |
| **Age Restrictions** | Tinea pedis/Tinea cruris=member is 12 years of age or older, Tinea corporis=member is 2 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 2 weeks |
| **Other Criteria** | None |

# LYNPARZA

## Products Affected

- LYNPARZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ovarian cancer, Pancreatic cancer, HER2-negative Metastatic breast cancer, Metastatic castration-resistant prostate cancer, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. METASTATIC BREAST CANCER (1) Prescriber attests to a diagnosis of HER2-negative, deleterious, or suspected deleterious, germline BRCA mutated metastatic breast cancer AND (2) Patient has been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting B. ADVANCED OVARIAN CANCER (1) Prescriber attests to a diagnosis of deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer AND (2) Has been treated with three or more prior lines of chemotherapy AND (3) Patient has had baseline monitoring for hematological toxicity AND (4) Will be used as monotherapy C. OVARIAN CANCER (1) Prescriber attests to a diagnosis of ovarian cancer and one of the following (1a) Patient has advanced disease with known or suspected BRCA-mutation confirmed by an approved test and has progressed on 3 or more prior lines of chemotherapy OR (1b) Patient has recurrent ovarian, fallopian tube, or primary peritoneal cancer and had a complete or partial response to 2 or more prior lines of platinum-based chemotherapy AND (2) Patient has had baseline monitoring for hematological toxicity D. PANCREATIC CANCER (1) Prescriber attests to a diagnosis of deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic cancer AND (2) Patient has not progressed on at least 16 weeks of a first-line platinum-based chemotherapeutic regimen |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 3months, Renewal: 6 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | E. METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (1) Prescriber attests to a diagnosis of metastatic castration-resistant prostate cancer AND (2) has a presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutation AND (3) Patient has progression following previous treatment with enzalutamide OR abiraterone RENEWAL FOR ALL DIAGNOSES (1) Patient has demonstrated a response to therapy |

# LYRICA

## Products Affected

- LYRICA
- *pregabalin oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of neuropathic pain associated with diabetic neuropathy or post-herpetic neuralgia, seizure disorder, fibromyalgia, or Central Pain Syndrome. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC NEUROPATHY OR POST-HERPETIC NEURALGIA (1) Prescriber attests that patient has a diagnosis of neuropathic pain associated with diabetic neuropathy or post-herpetic neuralgia (supported by documentation from the patients chart notes/medical records/electronic claims history) AND (2) Trial and failure or intolerant of a two month trial all of the following (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claims history) (2a) At least two tricyclic antidepressants (amitriptyline, desipramine, imipramine, and nortriptyline) (2b) A traditional anticonvulsant (e.g. carbamazepine, sodium valproate) (2c) venlafaxine (2d) gabapentin (2e) duloxetine<br>B. SEIZURE DISORDER (1) Prescriber attests that patient has diagnosis of seizure disorder (supported by documentation from the patients chart notes/medical records/electronic claims history) requiring adjunct therapy AND (2) Tried and failed or intolerance to a 30 day trial with the following-(2a) Dilantin (2b) Depakote (2c) Depakene (2d) Lamictal OR<br>C. FIBROMYALGIA (1) Prescriber attests that patient has diagnosis of fibromyalgia, is confirmed by a rheumatologist or neurologist (supported by documentation from the patients chart notes/medical records/electronic claims history) OR (2) The prescriber has conducted an evaluation confirming all of the following- (2a) Physical exam indicating presence of 11 of 18 tender points or Widespread Pain Index (WPI) greater than or equal to 7 and Symptom Severity (SS) scale score greater than or equal to 5 or WPI is between 3 and 6 and SS scale score greater than or equal to 9, AND |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | (2b) Symptoms have been present for at least 3 months AND (2c) Conditions mistaken for fibromyalgia have been ruled out (e.g. rheumatoid arthritis, peripheral neuropathies, infection) AND (2d) Tried and failed or intolerance to a 30 day trial with the following (supported by documentation from the patients chart notes/medical records/electronic claims history) - Gabapentin, Fluoxetine, Amitriptyline 10mg, Cyclobenzaprine, Nortriptyline, Duloxetine. D. CENTRAL PAIN SYNDROME (1) Prescriber attests that patient has diagnosis of Central Pain Syndrome (supported by documentation from the patients chart notes/medical records/electronic claims history) AND (2) Tried and failed or intolerance to all of the following- (2a) Amitriptyline (2b) Gabapentin (2c) Lamotrigine (2d)Duloxetine. |

# LYSODREN

## Products Affected

- LYSODREN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of adrenal cortical carcinoma. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADRENAL CORTICAL CARCINOMA (1) Prescriber attests that patient has a diagnosis of adrenal cortical carcinoma, AND (2) Patient is 18 years of age or older, AND (3) Prescribed by, or in consultation with, an Oncologist |
| **Age Restrictions** | Patient is 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# LYSTEDA NON FORMULARY

## Products Affected

- LYSTEDA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Menorrhagia, Hemophilia prophylaxis tooth extraction, Surgical bleeding prophylaxis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Active thromboembolic disease (e.g DVT, PE, cerebral thrombosis), history of thrombosis or thromboembolism (e.g hypercoagulopathy), intrinsic risk of thrombosis or thromboembolism (e.g inherited thrombophilias, greater than 35 year old female smoker), concurrent use of combination hormonal contraception |
| **Required Medical Information** | A. MENORRHAGIA (1) Prescriber attests to a diagnosis of cyclic heavy menstrual bleeding (menstrual flow greater than7days or blood loss greater than80ml per cycle) AND (2) patient is a premenopausal female AND (3) Absence of the following risks for thrombosis or contraindications to tranexamic acid (3a) active thromboembolic disease (e.g DVT, PE, cerebral thrombosis) AND (3b) history of thrombosis or thromboembolism (e.g hypercoagulopathy) AND (3c) intrinsic risk of thrombosis or thromboembolism (e.g inherited thrombophilias, greater than 35 year old female smoker) AND (3d) concurrent use of combination hormonal contraception AND (4) An inadequate response, intolerance or contraindication to NSAIDs AND (5) An inadequate response, intolerance, contraindication or refusal to use of oral contraceptives or intrauterine levonorgestrel B. HEMOPHILIA (1) Prescriber attests to a diagnosis of hemorrhage prophylaxis for a scheduled tooth extraction AND (2) patient is a hemophilia patient AND (3) being utilized for short term use (2 to 8 days of therapy) C. SURGICAL BLEEDING PROPHYLAXIS (1) Prescriber attests is being used as orthopedic surgical bleeding prophylaxis in primary total hip or knee arthroplasty |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MAKENA

## Products Affected

- MAKENA INTRAMUSCULAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Reduce the risk of preterm birth. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Current or history of thrombosis or thromboembolic disorders. (2) Known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions. (3) Undiagnosed abnormal vaginal bleeding unrelated to pregnancy. (4) Cholestatic jaundice of pregnancy. (5) Liver tumors, benign or malignant, or active liver disease. (6) Uncontrolled hypertension. |
| **Required Medical Information** | INITIAL A. REDUCE THE RISK OF PRETERM BIRTH (1) The current pregnancy is a singleton pregnancy AND (2) Patient has a history of singleton spontaneous preterm (delivery at less than 37 weeks) birth. AND (3) Treatment must begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation AND (4) Must be prescribed by, or in conjunction with, obstetrician/gynecologist AND (5) 16 years of age or older |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, obstetrician/gynecologist |
| **Coverage Duration** | Initial=21 weeks, Renewal=only for a separate gestation period after 24 weeks |
| **Other Criteria** | None |

# MATULANE

## Products Affected

- MATULANE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Hodgkin Lymphoma or non-Hodgkins Lymphoma. Diagnosis of stem cell transplant preparation prior to allogeneic transplantation in patients with severe aplastic anemia, in combination with cyclophosphamide and antithymocyte globulin. Diagnosis of high-grade malignant glioma, or medulloblastoma. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HODGKIN LYMPHOMA (1) Prescriber attests that patient has a diagnosis of Hodgkin Lymphoma, OR B. NON-HODGKINS LYMPHOMA (1) Prescriber attests that patient has a diagnosis of non-Hodgkins Lymphoma (NHL), AND (2) Requested medication will be used in combination with cyclophosphamide, etoposide, and prednisone, OR C. STEM CELL TRANSPLANT (1) Prescriber attests that patient has a diagnosis of stem cell transplant preparation prior to allogeneic transplantation in patients with severe aplastic anemia, in combination with cyclophosphamide and antithymocyte globulin, OR D. HIGH-GRADE MALIGNANT GLIOMA (1) Prescriber attests that patient has a diagnosis of high-grade malignant glioma OR E. MEDULLOBLASTOMA (1) Prescriber attests that patient has a diagnosis of medulloblastoma, as adjuvant treatment in combination with nitrogen mustard, vincristine, and prednisone |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a Hematologist or Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MAVYRET

## Products Affected

- MAVYRET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5, or 6. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation. Patients concurrently taking atazanavir (Reyataz/Evotaz) or rifampin. |
| **Required Medical Information** | A. CHRONIC HEPATITIS C, GT 1, 2, 3, 4, 5 or 6 (1) Prescriber attests that patient has a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5, or 6. AND (2) Must provide HCV RNA level dated within last 6 months AND (3) Must provide the following lab values dated within 12 weeks of initiating therapy-(3a) CBC with Platelets (3b) AST / ALT (3c) Total Bilirubin (3d) Serum Albumin (3e) PT / INR (3f) Serum Creatinine (3g) GFR. AND (4) The member does not have end stage renal disease requiring dialysis or a glomerular filtration rate less than 30 mL/minute/1.73m2 AND (5) The member does not have evidence or known diagnosis of malignancy of any body organ diagnosed within the last 12 months, or currently receiving or planning to receive chemotherapy or radiation therapy (exceptions will be made for hepatocellular carcinoma if the member is on a liver transplant waiting list) AND (6) The member is not currently enrolled in hospice AND (7) The member has not been denied Hepatitis C treatment by another insurance carrier for an acceptable cause. If approved for coverage by another carrier, Envision will only approve coverage as a secondary payer after the primary payer has paid AND (8) If Female, Must not be currently or may not become pregnant during HCV therapy. If the female member is less than 50 years old a negative pregnancy test must be obtained within the previous 30 days, and monthly thereafter (9) Patient must have had hepatitis B testing (HBsAg, anti-HBc, anti-HBs) prior to starting hepatitis C treatment |
| **Age Restrictions** | 12 years of age or older or weighing at least 45kg |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a Gastroenterologist, Hepatologist, or Infectious Disease Specialist |
| **Coverage Duration** | See Other Criteria |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | (1)GT 1,2,3,4,5 or 6, and no cirrhosis- 8 weeks (2) GT 1,2,3,4,5 or 6, and compensated cirrhosis 8 weeks (3) GT1 and previously treated with and NS5A inhibitor (Daklinza, Harvoni) without an NS3/4A protease inhibitor (Zepatier, Technivie, Viekira, Olysio, Vosevi, Incivek, Victrelis), with or without compensated cirrhosis- 16 weeks (4) GT 1,2, ,4,5,6 and previously treated with interferon, pegylated interferon, ribavirin and/or sofosbuvir and no cirrhosis- 8 weeks (5) GT 1,2,,4,5,6 and previously treated with interferon, pegylated interferon, ribavirin and/or sofosbuvir and compensated cirrhosis- 12 weeks (6) GT3 and previously treated with interferon, pegylated interferon, ribavirin and/or sofosbuvir with or without compensated cirrhosis- 16 weeks. (7) REFER to package insert for treatment duration for liver or kidney transplant recipients QUANTITY RESTRICTIONS: 84 or 112 day supply per approval dependent on coverage duration criteria |

# Medically Accepted Indication

## Products Affected

- *aminocaproic acid oral tablet*
- ELURYNG
- *ergoloid mesylates oral*
- *etonogestrel-ethinyl estradiol*
- NUVARING
- *raloxifene hcl*
- *sirolimus oral*
- XULANE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA approved indication |
| **Exclusion Criteria** | None |
| **Required Medical Information** | (1) Requested medication is being utilized for an FDA approved indication, or one recognized by the approved compendia (Micromedex, AHFS). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MEKINIST

## Products Affected

- MEKINIST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Unresectable or metastatic melanoma, anaplastic thyroid carcinoma, Non-small cell lung cancer, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. UNRESECTABLE OR METASTATIC MELANOMA (1) Prescriber attests to a diagnosis of unresectable or metastatic melanoma AND (2) BRAF mutation V600E or V600K AND (3) Confirmation of mutation by FDA-approved test AND (4) Baseline LVEF assessed prior to initiation of therapy and within acceptable limits AND (5) Performed ophthalmic evaluation AND (6) No concomitant BRAF-inhibitor or ipilimumab therapy B. ANAPLASTIC THYROID CARCINOMA (1) Prescriber attests to a diagnosis of Anaplastic thyroid carcinoma, locally advanced or metastatic AND (2) BRAF V600E mutation AND (3) Used in combination with dabrafenib AND (4) No satisfactory locoregional treatment options C. NON-SMALL CELL LUNG CANCER (1) Prescriber attests to a diagnosis of non-small cell lung cancer AND (2) BRAF V600E mutation AND (3) Used in combination with dabrafenib |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an Oncologist or Hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MESNEX

## Products Affected

- MESNEX ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hemorrhagic cystitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HEMORRHAGIC CYSTITIS (1) Prescriber attests to a diagnosis of prophylaxis of ifosfamide-induced or cyclophosphamide-induced hemorrhagic cystitis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MESTINON

## Products Affected

- MESTINON ORAL SOLUTION
- *pyridostigmine bromide oral solution*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Myasthenia gravis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MYASTHENIA GRAVIS (1) Prescriber attests to a diagnosis of myasthenia gravis AND (2) Clinical reason why pyridostigmine tablets are not appropriate for use |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# METHOTREXATE SUBQ SOLN NON FORMULARY

## Products Affected

- OTREXUP
- RASUVO
- XATMEP

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid arthritis, Polyarticular juvenile idiopathic arthritis, Psoriasis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SEVERE ACTIVE RHEUMATOID ARTHRITIS, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (1) Prescriber attests patient has diagnosis of Severe Active rheumatoid arthritis or Polyarticular juvenile idiopathic arthritis AND (2) Are intolerant of or had an inadequate response to first-line therapy AND (3) Diagnosis must be supported by any applicable labs and/or tests and medication usage must be supported by documentation from the patients medical records AND (4) Trial and failure of oral methotrexate AND (5) Clinical difficulty with using generic methotrexate solution vials B. SEVERE, RECALCITRANT, DISABLING PSORIASIS (1) Prescriber attests patient has diagnosis of severe, recalcitrant, disabling psoriasis AND (2) Is 18 years of age or older AND (3) are not adequately responsive to other forms of therapy AND (4) Diagnosis must be supported by any applicable labs and/or tests and medication usage must be supported by documentation from the patients medical records AND (5) Trial and failure of oral methotrexate AND (6) Clinical difficulty with using generic methotrexate solution vials QTY LIMIT FOR ALL DIAGNOSIS= Must be less than 30mg once weekly |
| **Age Restrictions** | RA,Ps= 18 years of age and older, PJIA= Less than 18 years of age |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None |

# METHOXSALEN

## Products Affected

- *methoxsalen rapid*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Psoriasis, Vitiligo, Primary cutaneous T-cell lymphoma, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PSORIASIS (1) Prescriber attests to a diagnosis of severe, recalcitrant, disabling psoriasis AND (2) not adequately responsive to other forms of therapy AND (3) the diagnosis has been supported by biopsy AND (4) Used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation B. VITILIGO (1) Prescriber attests to a diagnosis of idiopathic vitiligo AND (2) used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation C. T-CELL LYMPHOMA (1) Prescriber attests to a diagnosis of the skin manifestations of cutaneous T-cell lymphoma AND (2) such as but not limited to Mycosis Fungoides and Sezary Syndrome AND (3) used in conjunction with photopheresis with the UVAR instrument AND (4) has not been responsive to other forms of treatment |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MIRVASO

## Products Affected

- MIRVASO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rosacea,  Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ROSACEA (1) Prescriber attests to a diagnosis of rosacea AND (2) trial and failure or intolerant of generic topical metronidazole |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MOTOFEN

## Products Affected

- MOTOFEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Adjunct treatment for Acute Diarrhea and acute exacerbations of chronic diarrhea, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | (1) Prescriber attests that medication is being used as an adjunctive treatment in the management of acute, nonspecific diarrhea and acute exacerbations of chronic functional diarrhea AND (2) there has been a clinical trial and failure to both of the following: (2a) Loperamide (Capsule or Tablet) AND (2b) Diphenoxylate/Atropine (generic Lomotil) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MOVANTIK NON FORMULARY

## Products Affected

- MOVANTIK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Opioid-induced constipation, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. OPIOID INDUCED CONSTIPATION (1) Prescriber attests to a diagnosis of chronic non-cancer pain AND (2) Member has been taking an opioid analgesic for at least 4 weeks immediately prior to the request (as evidenced by pharmacy claims) AND (3) An inadequate response to at least one agent from within each of the following laxative types: (3a) Fiber laxatives (psyllium, methylcellulose, calcium polycarbophil) AND (3b) Stimulant laxatives (bisacodyl, senna) AND (3c) Osmotic laxatives (Polyethylene glycol, milk of magnesia, sorbitol, lactulose) |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MULTAQ NON FORMULARY

## Products Affected

- MULTAQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Atrial fibrillation, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV symptoms, Second or third-degree AV block or sick sinus syndrome (except when used with a functioning pacemaker), Bradycardia less than 50 beats per minute, Liver or lung toxicity related to previous use of amiodarone, Severe hepatic impairment, Patient is nursing |
| **Required Medical Information** | A. ATRIAL FIBRILLATION (1) Prescriber attests to a diagnosis of paroxysmal or persistent atrial fibrillation (AF), (non-permanent AF) AND (2) Patient has a trial and failure, intolerance, contraindication to therapy with amiodarone |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MYFORTIC

## Products Affected

- *mycophenolate sodium*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Renal transplant rejection prophylaxis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RENAL TRANSPLANT REJECTION (1) Prescriber attests to a diagnosis of transplant rejection prophylaxis (heart, liver, kidney) AND (2) Patient has had a clinical trial and failure, intolerance, or contraindication to therapy with Mycophenolate Capsule (250mg, or 500mg) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# MYORISAN

## Products Affected

- AMNESTEEM
- CLARAVIS
- *isotretinoin oral*
- MYORISAN
- ZENATANE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Nodulocystic acne, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NODULOCYSTIC ACNE INITIAL (1) Prescriber attests to a diagnosis of severe recalcitrant nodular acne, treatment-resistant or scarring acne AND (2) An inadequate response to a trial of 2 topical acne medications and a trial of an oral tetracycline or tetracycline derivative. RENEWAL (1) Documentation of the following (1a) A targeted cumulative dose of 120-150 mg/kg has not been achieved (Duration of approval - sufficient to achieve targeted cumulative dose of 120-150 mg/kg) OR (1b) There is a relapse of severe recalcitrant nodular acne, treatment resistant or scarring acne requiring a second treatment course AND there is a gap of at least 2 months since completing the initial treatment course |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | QUANTITY RESTRICTION, Maximum 60 capsules / 30 days |

# NAFTIN

## Products Affected

- *naftifine hcl external gel*
- NAFTIN EXTERNAL GEL 1 %

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Tinea corporis, Tinea cruris, Tinea pedis, Onychomycosis of the fingernail, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TINEA, CRURIS, PEDIS OR CORPORIS (1) Prescriber attests to a diagnosis of one of the following: Tinea corporis, Tinea Cruris, Tinea Pedis, Onychomycosis of the fingernail AND (2) Previous failure of two other formulary topical antifungals in the last 120 days (e.g. clotrimazole, econazole, ciclopirox, ketoconazole) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NAMENDA SOLUTION

## Products Affected

- *memantine hcl oral solution 2 mg/ml*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Alzheimers disease, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ALZHEIMERS DISEASE (1) Prescriber attests to a diagnosis of moderate to severe Alzheimers disease AND (2) Clinical reason why memantine tablets are not appropriate for use |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NATACYN

## Products Affected

- NATACYN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Fungal blepharitis, Fungal conjunctivitis, Fungal keratitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. FUNGAL BLEPHARITIS, FUNGAL CONJUNCTIVITIS, FUNGAL KERATITIS (1) Prescriber attests to a diagnosis of ONE of the following: (1a) Fungal blepharitis OR (1b) Fungal conjunctivitis OR (1c) Fungal keratitis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NATPARA NON FORMULARY

## Products Affected

- NATPARA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypocalcemia- Hypoparathyroidism, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPOCALCEMIA-HYPOPARATHROIDISM INITIAL (1) Prescriber attests to a diagnosis of hypocalcemia resulting from chronic hypoparathyroidism AND (2) 25-hydroxy vitamin D serum level is above the lower limit of the normal laboratory reference range AND (3) Member is currently on active vitamin D (calcitriol) therapy AND (4) Total serum calcium level (albumin corrected) is above 7.5 mg/Dl AND (5) One of the following: (5a) Member is currently taking calcium supplementation of 1-2 grams per day of elemental calcium in divided doses OR (5b) Member is receiving other formulation of calcium supplementation RENEWAL (1) Submission of medical records (e.g., chart notes, laboratory values) documenting total serum calcium level (albumin corrected) within the lower half of the normal range (approximately 8 to 9 mg/Dl) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with either an endocrinologist or a nephrologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NEULASTA

## Products Affected

- NEULASTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Febrile neutropenia, hematopoietic subsyndrome of acute radiation syndrome, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Treatment for afebrile neutropenia, unless below criteria are met, Mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation |
| **Required Medical Information** | (1a) Prescriber attests that use is for: Primary prophylaxis of febrile neutropenia (FN) in individuals with a high risk for FN (greater than 20%) based on chemotherapy regimen OR (1b) Prescriber attests that use is for: Primary prophylaxis in individuals with an intermediate risk for FN (10%-20%) based on chemotherapy regimen and individuals have one or more of the following risk factors for FN: a.65 years of age or older b. Previous chemotherapy or radiation therapy c. Pre-existing neutropenia d. Bone marrow involvement with tumor e. Previous episodes of FN f. Infection/open wounds g. Recent surgery h. Poor performance status i. Poor renal function j. Liver dysfunction (i.e. elevated bilirubin) k. HIV-infected patient OR (1c) Prescriber attests that use is for: Secondary prophylaxis in individuals who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose or treatment delay may compromise treatment outcome OR (1d) Prescriber attests that use is for an individual receiving dose-dense therapy (treatment given more frequently, such as every 3 weeks instead of every 4 weeks) for breast cancer, lymphoma, or urothelial cancer AND (1e) Trial, failure, or contraindication to Zarxio |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NEUPOGEN

## Products Affected

- ZARXIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Patients with nonmyeloid Cancer Receiving Myelosuppressive Chemotherapy, Patients with Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy, Patients with Cancer Undergoing Bone Marrow Transplantation, Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy Patients with Severe Chronic Neutropenia, NEUPOGEN ONLY: Patients Acutely Exposed to Myelosuppressive Doses of Radiation (Hematopoietic Syndrome of Acute Radiation Syndrome),<br>Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Treatment for afebrile neutropenia, unless below criteria are met |
| **Required Medical Information** | (1a) Prescriber attests that use is for: Primary prophylaxis of febrile neutropenia (FN) in individuals with a high risk for FN (greater than 20%) based on chemotherapy regimen OR (1b) Prescriber attests that use is for: Primary prophylaxis in individuals with an intermediate risk for FN (10%-20%) based on chemotherapy regimen and individuals have one or more of the following risk factors for FN: a.65 years of age or older b. Previous chemotherapy or radiation therapy c. Pre-existing neutropenia d. Bone marrow involvement with tumor e. Previous episodes of FN f. Infection/open wounds g. Recent surgery h. Poor performance status i. Poor renal function j. Liver dysfunction (i.e. elevated bilirubin) k. HIV-infected patient OR (1c) Prescriber attests that use is for: Secondary prophylaxis in individuals who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose or treatment delay may compromise treatment outcome OR (1d) Prescriber attests that use is for an individual receiving dose-dense therapy (treatment given more frequently, such as every 3 weeks instead of every 4 weeks) for breast cancer, lymphoma, or urothelial cancer OR (1e) Prescriber attests that use is for patients with acute myeloid leukemia (AML) following induction or consolidation chemotherapy OR (1f) Prescriber attests that use is for: Patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplantation OR (1g) Prescriber attests that use is for mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | (1h) Prescriber attests that use is for patients with severe chronic neutropenia  B. HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME (NEUPOGEN ONLY): (1) Prescriber attests that use is for hematopoietic subsyndrome of acute radiation syndrome |

# NEUPRO

## Products Affected

- NEUPRO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Parkinsons disease, Restless Leg Syndrome, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PARKINSONS DISEASE, RESTLESS LEG SYNDROME (1a) Prescriber attests the requested medication is being used in the treatment of signs and symptoms associated with Parkinsons disease OR (1b) Prescriber attests the requested medication is being used in the treatment of signs and symptoms associated with restless leg syndrome AND (2) patient has tried and failed or in intolerant to oral pramipexole AND oral ropinirole AND (3) Provider indicates therapy with oral agents is clinically inappropriate |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NEXAVAR

## Products Affected

- NEXAVAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Unresectable hepatocellular carcinoma, Advanced renal cell carcinoma, Metastatic thyroid cancer, Metastatic osteosarcoma, Gastrointestinal stromal tumors (GIST), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL A. HEPATOCELLULAR CARCINOMA, METASTATIC OSTEOSARCOMA (1a) Prescriber attests to a diagnosis of hepatocellular carcinoma and the carcinoma is surgically unresectable OR (1b) Prescriber attests to a diagnosis of relapsed/refractory metastatic osteosarcoma AND (2) The patient has tried and failed or intolerant to cisplatin and doxorubicin, or MAP (high dose methotrexate, cisplatin, and doxorubicin), or high dose methotrexate, doxorubicin, cisplatin, and ifosfamide, or ifosfamide, cisplatin and epirubicin chemotherapy regimen B. METASTATIC THYROID CANCER (1) Prescriber attests to diagnosis of metastatic (advanced) thyroid cancer AND (2) The patient has tried and failed or intolerant to vandetanib and carbozantinib C. GASTROINTESTINAL STROMAL TUMOR (1) Prescriber attests to a diagnosis of gastrointestinal Stromal Tumor (GIST) and GIST is unresectable and/or metastatic malignant AND (2) The patient has tried and failed or intolerant to imatinib and sunitinib D. RENAL CELL CARCINOMA (1) Prescriber attests to diagnosis of metastatic (advanced) renal cell carcinoma and the carcinoma is surgically unresectable AND (2) If the patient is female and of childbearing years, she is NOT pregnant, has NO plans for pregnancy and has been educated on the potential dangers of Nexavar therapy in pregnancy AND (3) The patient will NOT be treated with interferon alfa (Roferon-A, Pegasys, Intron-A, Peg-Intron) or interleukin-2 (Proleukin) therapy in combination with Nexavar treatment RENEWAL FOR ALL INDICATIONS (1) Evidence of clinical improvement from the pretreatment report and/ or the patient has stable disease (tumor size within 25% of baseline) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an oncologist or nephrologist |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# Nexium Granules et al NON FORMULARY

## Products Affected

- *esomeprazole magnesium oral packet*
- NEXIUM ORAL PACKET
- *omeprazole-sodium bicarbonate oral packet*
- ZEGERID ORAL PACKET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Medically accepted indications will be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL (1) Swallowing difficulties due to age/a clinical condition (supported by documentation from the patients chart notes/medical records) AND (2) Tried and failed, intolerance or contraindication to omeprazole suspension/Rx capsules (opened and sprinkled onto one tablespoon of applesauce) and lansoprazole suspension (FIRST-LANSOPRAZOLE) (medication usage must be supported by documentation from the patients chart notes/medical records) RENEWAL (1) Clinical benefit outweighs risk of chronic PPI use evidenced by chart notes/medical records documenting medical evaluation (office visit) within the past 90 days |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NON FORMULARY EXCEPTIONS

## Products Affected

- OMNITROPE PEN 10 INJ DEVICE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Documented diagnosis consistent with FDA approved uses |
| **Exclusion Criteria** | None |
| **Required Medical Information** | (1) Documented diagnosis consistent with FDA approved uses OR (2) Medically accepted indications which include any use of a drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, United States Pharmacopeia-Drug Information (or its successor publications), National Comprehensive Cancer Network AND (3) The requested dose and duration is consistent is member diagnosis as cited in compendia AND (4) There are no contraindications to drug are present within member information AND (5) Documented trial and failure or contraindication to two (2) formulary therapeutic alternative products and/or contraindications to similar drugs in therapy class are noted by prescriber. If there is only one formulary alternative cited for the requested diagnosis, then that alternative must have a documented trial, failure, or contraindication |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | See Other Criteria |
| **Other Criteria** | 12 months UNLESS (1) FDA approved or approved off-label citation states differently OR (2) Drug is within therapy class that has previously defined guidelines for duration of authorization |

# NORTHERA NON FORMULARY

## Products Affected

- NORTHERA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Symptomatic neurogenic orthostatic hypotension (Noh), Medically accepted indications will be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | SYMPTOMATIC NEUROGENIC ORTHOSTATIC HYPOTENSION (Noh) (1) Prescriber attests to a diagnosis of symptomatic neurogenic orthostatic hypotension (Noh) AND (2) Noh is being caused by one of the following diagnoses: (2a) Primary autonomic failure (i.e., Parkinsons disease, multiple system atrophy, or pure autonomic failure) OR (2b) Dopamine beta-hydroxylase deficiency OR (2c) Non-diabetic autoimmune neuropathy AND (3) Documentation that at least one of the following non-pharmacologic interventions has been tried but has not been successful: (3a) Discontinuation of drugs that can cause orthostatic hypotension OR (3b) Raising the head of the bed 10 to 20 degrees OR (3c) Wearing compression stockings OR (3d) Performing physical maneuvers to improve venous return OR (3e) Increasing salt and water intake (if appropriate) OR (3f) Avoiding factors that may cause symptoms (e.g., overexertion in the hot weather, standing or sitting up too quickly) AND (4) An inadequate response, intolerance, or contraindication to a trial of midodrine AND fludrocortisone RENEWAL (1) The neurogenic orthostatic hypotension has stabilized without adverse effects from Northera |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or neurologist |
| **Coverage Duration** | Initial: 3 months, Renewal: 6 months |
| **Other Criteria** | None |

# NOXAFIL

## Products Affected

- NOXAFIL
- *posaconazole*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Aspergillosis, Candidiasis in severely immunocompromised patients, Oropharyngeal candidiasis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Hypersensitivity to the active substance or any of its substituents, concomitant use with ergot alkaloids (ergotamine and dihydroergotamine), HMG-CoA reductase inhibitors primarily metabolized by CYP3A4 (eg, atorvastatin, lovastatin, and simvastatin), sirolimus, or CYP3A4 substrates that prolong the QT interval (pimozide and quinidine) |
| **Required Medical Information** | INITIAL A. INVASIVE ASPERGILLOSIS, CANDIDIASIS (1) Patient is recipient of hematopoietic stem cell transplant (HSCT) with Graft-vs-Host Disease (GVHD) and who is at risk of developing invasive Aspergillus fumigatus and/or Candida infections OR (2) Patient has hematological malignancies causing prolonged neutropenia from chemotherapy and who is at risk of developing Aspergillus fumigatus and/or Candida infections B. OROPHARYNGEAL CANDIDIASIS (1) Prescriber attests to a diagnosis of Oropharyngeal Candidiasis infection AND (2) Fungal culture and other relevant laboratory studies (including histopathology) obtained to isolate and identify causative organisms AND (3) Clinically documented Oropharyngeal Candidiasis refractory to standard course of fluconazole and/or itraconazole RENEWAL (1) Patient is tolerating and responding to medication and there continues to be a medical need for the medication. |
| **Age Restrictions** | Aspergillosis, Candidiasis= 13 years of age and older, Oropharyngeal candidiasis= 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NPLATE NON FORMULARY

## Products Affected

- NPLATE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Immune (idiopathic) thrombocytopenic purpura (ITP), Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC IMMUNE THROMBOCYTOPENIA (1) Prescriber attests to diagnosis of Chronic Immune (idiopathic) thrombocytopenic purpura (ITP) AND (2) Pretreatment platelet count less than 30,000/mm3 (30 x 109/L or 30,000/ml) or a platelet count less than 50,000/mm3 (50 x 109/L or 50,000/ml) with significant mucous membrane bleeding or risk factors for bleeding AND (3) Tried/failed/intolerance to corticosteroids, immunoglobulins (IVIG, IGIV, or anti-Rho[D]), or splenectomy RENEWAL (1) Platelet count of at least 50,000/mm3 (after 4 weeks at a maximum dose of 10mcg/kg per week) AND (2) Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding |
| **Age Restrictions** | 1 year of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NUCALA NON FORMULARY

## Products Affected

- NUCALA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Add-on maintenance treatment with severe Asthma, Eosinophilic granulomatosis with polyangiitis (EGPA). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. EOSINOPHILIC ASTHMA: INITIAL: (1) Prescriber attests to a documented diagnosis of severe asthma with an eosinophilic phenotype AND (2) Prescriber attests that medication is not be used for the relief of acute bronchospasm or status asthmaticus AND (3) Prescriber attests to a baseline absolute blood eosinophil count greater than or equal to 150 cells/microL at initiation of therapy or greater than or equal to 300 cells/microL within the last 12 months AND (4) Prescriber attests that the member must still be symptomatic despite being compliant to a trial of a combination of at least a medium dose inhaled corticosteroid with either a long acting beta agonist (LABA), leukotriene modifier, or theophylline. AND (5) Prescriber attests that Nucala will not be used in conjunction with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair) or reslizumab (Cinqair). RENEWAL: (1) Prescriber attests that the member has experienced ONE of the following: improved symptom control, disease remission, decrease hospitalizations, decreased exacerbations, decreased rescue medication use, and/or decreased oral corticosteroid therapy. AND (2) Prescriber attest that member continues to take at least a medium dose inhaled corticosteroid with either a LABA, leukotriene modifier, or theophylline. AND (3) Prescriber attests that Nucala will not be used in conjunction with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair) or reslizumab (Cinqair). B. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA): (1) Prescriber attests to a documented diagnosis of relapsed or refractory EPGA AND (2) Prescriber attests that the patient must also be receiving standard of care (i.e. corticosteroids). RENEWAL: (1) Prescriber attests that the member has experienced ONE of the following: improved symptom control, disease remission, decrease hospitalizations, decreased exacerbations, decreased rescue medication use, and/or decreased oral corticosteroid therapy. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | Eosinophilic asthma: 6 years of age or older. EGPA: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, an allergist, pulmonologist or immunologist |
| **Coverage Duration** | Initial= 6 months, Renewal= 12months |
| **Other Criteria** | None |

# NUCYNTA ER (TAPENTADOL ER)

## Products Affected

- NUCYNTA ER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe pain, Neuropathic pain, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MODERATE TO SEVERE PAIN (1) Prescriber attests to a diagnosis of moderate to severe pain AND (2) An inadequate response, intolerance or contraindication to at least a 2 week trial two formulary immediate release opioids AND (3) An inadequate response, intolerance, or contraindication to both of the following: (3a) Hysingla AND (3b) Morphine Sulfate ER B. NEUROPATHIC PAIN (1) Prescriber attests to a diagnosis of neuropathic pain AND (2) An inadequate response, intolerance or contraindication to all of the following: (2a) Tramadol AND (2b) Antidepressant AND (2c) Anticonvulsant |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# NUEDEXTA NON FORMULARY

## Products Affected

- NUEDEXTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pseudobulbar affect, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Hypersensitivity to dextromethorphan, quinidine, quinine, mefloquine, or any component of the formulation. Concomitant use with quinidine or other medications containing quinidine, quinine, or mefloquine. History of quinine-, mefloquine-, or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome. Concurrent administration with or within 14 days of discontinuing a MAO inhibitor, patients with prolonged QT interval, congenital QT syndrome, or history of torsades de pointes or heart failure Concurrent use of drugs that prolong the QT interval and are metabolized by CYP2D6 (eg, pimozide, thioridazine). Patients with complete atrioventricular (AV) block without an implanted pacemaker or patients at high risk of complete AV block |
| **Required Medical Information** | A. PSEUDOBULBAR AFFECT: INITAL : (1) Prescriber attests to a documented diagnosis of pseudobulbar affect (PBA) AND (2) Prescriber attests to a baseline score of at least 13 on the Center for Neurologic Studies-Lability Scale (CNS-LS) AND (3) Prescriber attests to a documented presence of a neurologic disease or brain injury (traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis (ALS), Parkinsons disease) AND (4) Prescriber attests that patient is having at least 4 episodes per day. RENEWAL: (1a) Prescriber attests that patient has a decrease in score on the CNS-LS OR (1b) Prescriber attests to a decrease in the number of episodes per day |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a Neurologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | None |

# NUVIGIL

## Products Affected

- *armodafinil*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Narcolepsy, Obstructive sleep apnea, Shift work sleep disorder, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Patients with known hypersensitivity to modafinil and armodafinil or its inactive ingredients. |
| **Required Medical Information** | A. NARCOLEPSY (1) Prescriber attests to a diagnosis of narcolepsy AND (2) Failed/intolerant to at least one formulary/preferred treatment, such as methylphenidate or dextroamphetamine, or a compelling rationale as to why these agents cannot be used B. SHIFT WORK SLEEP DISORDER (1) Prescriber attests to a diagnosis of shift work sleep disorder AND (2) Documentation of the patient work shift C. OBSTRUCTIVE SLEEP APNEA (1) Prescriber attests to a diagnosis of obstructive sleep apnea AND (2) Documentation that the patient has been compliant with continuous positive airway pressure (CPAP) for at least 2 months for at least 4 hours per night RENEWAL (1) Patient is tolerating and responding to medication and there continues to be a medical need for the medication. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Must be prescribed by or in conjunction with a neurologist. For sleep apnea, must be prescribed by or in conjunction with a neurologist or a pulmonary specialist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# OCALIVA NON FORMULARY

## Products Affected

- OCALIVA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary biliary cholangitis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Members who have complete biliary obstruction, or who have developed complete biliary obstruction while taking Ocaliva |
| **Required Medical Information** | A. PRIMARY BILIARY CHOLANGITIS (1) Prescriber attests to a diagnosis of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA AND (2) Member must have documented inadequate response to UDCA OR (3) Member must have clinical documentation that patient is unable to tolerate UDCA AND (4) Alkaline phosphatase, serum transaminases and total bilirubin levels collected prior to treatment RENEWAL (1) Confirmation that the member continues to have a beneficial response to therapy as assessed by a decrease in serum ALP by the members specialist provider |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Must be prescribed by a gastroenterologist or hepatologist |
| **Coverage Duration** | Initial: 3 months, Renewal: 12 months |
| **Other Criteria** | None |

# OCREVUS NON FORMULARY

## Products Affected

- OCREVUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing forms of Multiple Sclerosis, Primary progressive Multiple Sclerosis , Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Patients with active Hepatitis B virus( HBV) infection, History of life-threatening infusion reaction to Ocrevus, Pregnancy |
| **Required Medical Information** | A. PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (PPMS) (1) Prescriber attests to a diagnosis of primary progressive multiple sclerosis (PPMS) AND (2) Hepatitis B virus (HBV) negative carrier or consult with liver expert prior to treatment initiation B. RELAPSING FORMS OF MULTIPLE SCLEROSIS (1) Prescriber attests to a diagnosis of a relapsing form of multiple sclerosis (i.e. RRMS, SPMS) AND (2) Hepatitis B virus (HBV) negative carrier or consult with liver expert prior to treatment initiation AND (3) There is clinical documentation that at least two (2) formulary disease-modifying therapies for multiple sclerosis are contraindicated or not tolerated OR (4) There is clinical documentation that at least two (2) formulary disease-modifying therapies for multiple sclerosis were ineffective, defined as meeting at least two (2) of the following: (2a) The patient continues to have clinical relapses (at least two relapses within the past 12 months) OR (2b) The patient continues to have CNS lesion progression as measured by MRI OR (3c) The patient continues to have worsening disability. Examples of worsening disability include, but are not limited to, decreased mobility, decreased ability to perform activities of daily living due to disease progression, or EDSS greater than 3.5 |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a specialist in neurology or multiple sclerosis |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ODOMZO NON FORMULARY

## Products Affected

- ODOMZO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Basal cell carcinoma, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BASAL CELL CARCINOMA (1) Prescriber attests to a diagnosis of locally advanced basal cell carcinoma (BCC) that reoccurred following surgery or radiation therapy OR patient is not a candidate for surgery or radiation therapy OR (2) Prescriber attests to a diagnosis of nodal or distant basal cell carcinoma metastases AND (3) Baseline serum creatinine kinase and creatinine levels are obtained prior to initiating treatment and will be monitored periodically throughout treatment |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# OFEV NON FORMULARY

## Products Affected

- OFEV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Idiopathic pulmonary fibrosis (IPF), Progressive Fibrosing- Interstitial Lung Disease (PF-ILD), Chronic fibrosing interstitial lung disease (LDs) with a progressive phenotype, slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial disease (SSc-ILD), Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Patients with moderate or severe hepatic impairment, patients with severe renal impairment and end-stage renal disease., concomitant use with Esbriet (pirfenidone) |
| **Required Medical Information** | A. IDIOPATHIC PULMONARY FIBROSIS, PROGRESSIVE FIBROSING-INTERSTITIAL LUNG DISEASE: INITIAL: (1a) Prescriber attests to a diagnosis of idiopathic pulmonary fibrosis confirmed by the presence of usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) and/or surgical lung biopsy OR (1b) Prescriber attests to a diagnosis of progressive fibrosing-interstitial lung disease AND (2) Other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity have been excluded AND (3) The baseline percent predicted forced vital capacity (FVC) is greater than or equal to 50% AND (4) The baseline percent predicted diffusing capacity of the lung for carbon monoxide (DLCO) is between 30-79% AND (5) There is clinical documentation that the patient is a nonsmoker or has been abstinent from smoking for at least six weeks AND (6) Trial/failure/contraindication to Esbriet (pirfenidone) QTY: Authorized in quantities of 60 capsules per month RENEWAL: (1) Prescriber attests Ofev treatment is effective, defined as improvement or maintenance (less than 10% decline in percent predicted FVC or less than 200mL decrease in FVC ) AND (2) Prescriber attests that the patient has remained abstinent from smoking tobacco. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, a pulmonologist |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial= 6 months, Renewal= 6 months |
| **Other Criteria** | C. SYSTEMIC SCLEROSIS- ASSOCIATED INTERSTITIAL DISEASE (SSc-ILD): INITIAL: (1) Prescriber attests to a diagnosis of SSc-ILD AND (2) Prescriber attests to one of the following (2a) skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints or (2b)two of the following: Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers), fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars), telangiectasia, abnormal nail fold capillaries, pulmonary arterial hypertension, Raynauds phenomenon, SSc-related autoantibodies (e.g., anticentromere, antitopoisomerase I, anti-RNA polymerase III). AND (3) Prescriber attests to presence of ILD as determined by finding evidence of pulmonary fibrosis on HRCT, involving at least 10% of the lungs RENEWAL: (1) Prescriber attests that patient has had disease improvement or stabilization while using Ofev. |

# ONCOLOGY

## Products Affected

- ERBITUX INTRAVENOUS SOLUTION 100 MG/50ML
- HERCEPTIN
- IDHIFA ORAL TABLET 100 MG
- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG 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)
- LEUKERAN
- TEMODAR INTRAVENOUS
- *temozolomide*
- *tretinoin oral*
- ZELBORAF

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA-approved indications, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Contraindications to the use of any requested ingredients, request is for experimental or investigational use, member is enrolled in a clinical trial. |
| **Required Medical Information** | INITIAL: A. FOR ALL INDICATIONS: (1) Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1, 2a, 2b only) and Clinical Pharmacology (strong recommendation) AND (2) Documentation of dose and dates of all previous therapies and the resulting outcomes AND (3) Documentation that the proper succession of the therapies have been tried and failed (i.e. intolerance, contraindication, or progression) AND (4) Chart notes detailing the members current clinical status AND (5) Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment. RENEWAL: (1) Current chart notes detailing response and adherence to therapy AND (2) Documented clinically significant improvements in the disease state and stability on the medication. |
| **Age Restrictions** | As noted in the package insert and approved compendia |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, an oncologist, hematologist, or other specialist treating cancer. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Criteria for discontinuation of therapy: Patient is non-adherent with medical or pharmacologic therapy, No demonstrable clinically significant improvement in condition has occurred after initiation of therapy |

# ONFI

## Products Affected

- *clobazam*
- ONFI
- SYMPAZAN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Lennox-Gastaut syndrome, Refractory seizures, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. LENNOX-GASTAUT SYNDROME (1) Prescriber attests to a diagnosis of seizures associated with Lennox-Gastaut syndrome (supported by documentation from the patients chart notes/medical records) AND (2) Currently receiving treatment with at least one other antiepileptic medication (medication usage must be supported by documentation from the patients chart notes/medical records) AND (3) Tried and failed, intolerance or contraindication to one of the following: lamotrigine, topiramate, or valproate (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) B. REFRACTORY SEIZURES (1) Prescriber attests to a diagnosis of refractory seizures (supported by documentation from the patients chart notes/medical records) AND (2) Currently receiving treatment with at least one other antiepileptic medication (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) AND (3) An inadequate response or intolerance to a trial of any two preferred anticonvulsants (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# OPANA ER (OXYMORPHONE EXTENDED-RELEASE)

## Products Affected

- OPANA
- *oxymorphone hcl er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Pain, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Moderate and severe hepatic impairment, Paralytic ileus |
| **Required Medical Information** | A. CHRONIC PAIN (1) Prescriber attests to a diagnosis of chronic pain requiring an opioid analgesic AND (2) used for management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time AND (3) not intended for use as a prn analgesic AND (4) trial/failure to ALL of the opioids (hydrocodone/APAP, morphine IR, oxycodone IR, hydromorphone IR, morphine ER) AND (5) An inadequate response, intolerance, or contraindication to both of the following: Hysingla ER AND Oxycontin AND (6) Patient has been warned that: Co-administration with alcohol may increase oxymorphone plasma levels and the risk of potentially fatal toxicity AND Opana should be taken on an empty stomach since food can increase the rate of absorption by 50% |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# OPIOID DEPENDENCE

## Products Affected

- BUNAVAIL
- *buprenorphine hcl sublingual*
- *buprenorphine hcl-naloxone hcl sublingual film*
- SUBOXONE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Opioid Use Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Hypersensitivity to buprenorphine, naloxone, or any component of the formulation, Patient is using short or long acting narcotics concurrently, Indications other than opioid dependence, Doses exceeding 32 mg/ day (buprenorphine) |
| **Required Medical Information** | STEP ALERT: PATIENT MUST TRY AND FAIL BUPRENORPHINE/NALOXONE AND SUBOXONE BEFORE BUNAVAIL A. OPIOID DEPENDENCE: BUPRENORPHINE/NALOXONE: INITIAL: (1) Must have a documented diagnosis of opioid dependence AND (2) The prescriber must be qualified to prescribe (see below) AND (3) The member has been referred or is participating in a substance abuse or behavioral health treatment program, behavioral health counseling, or an addictions recovery program. (During the initial course of treatment, referral and enrollment must be with a licensed Drug and Alcohol or behavioral health provider) AND (4) The patient must not be using short or long acting narcotics concurrently AND (5) Prescriber attests to liver function being monitored before and during treatment RENEWAL:(1) Member must remain compliant with comprehensive treatment program including: a. Prescriber must attest that member has consistent participation in a substance abuse or behavioral health treatment program, behavioral health counseling, or an addictions recovery program AND b. Prescriber attests to standard drug screen monitoring. AND (2) Member must meet the continuation of therapy criteria above BUPRENORPHINE: INITIAL: (1) Must meet the initial therapy criteria above AND (2a) Member must be pregnant OR (2b) Prescriber provides chart notes that the member cannot tolerate naloxone or naloxone containing formulations. AND RENEWAL: (1) Member must remain compliant with comprehensive treatment program including: a. Prescriber must attest that member has consistent participation in a substance abuse or behavioral health treatment program, behavioral health counseling, or an addictions recovery program AND b. Prescriber attests to standard drug screen monitoring AND (2) Member must meet the continuation of therapy criteria above AND (3a) Member |

| PA Criteria | Criteria Details |
|---|---|
| | must be pregnant OR (3b) Prescriber provides chart notes that the member cannot tolerate naloxone or naloxone containing formulations. |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | The prescriber is a licensed physician who is treating the member and is qualified to prescribe this therapy according the DATA 2000 and SAMHSA. Physician must be listed on the Buprenorphine Physician Locator maintained by the Substance Abuse and Mental Health Services Administration (SAMSHA). https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatment-practitioner |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | Buprenorphine HCl-Naloxone HCl 8/2 mg, 12/3mg films: 60 per 30 days (2) Buprenorphine HCl-Naloxone HCl 8/2mg tabs: 90 films per 30 days (3) Buprenorphine HCl-Naloxone HCl 2/0.5mg films/tablets, Buprenorphine HCl-Naloxone HCl 4/1 films : 90 per 30 days (4) Buprenorphine sl: maximum daily dose is less than or equal to 16 mg/day |

# OPSUMIT

## Products Affected

- OPSUMIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Hypertension, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | A. PULMONARY HYPERTENSION (1) Prescriber attests to a diagnosis of pulmonary arterial hypertension WHO Group 1, patients with NYHA class II-IV AND (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records AND (3) Patient is not smoking cigarettes AND (4) Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test AND (5) Must have tried and failed sildenafil or tadalafil AND (6) Must have tried and failed either bosentan or ambrisentan AND (7) Requested dose does not exceed 10mg per day (QL of 30/30) RENEWAL (1) Patient responding to treatment without disease progression AND (2) Patient tolerating treatment AND (3) Prescriber is monitoring for anemia, hepatotoxicity |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cardiologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ORACEA NON FORMULARY

## Products Affected

- *doxycycline*
- ORACEA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rosacea. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ROSACEA (1) Prescriber attests patient has diagnosis of Rosacea (2) Patient is 18 years of age or older (3) Patient has had an inadequate response to a trial of covered oral generic doxycycline for at least 60 days in the past 90 days (4) Patient has had an inadequate response or intolerance to trials of both tetracycline and minocycline |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ORALAIR NON FORMULARY

## Products Affected

- ORALAIR
- ORALAIR ADULT SAMPLE KIT
- ORALAIR ADULT STARTER PACK
- ORALAIR CHILDRENS STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Grass Pollen-Induced Allergic Rhinitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. GRASS POLLEN-INDUCED ALLERGIC RHINITIS (1) Prescriber attests patient has diagnosis of Grass Pollen-Induced Allergic Rhinitis confirmed by either a positive skin test response to a grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass) or a positive in vitro test (blood test for allergen-specific IgE antibodies) for a grass in the Pooideae subfamily of grasses (2) Patient is between 5 years of age and 65 years of age (3) Prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist (4) Therapy is initiated 3 months prior to the expected onset of the grass pollen season (5) Patient is NOT currently receiving subcutaneous allergen immunotherapy |
| **Age Restrictions** | Between 5 years of age and 65 years of age |
| **Prescriber Restrictions** | Prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | When approved, members may obtain 30 sublingual Oralair tablets per 30 days |

# ORAVIG NON FORMULARY

## Products Affected

- ORAVIG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Oropharyngeal Candidiasis (Thrush). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. OROPHARYNGEAL CANDIDIASIS (THRUSH) (1) Prescriber attests patient has diagnosis of Oropharyngeal Candidiasis (Thrush) (2) Patient is 16 years of age or older (3) Patient must try and fail nystatin suspension (4) Patient must try and fail clotrimazole troches |
| **Age Restrictions** | 16 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ORENCIA

## Products Affected

- ORENCIA
- ORENCIA CLICKJECT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, or Psoriatic Arthritis (PsA). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RHEUMATOID ARTHRITIS (1) Prescriber attests patient has diagnosis of adult Rheumatoid Arthritis (2) Prescribed by a rheumatologist (3) Must have a negative tuberculosis test or received treatment if tested positive (4) Intolerant or inadequate response after 3 months of treatment to methotrexate (5) Intolerant or inadequate response after 3 months of treatment to etanercept (Enbrel) and adalimumab (Humira) (6) Intolerant or inadequate response after 3 months of treatment to Remicade B. JUVENILE RHEUMATOID ARTHRITIS (1) Prescriber attests patient has diagnosis of Juvenile Rheumatoid Arthritis (2) Prescribed by a rheumatologist (3) Must have a negative tuberculosis test or received treatment if tested positive (4) Intolerant or inadequate response after 3 months of treatment to methotrexate (5) Intolerant or inadequate response after 3 months of treatment to etanercept (Enbrel) and adalimumab (Humira) C. PSORIATIC ARTHRITIS (PSA) (1) Prescriber attests patient has diagnosis of Psoriatic Arthritis (2) Prescribed by a rheumatologist (3) Must have a negative tuberculosis test or received treatment if tested positive (4) Patient is 18 years of age or older with active PsA (5) Tried and failed, or is intolerant to, or has a medical contraindication to conventional therapy (such as non-biologic DMARDs) (6) Inadequate response to TWO preferred biologic therapies in the previous 180 days (Current preferred biologics include - Enbrel (etanercept), Humira (adalimumab)) |
| **Age Restrictions** | PsA: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by a Rheumatologist |
| **Coverage Duration** | 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | None |

# ORENITRAM

## Products Affected

- ORENITRAM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Arterial Hypertension WHO Group 1. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Any contraindication to treatment (2) Orenitram is being used in combination with other vasodilators |
| **Required Medical Information** | A. PULMONARY ARTERIAL HYPERTENSION WHO GROUP 1 (1) Prescriber attests patient has diagnosis of Pulmonary Arterial Hypertension WHO Group I (2) The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patients medical records (3) Prescribed by pulmonologist or cardiologist (4) Patient is not using any tobacco products (5) Patient has WHO Functional Class II or III symptoms (6) Must have tried and failed a calcium channel blocker if the patient has had a positive vasoreactivity test (7) Must have tried and failed sildenafil (8) Must have tried and failed either bosentan (Tracleer) or ambrisentan (Letairis) B. CONTINUATION OF THERAPY (1) Patient is tolerating treatment (2) Prescriber attests that patient has had disease improvement or stabilization since using the medication |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by pulmonologist or cardiologist |
| **Coverage Duration** | Initial: 3 months, Renewal: 12 months |
| **Other Criteria** | Quantity Limitation: 60/30 |

# ORFADIN NON FORMULARY

## Products Affected

- *nitisinone*
- ORFADIN ORAL CAPSULE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Type 1 Hereditary Tyrosinemia (HT-1). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TYPE 1 HEREDITARY TYROSINEMIA (HT-1) (1) Prescriber attests patient has diagnosis of Type 1 Hereditary Tyrosinemia (HT-1) (2) Patient is on a Tyrosine and Phenylalanine restricted diet (3) Plasma Tyrosine level must be less than 500 micromol/L (4) Current Liver Function Tests (LFTs) within normal limits |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ORKAMBI

## Products Affected

- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CYSTIC FIBROSIS (1) Prescriber attests patient has diagnosis of Cystic Fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test (2) Must be greater than or equal to 2 years of age (3) Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation (4) Baseline FEV1 greater than or equal to 40% (5) Baseline liver function tests (ALT/AST and bilirubin) provided (6) If less than 18 years of age, baseline ophthalmological exam completed B. CONTINUATION OF THERAPY (1) Documentation patient is tolerating and responding to medication (i.e. improved FEV1, weight gain, decreased exacerbations, etc.) (2) Adherence to therapy is confirmed (supported by documentation from patients chart notes or electronic claim history) (3) Liver function tests (ALT/AST and bilirubin) provided every 3 months during first year of treatment and annually thereafter (4) ALT or AST does not exceed 5 times the upper limit of normal (5) ALT or AST does not exceed 3 times upper limit of normal with bilirubin greater than 2 times upper limit of normal |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |

# OTEZLA

## Products Affected

- OTEZLA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Psoriatic Arthritis, Moderate to Severe Plaque Psoriasis, or Oral Ulcers Associated with Behcets Disease. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PSORIATIC ARTHRITIS AND MODERATE TO SEVERE PLAQUE PSORIASIS (1) Prescriber attests patient has diagnosis of Psoriatic Arthritis or Moderate to Severe Plaque Psoriasis who are candidates for phototherapy or systemic therapy for at least 6 months (2) Age is 18 years or older (3) Failed response, intolerance, or contraindication to two DMARDs (i.e. methotrexate, leflunomide, sulfasalazine, azathioprine, cyclosporine) (4) An inadequate response, intolerance, or contraindication to a one month trial of Enbrel and Humira B. ORAL ULCERS ASSOICATED WITH BEHCETS DISEASE (1) Prescriber attests patient has diagnosis of Oral Ulcers Associated with Behcets Disease |
| **Age Restrictions** | PsA and Psoriasis: 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# OXANDRIN (OXANROLONE)

## Products Affected

- *oxandrolone oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Promote Weight Gain, Offset Protein Catabolism, Bone Pain Associated with Osteoporosis, Turners Syndrome, Cachexia Associated with AIDS or Chronic Disease, or Hereditary Angioedema. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Known or suspected carcinoma of the prostate or the male breast (2) Carcinoma of the breast in females with hypercalcemia (anabolic steroids stimulate osteolytic bone resorption) (3) Pregnancy (Pregnancy Category X) (4) Hypersensitivity to the drug (5) Nephrosis (6) Hypercalcemia |
| **Required Medical Information** | A. PROMOTE WEIGHT GAIN, OFFSET PROTEIN CATABOLISM, BONE PAIN ASSOCIATED WITH OSTEOPOROSIS, TURNERS SYNDROME, CACHEXIA ASSOCIATED WITH AIDS OR CHRONIC DISEASE, AND HEREDITARY ANGIOEDEMA (1) Prescriber attests patient has diagnosis of Adjunctive therapy to promote weight gain following: (i) Extensive Surgery (ii) Chronic Infection (iii) Severe Trauma, Therapy to offset protein catabolism associated with long term use of corticosteroids, Treatment of bone pain associated with osteoporosis, Turners syndrome, Cachexia associate with AIDS (HIV wasting) or due to chronic disease, Hereditary angioedema |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# OXYCONTIN NON FORMULARY

## Products Affected

- *oxycodone hcl er*
- OXYCONTIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Severe Pain in Opioid-Tolerant Patients Requiring a Long-Term Daily Around-the-Clock Opioid Analgesic. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC SEVERE PAIN IN OPIOID-TOLERANT PATIENTS REQUIRING A LONG-TERM DAILY AROUND-THE-CLOCK OPIOID ANALGESIC (1) Prescriber attests patient has diagnosis of Chronic, severe pain in opioid-tolerant patients requiring a long-term daily around-the-clock opioid analgesic (2) Documented trial and failure at therapeutic maximum doses or intolerance to NSAIDs (3) Documented trial and failure at therapeutic maximum doses or intolerance to tramadol (4) Documented trial and failure at therapeutic maximum doses or intolerance to a short acting (immediate release) opioid |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PAXIL SUSPENSION

## Products Affected

- PAXIL ORAL SUSPENSION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Depression, Generalized Anxiety Disorder, Hot Flashes, Menopause, Obsessive-Compulsive Disorder, Panic Disorder, Post-Traumatic Stress Disorder, Premenstrual Dysphoric Disorder, or Social Phobia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. DEPRESSION, GENERALIZED ANXIETY DISORDER, HOT FLASHES, MENOPAUSE, OBSESSIVE-COMPULSIVE DISORDER, PANIC DISORDER, POST-TRAUMATIC STRESS DISORDER, PREMENSTRUAL DYSPHORIC DISORDER, AND SOCIAL PHOBIA (1) Prescriber attests patient has diagnosis of Depression, Generalized Anxiety Disorder, Hot Flashes, Menopause, Obsessive-Compulsive Disorder, Panic Disorder, Post-Traumatic Stress Disorder, Premenstrual Dysphoric Disorder, or Social Phobia (2) Patient has an inability to take oral dosage form Paroxetine tablet |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PEGASYS/PEGINTRON

## Products Affected

- PEGASYS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Hepatitis C Infection. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC HEPATITIS C INFECTION (1) Prescriber attests patient has diagnosis of Chronic Hepatitis C Infection (2) Patient has compensated liver disease (3) The requested medication will be used in conjunction with one of the following or has a contraindication or intolerance to all of the following other HCV agents: (i) Sovaldi (sofosbuvir) (ii) Ribavirin B. CONTINUATION OF THERAPY (1) Patient has undetectable HCV RNA at week 24 (2) Prescriber attests that patient requires additional treatment weeks of peginterferon to complete treatment regimen (3) Patient has not exceeded 48 weeks of therapy with peginterferon |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 28 weeks, Renewal: 20 weeks |
| **Other Criteria** | None |

# PERFOROMIST

## Products Affected

- PERFOROMIST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Obstructive Pulmonary Disease (COPD), Asthma, or Exercise-Induced Bronchospasm. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) (1) Prescriber attests patient has diagnosis of Chronic Obstructive Pulmonary Disease (COPD) (2) Trial and failure, contraindication, or intolerance to all of the following: (i) Serevent (ii) Spiriva (iii) Stiolto B. ASTHMA AND EXERCISE-INDUCED BRONCHOSPASM (1) Prescriber attests patient has diagnosis of Asthma or Exercise-Induced Bronchospasm (2) Trial and Failure, contraindication, or intolerance to all of the following: (i) Serevent (ii) Spiriva |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PEXAVA NON FORMULARY

## Products Affected

- PEXEVA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Generalized Anxiety Disorder, Major Depressive Disorder, Obsessive-Compulsive Disorder, or Panic Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. GENERALIZED ANXIETY DISORDER, MAJOR DEPRESSIVE DISORDER, OBSESSIVE-COMPULSIVE DISORDER, AND PANIC DISORDER (1) Prescriber attests patient has diagnosis of Generalized Anxiety Disorder, Major Depressive Disorder, Obsessive-Compulsive Disorder, or Panic Disorder (2) Trial and failure or intolerance of a two month trial of paroxetine immediate-release AND the other formulary generic SSRIs (i.e. fluvoxamine, citalopram, escitalopram, paroxetine, sertraline) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PHOSLYRA

## Products Affected

- PHOSLYRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hyperphosphatemia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPERPHOSPHATEMIA (1) Prescriber attests patient has diagnosis of Hyperphosphatemia associated with chronic kidney disease, dialysis, end stage renal disease (ESRD), or renal failure (2) Prescribed by a nephrologist (3) Patient is on a phosphate-restricted diet (4) Tried and failed (phosphorus level greater than4.5mg/dl or calcium levels above 9.6 as documented by lab test for 2 to 3 consecutive months) or intolerance to both of the following: (i) calcium acetate (ii) sevelamer carbonate |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PKU

## Products Affected

- PKU AIR15 GOLD
- PKU AIR15 GREEN
- PKU AIR15 YELLOW
- PKU AIR20 GOLD
- PKU AIR20 GREEN
- PKU AIR20 YELLOW
- PKU COOLER 10
- PKU COOLER 15
- PKU COOLER 20
- PKU EXPRESS
- PKU EXPRESS20
- PKU GEL
- PKU SPHERE 20 ORAL PACKET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Phenylketonuria. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PHENYLKETONURIA (1) Prescriber attests patient has diagnosis of Phenylketonuria (2) One of the following: (i) Patient is male and 21 years of age or younger (ii) Patient is female and 35 years of age or younger |
| **Age Restrictions** | Male: 21 years of age or younger, Female: 35 years of age or younger |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PLEGRIDY

## Products Affected

- PLEGRIDY
- PLEGRIDY STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing Multiple Sclerosis or at Risk of MS. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RELAPSING MULTIPLE SCLEROSIS (1) Prescriber attests patient has diagnosis of relapsing multiple sclerosis, supported by documentation from the patients medical records/most recent brain MRI (Note: Relapsing forms of MS include relapsing-remitting, secondary progressive with relapses, and progressive relapsing) or have experienced an attack and who are at risk of MS (2) Prescribed by a neurologist B. CONTINUATION OF THERAPY (1) Medical records/chart notes from neurology consultation documenting the improvement of the relapsing rate or that the patients clinical condition is stabilized with the current therapy with no significant adverse effects |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# POMALYST

## Products Affected

- POMALYST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Multiple Myeloma, Kaposis Sarcoma or Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MULTIPLE MYELOMA (1) Prescriber attests patient has diagnosis of Multiple myeloma (2) Patient has had a clinical trial and failure, intolerance, or contraindication to at least two prior therapies including both of the following: (I) Revlimid (lenalidomide) (II) Proteasome inhibitor (i.e. Velcade, Kyprolis) (3) Patient has experienced disease progression on or within 60 days of completion of last therapy (4) Prescribed by or in consultation with an oncologist/hematologist (5) Will be used in combination with dexamethasone B. KAPOSIS SARCOMA (1) Prescriber attests patient has diagnosis of Kaposis Sarcoma AND (2) Patient is HIV-negative OR (3) Patient has AIDS-related disease after failure of Highly Active Antiretroviral Therapy (HAART) C. CONTINUATION OF THERAPY (1) Patient continues to meet initial criteria (2) Prescriber attests that patient has had a positive clinical response to treatment (no evidence of progressive disease) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PRADAXA

## Products Affected

- PRADAXA ORAL CAPSULE 150 MG, 75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-Valvular Atrial Fibrillation, Postoperative Deep Vein Thrombosis Prophylaxis for Total Hip Replacement, Prophylaxis of Pulmonary Embolism for Total Hip Replacement, or Prophylaxis of Venous Thromboembolism Following Parental Therapy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NON-VALVULAR ATRIAL FIBRILLATION, POSTOPERATIVE DEEP VEIN THROMBOSIS PROPHYLAXIS FOR TOTAL HIP REPLACEMENT, PROPHYLAXIS OF PULMONARY EMBOLISM FOR TOTAL HIP REPLACEMENT, AND PROPHYLAXIS OF VENOUS THROMBOEMBOLISM FOLLOWING PARENTAL THERAPY (1) Prescriber attests patient has diagnosis of Non-Valvular Atrial Fibrillation, Postoperative Deep Vein Thrombosis Prophylaxis for Total Hip Replacement, Prophylaxis of Pulmonary Embolism for Total Hip Replacement, or Prophylaxis of Venous Thromboembolism Following Parental Therapy (2) Patient has had a trial and failure, intolerance or contraindication to therapy with warfarin (3) Patient has had a trial and failure, intolerance, or contraindication to therapy with both of the following: (i) Eliquis (ii) Xarelto |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PRALUENT

## Products Affected

- PRALUENT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Heterozygous Familial Hypercholesterolemia (HeFH) or Clinical Atherosclerotic Cardiovascular Disease (CVD). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) (1) Prescriber attests patient has diagnosis of (HeFH) confirmed by genotyping or the following Simon Broome criteria: (i) Total cholesterol greater than 290mg/dL or LDL cholesterol greater than 190mg/dL (ii) One of the following: (a) Tendon xanthomas in patient, or in 1st degree relative (parent, sibling, child), or in 2nd degree relative (grandparent, uncle, aunt) (b) DNA-based evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation B. CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (CVD) (1) Prescriber attests patient has diagnosis of CVD as defined by one of the following: (i) acute coronary syndrome (ii) history of myocardial infarction (iii) stable/unstable angina (iv) coronary or other arterial revascularization (v) stroke (vi) transient ischemic stroke (vii) peripheral arterial disease presumed to be atherosclerotic (2) Appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment, supported by documentation of counseling in chart notes and: (i) Total dietary fat less than 35% of total calories (ii) Weight loss in overweight patients (iii) Aerobic exercise (iv) Diet rich in fruits and vegetables (3) Baseline and current LDL-C provided (4) Require additional LDL-C reduction after a 12-week trial of both of the following: (i) a high-intensity statin (atorvastatin 40-80mg, rosuvastatin 20-40mg) (ii) in combination with ezetimibe (5) Patient has been adherent to lipid-lowering therapy (proportion of days covered (PDC) greater than or equal to 80%) (6) LDL-C greater than or equal to100 mg/dL (7) One of the following: (i) Used in combination with maximally tolerated high-intensity statin (ii) Patient is statin intolerant, as demonstrated by experiencing: (a) Documented statin-associated rhabdomyolysis to one statin (b) Documented skeletal-muscle related symptoms with either rosuvastatin or atorvastatin |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a cardiologist, endocrinologist, or lipid specialist |
| **Coverage Duration** | Initial: 4 weeks, Renewal: 12 months |
| **Other Criteria** | C. CONTINUATION OF THERAPY (1) Documented response to Praluent, defined as ONE of the following: (I) Percentage reduction of LDL is greater than 40% compared to baseline level (II) Absolute LDL is less than 70 mg/Dl (2) The patient is tolerating the medication (3) Will continue to be used in combination with a maximally tolerated statin or is statin intolerant demonstrated by: (i) Documented statin-associated rhabdomyolysis to one statin (ii) Documented skeletal-muscle related symptoms with either rosuvastatin or atorvastatin (4) Patient has remained adherent to therapy, defined as proportion of days covered (PDC) greater than or equal to 80% |

# PREVYMIS NON FORMULARY

## Products Affected

- PREVYMIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | CMV Prophylaxis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Co-administration with pimozide or ergot alkaloids (2) Co-administration with pitavastatin and simvastatin when co-administered with cyclosporine |
| **Required Medical Information** | A. CMV PROPHYLAXIS (1) Prescriber attests patient has diagnosis of seropositive CMV (2) Must have received an allogenic HSCT within the last 28 days (prescriber must provide transplant date) (3) Must be prescribed by, or in conjunction with a hematologist, oncologist, or infectious disease specialist |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with a hematologist, oncologist, or infectious disease specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PROLENSA NON FORMULARY

## Products Affected

- BROMSITE
- PROLENSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postoperative Ocular Pain/Inflammation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. POSTOPERATIVE OCULAR PAIN/INFLAMMATION (1) Prescriber attests patient has diagnosis of Postoperative Ocular Pain/Inflammation (2) Must have an inadequate response or intolerance to trials of all of the following: (i) diclofenac (ii) bromfenac (iii) ketorolac |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# PROLIA

## Products Affected

- PROLIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postmenopausal Osteoporosis, Osteoporosis in Men, Non-Metastatic Breast Cancer Receiving Adjuvant Aromatase Inhibitor Therapy, or Non-Metastatic Prostate Cancer Receiving Androgen Deprivation Therapy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. POSTMENOPAUSAL OSTEOPOROSIS, OSTEOPOROSIS IN MEN, NON-METASTATIC BREAST CANCER RECEIVING ADJUVANT AROMATASE INHIBITOR THERAPY, AND NON-METASTATIC PROSTATE CANCER RECEIVING ANDROGEN DEPRIVATION THERAPY (1) Prescriber attests patient has diagnosis of Postmenopausal Osteoporosis, Osteoporosis in Men, Non-Metastatic Breast Cancer Receiving Adjuvant Aromatase Inhibitor Therapy, or Non-Metastatic Prostate Cancer Receiving Androgen Deprivation Therapy (2) One of the following: (i) T-score less than or equal to -2.5 as evidenced via a DXA bone density scan (ii) T-score is between -1.0 and -2.5 as evidenced via a DXA bone density scan and multiple risk factors for fractures (must document risk factors) (3) An inadequate response (defined as a declining T-score from baseline or a fragility fracture) or intolerance to a trial of at least one oral bisphosphonate, or contraindication to oral bisphosphonates (i.e. esophageal stricture, achalasia, etc) (4) An inadequate response (defined as a declining T-score from baseline or a fragility fracture) or intolerance to a trial of one injectable bisphosphonate, or contraindication to injectable bisphosphonates |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Risk factors for fracture include: (1) advanced age (2) prior history of fragility fracture (3) chronic glucocorticoid use (4) low BMI (5) parental |

| PA Criteria | Criteria Details |
| --- | --- |
| | history of hip fracture (6) family history of osteoporosis (7) cigarette smoking (8) excess alcohol consumption (9) presence of medical diseases that are associated with low BMD, such as: (i) rheumatoid arthritis (ii) inflammatory bowel disease (iii) type 1 diabetes (iv) chronic liver disease |

# PROMACTA

## Products Affected

- PROMACTA ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Immune (Idiopathic) Thrombocytopenia Purpura (ITP), Thrombocytopenia Secondary to Cirrhosis of the Liver Due to Hepatitis C, Chronic Hepatitis C Infection Associated with Thrombocytopenia, Severe Aplastic Anemia in Combination with Standard Immunosuppressive Therapy, Severe Aplastic Anemia with Insufficient Response to Immunosuppressive Therapy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ITP (1) Prescriber attests patient has diagnosis of Chronic Immune (Idiopathic) Thrombocytopenia Purpura (ITP) (2) Patient is 1 year of age or older (2) Pretreatment PLT count less than 30,000/mm3 or a PLT count less than 50,000/mm3 with significant mucous membrane bleeding or risk factors for bleeding (3) Tried/failed/intolerant to corticosteroids, immunoglobulins (IVIG, IGIV, or anti-Rho[D]), or splenectomy B. THROMBOCYTOPENIA SECONDARY TO CIRRHOSIS OF THE LIVER DUE TO HEPATITIS C (1) Prescriber attests patient has diagnosis of Thrombocytopenia Secondary to Cirrhosis of the Liver Due to HCV C. CHRONIC HEPATITIS C INFECTION ASSOCIATED WITH THROMBOCYTOPENIA (1) Prescriber attests patient has diagnosis of Chronic HCV Associated with Thrombocytopenia (2) Patient is 18 years of age or older (3) Patient receiving interferon based therapy for the treatment of HCV D. SEVERE APLASTIC ANEMIA IN COMBINATION WITH STANDARD IMMUNOSUPPRESSIVE THERAPY (1) Prescriber attests patient has diagnosis of Severe Aplastic Anemia in Combination with Standard Immunosuppressive Therapy (2) Patient is 2 years of age or older (3) PLT count approximating 30,000 per microliter or lower or patient is PLT transfusion dependent, hemoglobin approximating 8.4 g/dL or lower or patient is dependent on transfusions of red blood cells (RBCs), absolute neutrophil count (ANC) approximating 0.5 x 10/L E. SEVERE APLASTIC ANEMIA WITH INSUFFICIENT RESPONSE TO IMMUNOSUPPRESSIVE THERAPY (1) Prescriber attests patient has diagnosis of Severe Aplastic Anemia with Insufficient Response to Immunosuppressive Therapy (2) Patient is 18 years of age or older (3) PLT count approximating 30,000 per microliter or lower or patient is PLT transfusion dependent, hemoglobin approximating 8.4 g/dL |

| PA Criteria | Criteria Details |
|---|---|
| | or lower or patient is dependent on transfusions of RBCs, ANC approximating 0.65 x 10/L (4) Must have tried/failed at least one prior immunosuppressive therapy F. CONTINUATION OF THERAPY See Other Criteria |
| **Age Restrictions** | ITP: 1 year of age or older, HCV with Thrombocytopenia: 18 years of age or older, AA with Immunosuppression: 2 years of age or older, AA with insufficient response to immunosuppression: 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | F. CONTINUATION OF THERAPY ITP AND THROMBOCYTOPENIA SECONDARY TO CIRRHOSIS OF THE LIVER DUE TO HEPATITIC C (1) One of the following: (i) PLT count of at least 50,000/mm3 (after 4 weeks at a maximum dose of 75 mg/day) (ii) Increase in PLT count over baseline to a level sufficient to avoid clinically important bleeding G. CONTINUATION OF THERAPY CHRONIC HEPATITIS C INFECTION ASSOCIATED WITH THROMBOCYTOPENIA (1) Patient must show a response to treatment with a platelet count of at least 50,000/mcL but less than 200,000 /mcL (response rates should be seen at least 1 week after initiation or treatment with a maximum response seen at 2 weeks) (2) Promacta should be discontinued when antiviral therapy is discontinued H. SEVERE APLASTIC ANEMIA IN COMBINATION WITH STANDARD IMMUNOSUPPRESIVE THERAPY AND SEVERE APLASTIC ANEMIA WITH INSUFFICIENT RESPONSE TO IMMUNOSUPPRESIVE THERAPY (1) PLT count increases to 20 x 10^9/L above baseline, or stable PLT counts with transfusion independence for a minimum of 8 weeks (2) Hemoglobin increase by greater than 1.5 g/dL or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks (3) ANC increase of 100% or an ANC increase greater than 0.5 x 10^9/L |

# PROVIGIL

## Products Affected

- *modafinil*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Narcolepsy, Obstructive Sleep Apnea (OSA), Shift Work Disorder (SWD), Multiple Sclerosis-Related Fatigue, Cancer-Related Fatigue, Fibromyalgia, Steinert Myotonic Dystrophy Syndrome, HIV/AIDS-Related Fatigue, or Attention Deficit Hyperactivity Disorder (ADHD). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NARCOLEPSY (1) Prescriber attests patient has diagnosis of Narcolepsy not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or another general medical condition (2) One of the following: (i) Cataplexy, accompanied by irresistible attacks of refreshing sleep that occur daily over at least 3 months (ii) Polysomnogram indicating or suggesting narcolepsy, including at least one of the following: (a) Sleep latency less than 10 minutes (b) REM sleep latency less than 20 minutes (presence of a sleep-onset REM period) (c) A Multiple Sleep Latency Test (MSLT) demonstrates a mean sleep latency of less than 5 minutes PLUS two or more sleep-onset REM periods B. OSA (1) Prescriber attests patient has diagnosis of Obstructive Sleep Apnea (OSA) (2) Presence of residual excessive sleepiness (ES) defined as Epworth Sleepiness Scale score greater than 10 (3) Documentation that the patient has been using CPAP for at least 2 months on average greater than 4 hours per night C. SWD (1) Prescriber attests patient has diagnosis of Shift Work Disorder (SWD) (2) Patient has a primary complaint of insomnia or excessive sleepiness (3) Primary complaint is temporally associated with a work period (usually night work) that occurs during the habitual sleep phase (4) Sleep disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning (5) Sleep disturbance does not occur exclusively during the course of another sleep disorder or other mental disorder (6) Sleep disturbance is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (7) Symptomatic for at least 3 months D. SEE OTHER CRITERIA FOR ADDITIONAL DIAGNOSES |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | D. MULTIPLE SCLEROSIS-RELATED FATIGUE (1) Prescriber attests patient has diagnosis of Multiple Sclerosis-related Fatigue (2) Tried/failed/intolerant to non-pharmacologic therapies (3) Tried/failed/intolerant to amantadine OR CNS stimulant (e.g., methylphenidate, amphetamine salts) (4) Fatigue is not due to the direct physiological effects of a substance (e.g., benzodiazepine, sedating antidepressant, or sleep agent) E. CANCER-REALATED FATIGUE, FIBROMYALGIA, STEINERT MYOTONIC DYSTROPHY SYNDROME, AND HIV/AIDS-RELATED FATIGUE (1) Prescriber attests patient has diagnosis of Cancer-related Fatigue, Fibromyalgia, Steinert myotonic dystrophy syndrome, or HIV/AIDS-related Fatigue F. ADHD (1) Prescriber attests patient has diagnosis of Attention deficit hyperactivity disorder (2) Tried/failed/in tolerant to two generic formulary stimulants |

# PULMOZYME

## Products Affected

- PULMOZYME

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | If the patient is being treated in a hospital or long-term facility (LTC) or a skilled nursing facility (SNF) and the payer of the stay is Medicare Part A, if applicable. The patient is being treated at home. (Patients using medication with a nebulizer are covered under Medicare Part B, if applicable). Hypersensitivity to dornase alfa, Chinese hamster ovary cell products, or any component of the formulation. |
| **Required Medical Information** | A. CYSTIC FIBROSIS, INITIAL: (1) Prescriber attests to a documented cystic fibrosis diagnosis and medication is being used to improve pulmonary function and/or reduce the frequency of respiratory infections AND (2) Patients forced vital capacity (FVC) is at least 40% of predicted AND (3) Used in conjunction with standard cystic fibrosis therapies, including but not limited to: chest physiotherapy, bronchodilators, antibiotics, anti-inflammatories CONTINUATION OF THERAPY: (1) Prescriber attests that patient meets initial criteria AND (2) Prescriber attests to a decrease in frequency of respiratory infection and/or improvement in pulmonary function. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# QUIXIIN (LEVOFLOXACIN) OPHTHALMIC

## Products Affected

- *levofloxacin ophthalmic*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Bacterial Conjunctivitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BACTERIAL CONJUNCTIVITIS (1) Prescriber attests patient has diagnosis of Bacterial Conjunctivitis (2) An inadequate response or intolerance or contraindication to a trial of two of the following: (i) ciprofloxacin 0.3% ophthalmic solution (ii) tobramycin 0.3% ophthalmic solution (or tobramycin/dexamethasone solution) (iii) ofloxacin 0.3% ophthalmic solution |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RADIOGARDASE NON FORMULARY

## Products Affected

- RADIOGARDASE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Suspected or Known Internal Contamination with Radioactive Cesium or Suspected or Known Internal Contamination with Radioactive or Non-Radioactive Thallium. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SUSPECTED OR KNOWN INTERNAL CONTAMINATION WITH RADIOACTIVE CESIUM OR SUSPECTED OR KNOWN INTERNAL CONTAMINATION WITH RADIOACTIVE OR NON-RADIOACTIVE THALLIUM (1) Prescriber attests patient has diagnosis of Suspected or Known Internal Contamination with Radioactive Cesium or Suspected or Known Internal Contamination with Radioactive or Non-Radioactive Thallium (2) Patient is at least 2 years of age or older B. CONTINUATION OF THERAPY (1) Prescriber attests to clinical improvement in patients condition while on therapy as defined as: Radioactivity in urine and feces have been reduced but there is still a high level of contamination (2) Patient is adherent to therapy |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | None |

# RAGWITEK NON FORMULARY

## Products Affected

- RAGWITEK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Short Ragweed Pollen-Induced Allergic Rhinitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Currently receiving subcutaneous allergen immunotherapy |
| **Required Medical Information** | A. SHORT RAGWEED POLLEN-INDUCED ALLERGIC RHINITIS (1) Prescriber attests patient has diagnosis of Short Ragweed Pollen-Induced Allergic Rhinitis confirmed by either a positive skin test response to short ragweed pollen OR positive in vitro test for short ragweed pollen (blood test for allergen-specific IgE antibodies) (2) Patient is 18 years of age or older (3) Prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist (4) Therapy is initiated 12 weeks prior to the expected onset of the short ragweed pollen season (5) Patient is NOT currently receiving subcutaneous allergen immunotherapy |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | When approved, patients may obtain 30 sublingual tablets per 30 days |

# RANEXA

## Products Affected

- RANEXA
- *ranolazine er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Angina. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC ANGINA (1) Prescriber attests patient has diagnosis of Chronic Angina as determined by a cardiologist (2) Tried and failed, intolerance or contraindication to all of the following at maximum dosages (alone or in combination, medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) (i) calcium channel blocker (ii) beta-blocker (iii) nitrate (3) No contraindication to the requested medication (i.e., clinically significant hepatic impairment, concurrent use any of the following medications: carbamazepine, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, phenobarbital, phenytoin, rifabutin, rifampin, ritonavir, saquinavir, or St. Johns wort) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RAPAFLO

## Products Affected

- RAPAFLO
- *silodosin*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Benign Prostatic Hyperplasia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BENIGN PROSTATIC HYPERPLASIA (1) Prescriber attests patient has diagnosis of Benign Prostatic Hyperplasia (BPH) (2) Trial and failure of at least TWO of the following: (i) tamsulosin (ii) doxazosin (iii) alfuzosin (iv) terazosin |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RAPAMUNE

## Products Affected

- RAPAMUNE ORAL SOLUTION
- *sirolimus oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Solid Organ Transplant or Lymphangioleiomyomatosis (LAM). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SOLID ORGAN TRANSPLANT (1) Prescriber attests patient has undergone a solid organ transplant (2) Prescribed by, or in consultation with, a transplant specialist (3) Patient meets at least ONE of the following: (i) Has had a trial and failure on an anti-rejection regimen containing at least two (2) of the following: (a) cyclosporine (b) tacrolimus (c) azathioprine (d) mycophenolate mofetil/sodium (ii) Has renal dysfunction (iii) Patient has a coronary allograft vasculopathy following heart transplant B. LYMPHANGIOLEIOMYOMATOSIS (LAM) (1) Prescriber attests patient has diagnosis of Lymphangioleiomyomatosis (LAM) (2) Patient is 18 years of age or older (3) Prescribed by, or in consultation with, a transplant specialist (4) Diagnosis of LAM has been confirmed by lung biopsy or HRCT showing cystic lung disease (5) Patient has one of the following conditions: (i) Diagnosis of Tuberous Sclerosis Complex (TSC) (ii) Chylous Pleural Effusion (iii) Angioleiomyoma |
| **Age Restrictions** | LAM: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a transplant specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# REBETOL / RIBAPAK / RIBASPHERE (RIBAVIRIN)

## Products Affected

- *ribavirin oral capsule*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hepatitis C. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) When known contraindications to ribavirin therapy are documented (2) Decompensated Liver Disease |
| **Required Medical Information** | A. HEPATITIS C (1) Prescriber attests patient has diagnosis of Hepatitis C with detectable HCV RNA levels (2) Used as treatment of hepatitis C in combination with peg interferon alfa-2b, interferon alpha-2a or interferon alfa-2b. Should not be used as monotherapy for this indication (only approved when used in combination with other FDA approved products) (3) Patients have not been previously treated with interferon alpha (4) Liver biopsy, unless contraindicated, shows fibrosis and inflammatory necrosis (4) Lab requirements: (i) Bilirubin less than/=2 mg/dL (ii) Albumin Stable and within normal limits (iii) Prothrombin Time less than3 seconds prolonged (iv) WBC greater than/=3000/mm (v) Platelets greater than/=70,000/mm (vi) Serum creatinine should be normal or near normal (vii) HCV RNA (viii) HCV genotype (ix) Early Virological Response (EVR) (x) Liver Function Tests B. HEPATITIS C IN PEDIATRIC PATIENTS (1) Prescriber attests patient has diagnosis of Hepatitis C with compensated liver disease previously untreated with alpha interferon or relapsed following alpha interferon therapy (2) Must be used in combination with interferon alfa-2b for injection (3) Must be 5 years of age or older for capsule use or 3 years of age or older for solution use (4) Lab requirements: (i) Bilirubin less than/=2 mg/dL (ii) Albumin Stable and within normal limits (iii) Prothrombin Time less than3 seconds prolonged (iv) WBC greater than/=3000/mm (v) Platelets greater than/=70,000/mm (vi) Serum creatinine should be normal or near normal (vii) HCV RNA (viii) HCV genotype (ix) Early Virological Response (EVR) (x) Liver Function Tests |
| **Age Restrictions** | Capsule: 5 years of age or older, Solution: 3 years of age or older |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | Coverage of ribavirin is not recommended in the following circumstances: (1) Hypersensitivity to ribavirin or any components of the tablet (2) Women who are pregnant (3) Men whose female partners are pregnant (4) Patients with hemoglobinopathies (5) Patients with a history of significant or unstable cardiac disease (6) Creatinine clearance less than 50ml/min (7) Coverage is not recommended |

# REGRANEX

## Products Affected

- REGRANEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diabetic Neuropathic Ulcer. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. DIABETIC NEUROPATHIC ULCER (1) Prescriber attests patient has diagnosis of Diabetic Neuropathic Ulcer (2) Ulcer must be on lower extremity with adequate blood (3) Full-thickness ulcer (i.e., Stage III or IV), extending through dermis into subcutaneous tissues (4) Wound is free from infection (5) Prescriber confirms to provide wound follow-up care, including debridement if needed |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RELISTOR NON FORMULARY

## Products Affected

- RELISTOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Opioid-Induced Constipation (OIC) from Chronic Non-Cancer Pain or Opioid-Induced Constipation (OIC) from Advanced Illness. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. OIC FROM CHRONIC NON-CANCER PAIN (TABLETS) (1) Prescriber attests patient has diagnosis of Chronic Non-Cancer Pain, (back pain, fibromyalgia, joint/extremity pain, rheumatoid arthritis, neurologic/neuropathic pain) as well as Opioid-Induced Constipation (2) Patient has been taking an opioid analgesic for at least 4 weeks immediately prior to request (evidenced by pharmacy claims) (3) An inadequate response to at least one agent from within each of the following laxative types: (i) Fiber laxatives (psyllium, methylcellulose, calcium polycarbophil) (ii) Stimulant laxatives (bisacodyl, senna) (iii) Osmotic laxatives (Polyethylene glycol, milk of magnesia, sorbitol, lactulose) (4) An inadequate response, intolerance, or contraindication to two of the following: (i) Amitiza (lubiprostone) (ii) Symproic (naldemedine) (iii) Movantik (naloxegol) B. OIC FROM CHRONIC NON-CANCER PAIN (INJECTIONS) (1) Prescriber attests patient has diagnosis of Chronic Non-Cancer Pain as well as Opioid-Induced Constipation (2) Patient has been taking an opioid analgesic for at least 4 weeks immediately prior to request (evidenced by pharmacy claims) (3) An inadequate response to at least one agent from within each of the following laxative types: (i) Fiber laxatives) (ii) Stimulant laxatives (iii) Osmotic laxatives (4) An inadequate response, intolerance, or contraindication to two of the following: (i) Amitiza (ii) Symproic (iii) Movantik (5) An inadequate response, intolerance, or inability to take Relistor tablets C. OIC FROM ADVANCED ILLNESS (1) Prescriber attests patient has diagnosis of an advanced illness, such as incurable cancer or end-stage life threatening disease, requiring palliative therapy with opioids (diagnosis and specific opioid therapy must be documented) as well as Opioid-Induced Constipation (2) An inadequate response to at least one agent from within each of the following laxative types: (i) Fiber laxatives (ii) Stimulant laxatives (iii) Osmotic laxatives |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RENVELA/ RENAGEL (SEVELAMER CARBONATE)

## Products Affected

- RENAGEL
- RENVELA
- *sevelamer carbonate*
- *sevelamer hcl oral tablet 800 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hyperphosphatemia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPERPHOSPHATEMIA (1) Prescriber attests patient has diagnosis of Hyperphosphatemia associated with chronic kidney disease, dialysis, end stage renal disease (ESRD), or renal failure (2) Prescribed by a nephrologist (3) Patient is on a phosphate-restricted diet (4) One of the following: (i) Tried and failed (phosphorus level greater than4.5mg/dl or calcium levels above 9.6 as documented by lab test for 2 to 3 consecutive months) or intolerance to calcium-based phosphate binding agents (i.e. calcium carbonate or calcium acetate) (supported by documentation from the patients chart notes/medical records/electronic claims history) (ii) Serum levels of calcium x phosphate product greater than or equal to 55 mg2/dL2 (documented by lab test) (iii) Patient has a history of severe vascular and/or soft-tissue calcifications (5) Clinical inability to swallow a tablet (Renvela suspension only) (supported by documentation from the patients chart notes/medical records and prescription claim history illustrating an absence of any oral tablet/capsule therapy) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a nephrologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# REPATHA NON FORMULARY

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Heterozygous Familial Hypercholesterolemia (HeFH), Homozygous Familial Hypercholesterolemia (HoFH), or Clinical Atherosclerotic Cardiovascular Disease (CVD). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) (1) Prescriber attests patient has diagnosis of (HeFH) confirmed by genotyping or the following Simon Broome criteria: (i) Total cholesterol greater than 290mg/dL or LDL cholesterol greater than 190mg/dL (ii) One of the following: (a) Tendon xanthomas in patient, or in 1st degree relative (parent, sibling, child), or in 2nd degree relative (grandparent, uncle, aunt) (b) DNA-based evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation B. HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH) (1) Prescriber attests patient has diagnosis of (HoFH) confirmed by genotyping or a clinical diagnosis based on the following: (i) Documented history of untreated LDL-C greater than 500 mg/dL AND xanthoma before 10 years of age (ii) Documented evidence of HeFH in both parents C. CVD See Other Criteria D. CONTINUATION OF THERAPY See Other Criteria |
| **Age Restrictions** | CVD: 18 years of age or older, HeFH: 18 years of age or older, HoFH: 13 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or lipid specialist |
| **Coverage Duration** | Initial: 4 weeks, Renewal: 12 months |
| **Other Criteria** | C. CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (CVD) (1) Prescriber attests patient has diagnosis of CVD as defined by one of the following: (i) acute coronary syndrome (ii) history of myocardial infarction (iii) stable/unstable angina (iv) coronary or other arterial revascularization (v) stroke (vi) transient ischemic stroke (vii) |

| PA Criteria | Criteria Details |
|---|---|
| | peripheral arterial disease presumed to be atherosclerotic (2) Appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment, supported by documentation of counseling in chart notes and: (i) Total dietary fat less than 35% of total calories (ii) Weight loss in overweight patients (iii) Aerobic exercise (iv) Diet rich in fruits and vegetables (3) Baseline and current LDL-C provided (4) Require additional LDL-C reduction after a 12-week trial of both of the following: (i) a high-intensity statin (atorvastatin 40-80mg, rosuvastatin 20-40mg) (ii) in combination with ezetimibe (5) Patient has been adherent to lipid-lowering therapy (proportion of days covered (PDC) greater than or equal to80%) (6) LDL-C greater than or equal to100 mg/dL (7) One of the following: (i) Used in combination with maximally tolerated high-intensity statin (ii) Patient is statin intolerant, as demonstrated by experiencing: (a) Documented statin-associated rhabdomyolysis to one statin (b) Documented skeletal-muscle related symptoms with either rosuvastatin or atorvastatin D. CONTINUATION OF THERAPY (1) Documented response to Repatha, defined as ONE of the following: (I) Percentage reduction of LDL is ?40% compared to baseline level (II) Absolute LDL is less than 70 mg/Dl (2) The patient is tolerating the medication (3) Will continue to be used in combination with a maximally tolerated statin or is statin intolerant demonstrated by: (i) Documented statin-associated rhabdomyolysis to one statin (ii) Documented skeletal-muscle related symptoms with either rosuvastatin or atorvastatin (4) Patient has remained adherent to therapy, defined as proportion of days covered (PDC) greater than or equal to80% |

# REVATIO (SILDENAFIL CITRATE)

## Products Affected

- *sildenafil citrate oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Hypertension WHO Group 1. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Patient receiving organic nitrates in any form, either regularly or intermittently due to potentiation of the hypotensive effects of nitrates (2) Hypersensitivity reaction or contraindication to Revatio |
| **Required Medical Information** | A. PULMONARY HYPERTENSION WHO GROUP 1 (1) Prescriber attests patient has diagnosis of Pulmonary Hypertension WHO group I (defined by pulmonary artery pressure greater than 25mm Hg at rest or greater than 30mm Hg with exertion) (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records (3) Patient is 18 years of age or older (4) Prescribed by a cardiologist or pulmonologist (5) Patients with NYHA class II-IV (6) Not on current nitrate therapy AND must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test (7) Patient has been evaluated for retinitis pigmentosa and completed counseling on the risk of ocular disturbances, non-arteritic anterior ischemic optic neuropathy (NAION), and potential for blindness |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by a cardiologist or pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# REVLIMID

## Products Affected

- REVLIMID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Multiple Myeloma, Follicular Lymphoma, Marginal Zone Lymphoma, Mantle Cell Lymphoma, Myelodysplastic Syndrome, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MULTIPLE MYELOMA (1) Prescriber attests patient has diagnosis of Multiple myeloma (2) Prescribed by an oncologist or hematologist (3) Failed or intolerant to at least one prior treatment (4) Must be receiving concurrent treatment with dexamethasone (5) Absolute neutrophil count (ANC) of at least 500/mL (6) Platelet count of at least 50,000/mL (7) Serum creatinine less than 2.5 mg/Dl B. FOLLICULAR LYMPHOMA AND MARGINAL ZONE LYMPHOMA (1) Prescriber attests patient has diagnosis of Follicular Lymphoma or Marginal Zone Lymphoma (2) Previously treated (3) Used in combination with a rituximab product C. MANTLE CELL LYMPHOMA (1) Prescriber attests patient has diagnosis of Mantle Cell Lymphoma (2) Relapse or progression after two prior therapies, one of which includes bortezomib D. MYELODYSPLASTIC SYNDROME (1) Prescriber attests patient has diagnosis of Myelodysplastic Syndrome (2) Has transfusion-dependent anemia (3) Is at low or intermediate-1 risk with deletion 5q abnormality |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | See Required Medical Info |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# REXULTI

## Products Affected

- REXULTI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Schizophrenia or Major Depressive Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SCHIZOPHRENIA (1) Prescriber attests patient has diagnosis of Schizophrenia (2) Patient is 18 years of age or older (3) Tried and failed, intolerant to or contraindicated to at least three formulary alternative antipsychotics including, but not limited to, risperidone, olanzapine, aripiprazole, ziprasidone, and quetiapine B. MAJOR DEPRESSIVE DISORDER (1) Prescriber attests patient has diagnosis of Major Depressive Disorder (2) Patient is 18 years of age or older (3) Tried and failed, intolerant to or contraindicated to at least two formulary alternative antidepressants including, but not limited to fluoxetine, paroxetine, sertraline, citalopram, venlafaxine, bupropion, escitalopram, desvenlafaxine (4) Trial and failure, intolerant to or contraindicated to at least three formulary alternative antipsychotics including, but not limited to olanzapine, aripiprazole, quetiapine ER (5) Must be used as adjunctive or add-on treatment to ADT and not as monotherapy |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RIDAURA

## Products Affected

- RIDAURA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid Arthritis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RHEUMATOID ARTHRITIS (1) Prescriber attests patient has diagnosis of Rheumatoid Arthritis (2) Patient 18 years of age or older (3) Prescribed by, or in consultation with, a Rheumatologist (4) Patient has had a clinical trial and failure, intolerance, or contraindication to at least three of the following disease modifying anti-rheumatic drugs (DMARDs): (i) hydroxychloroquine (Plaquenil) (ii) leflunomide (Arava) (iii) methotrexate (iv) sulfasalazine |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a Rheumatologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RIFABUTIN

## Products Affected

- MYCOBUTIN
- *rifabutin*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mycobacterium Avium Complex Infection (MAC), Mycobacterium Avium Complex Prophylaxis in HIV-Infected Patients with Advanced Disease, Tuberculosis Infection, Tuberculosis Prophylaxis in HIV-Infected Patients. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MYCOBACTERIUM AVIUM COMPLEX INFECTION (MAC) (1) Prescriber attests patient has diagnosis of Mycobacterium Avium Complex infection (2) One of the following: (i) Disseminated MAC (ii) MAC pulmonary disease in patient with a trial and failure, intolerance, or contraindication to rifampin (iii) MAC in HIV-infected patients B. MYCOBACTERIUM AVIUM COMPLEX PROPHYLAXIS IN HIV-INFECTED PATIENTS WITH ADVANCED DISEASE (1) Prescriber attests patient has diagnosis of MAC prophylaxis in HIV-infected patients with advanced disease (2) One of the following: (i) For primary prophylaxis patient has had a clinical trial and failure, intolerance, or contraindication to both Clarithromycin and Azithromycin (ii) Used for secondary prophylaxis in HIV-infected patient with disseminated disease after treatment of acute illness C. TUBERCULOSIS INFECTION (1) Prescriber attests patient has diagnosis of Tuberculosis Infection (2) Patient has a contraindication to use of rifampin due to concomitant protease inhibitor or non-nucleoside reverse transcriptase inhibitors or patient has experienced an intolerance to rifampin D. TUBERCULOSIS PROPHYLAXIS IN HIV-INFECTED PATIENTS (1) Prescriber attests patient has diagnosis of Tuberculosis prophylaxis in an HIV-infected patient (2) Patient is contraindicated to receive rifampin due to concomitant therapy with protease inhibitors or non-nucleoside reverse transcriptase inhibitors |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# RINVOQ NON FORMULARY

## Products Affected

- RINVOQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid arthritis. Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | Concurrent biologic DMARD, concurrent use with other potent immunosuppressants (i.e. azathioprine, cyclosporine, etc.), plaque psoriasis. |
| **Required Medical Information** | A. RHEUMATOID ARTHRITIS (RA): INITIAL: (1) Prescriber attests that patient has a moderately to severely active RA AND (2) Prescriber attests that patient has had an inadequate response to methotrexate or a contraindication to methotrexate AND (3) Prior to therapy initiation, tuberculin skin test results or chest x-ray within the previous six months are required to evaluate for latent tuberculosis infection (note, If there is evidence of latent tuberculosis infection, treatment should be initiated prior to therapy with RINVOQ) AND (4) Laboratory documentation of ALL of the following is provided, along with date performed within the last 3 months, Absolute neutrophil count (ANC) at least 1000 cell/mm3, lymphocyte count at least 500 cells/mm3, hemoglobin level at least 9 g/dL. AND (5) Prescriber attests to considering and discussing the risks and benefits prior to treating a patient who may be at increased risk of thrombosis RENEWAL: (1) Prescriber attests to documentation of response to therapy using quantitative measures (e.g., RA: reduction in ESR, CRP, and reduction in duration of morning stiffness and/or number of swollen/painful joints, or fatigue etc.) AND (2) Prescriber attests to documentation of ALL of the following, along with date performed, absolute neutrophil count (ANC) at least 1000 cell/mm3, lymphocyte count at least 500 cells/mm, hemoglobin level at least 9 g/dL. AND (3) Prescriber attests that patient has been evaluated and educated on thrombosis risk. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | None |

# RITUXAN NON FORMULARY

## Products Affected

- RITUXAN
- RITUXAN HYCELA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA approved indications, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RITUXAN (RITUXIMAB): INITIAL: a.CD20 (+) CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): (1) Prescriber attests to diagnosis of CD20 (+) CLL. AND (2) Trial and failure of Truxima AND Ruxience b. CD20 (+) NON-HODGKINS LYMPHOMA (Diffuse large B-cell, Follicular, etc): (1) Prescriber attests to diagnosis of CD20 (+) non-hodgkins lymphoma AND (2) Trial and failure of Truxima AND Ruxience c. RHEUMATOID ARTHRITIS (RA): (1) Prescriber attests to diagnosis of moderate to severe RA (RITUXAN ONLY) AND (2) Patient must be taking concurrent methotrexate unless contraindicated or patient has a documented intolerance AND (3) Patient must have had an adequate trial (greater than 3 months of continuous therapy) and failed or intolerant to each of the following, Enbrel (etanercept), Humira (adalimumab) and Xeljanz (tofacitinib) AND (4) Trial and failure of Truxima d. GRANULOMATOSIS WITH POLYANGIITIS (GPA): (1) Prescriber attests to diagnosis of GPA (Wegener's Granulomatosis) AND (2) Patient must use in combination with glucocorticoids AND (3) Patient must have tried, failed or have a contraindication to the use of methotrexate or cyclophosphamide AND (4) Trial and failure of Truxima AND Ruxience e. MICROSCOPIC POLYANGIITIS (MPA): (1)Prescriber attests to a diagnosis of MPA AND (2) Patient must use in combination with glucocorticoids AND (3) Patient must have tried failed or have a contraindication to the use of methotrexate or cyclophosphamide AND (3) Trial and failure of Truxima AND Ruxience f. PEMPHIGUS VULGARIS: (1) Prescriber attests to a diagnosis of pemphigus vulgaris AND (2) Prescriber attests to use in combination with glucocorticoids. B. RITUXAN HYCELA- (NOTE, non-malignant conditions are not covered by the subcutaneous product) (1) For all indications the first dose must be given by IV infusion AND (2) Prescriber attests to documentation of patient and/or caregiver self-administration training AND (SEE OTHER CRITERIA) |
| **Age Restrictions** | 18 years of age or older, GPA (RITUXAN ONLY): 2 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a specialist in the specific disease state of treatment. |
| **Coverage Duration** | Oncology/unspecified: Initial/Renew: 12 month, RA: Initial/Renew: 90 day, PV Initial: Renew: 6 month |
| **Other Criteria** | (3a) Diagnosis of CD20(+) follicular lymphoma (a form of Non-hodgkins lymphoma) and any of the following, relapsed or refractory, previously untreated in combination with chemotherapy or non-progressing after first line CVP chemotherapy OR (3b) Diagnosis of CD20(+) diffuse large B-cell lymphoma (a form of Non-hodgkins lymphoma) AND patient is concurrently on CHOP chemotherapy or other anthracycline-based chemotherapy OR (4a) Diagnosis of CD20(+) chronic lymphocytic leukemia used in combination with fludarabine and cyclophosphamide RENEWAL FOR INDICATIONS NOT SPECIFIED: (1) Prescriber attests patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patient's condition AND (2) Prescriber attests that the patient has disease stabilization or improvement as defined by standard monitoring for the patients condition RENEWAL FOR RA and PV: (1) Prescriber attests patient has been evaluated within the last 6 months, unless an evaluation is not clinically appropriate for patient's condition AND (2) Prescriber attests that the patient has disease stabilization or improvement as defined by standard monitoring for the patients condition AND (3) At least 16 weeks has passed since the subsequent administration or Rituxan. |

# SABRIL

## Products Affected

- *vigabatrin oral packet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Refractory Complex Partial Seizures or Infantile Spasms. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. REFRACTORY COMPLEX PARTIAL SEIZURES (1) Prescriber attests patient has diagnosis of Refractory Complex Partial Seizures (2) Prescribed by a neurologist (3) 2 years of age or older (4) Tried/failed/intolerant to two formulary anticonvulsants (5) Prescriber confirmation that potential benefit outweighs the potential risk of vision loss (6) Vision tested at baseline before beginning treatment and will be tested every 3 months thereafter B. INFANTILE SPASMS (1) Prescriber attests patient has diagnosis of Infantile Spasms (2) Patient is greater than or equal to 1 month old and less than or equal to 2 years old (3) Prescriber confirmation that potential benefit outweighs the potential risk of vision loss (4) Vision tested, when possible, at baseline before beginning treatment and will be tested every 3 months thereafter C. CONTINUATION OF THERAPY (1) Clinical benefit has been demonstrated (2) Confirmation of vision test within the last 3 months |
| **Age Restrictions** | Refractory Complex Partial Seizures: 2 years of age or older, Infantile spasms greater than/= 1 month to less than/= 2 years of age |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SAMSCA NON FORMULARY

## Products Affected

- SAMSCA ORAL TABLET 15 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypervolemic/Euvolemic Hyponatremia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Need to raise serum sodium acutely (2) Patients who are unable to respond appropriately to thirst (3) Hypovolemic hyponatremia (4) Concomitant use of strong cytochrome P450 3A inhibitors (5) Anuric (6) Hypersensitivity |
| **Required Medical Information** | A. HYPERVOLEMIC/EUVOLEMIC HYPONATREMIA (1) Prescriber attests patient has diagnosis of clinically significant hypervolemic or euvolemic hyponatremia (serum sodium less than 125 mEq/L) or Serum sodium less than 130 mEq/L with symptoms (must be specified) that have not responded to fluid restriction and a treatment failure, allergy, or intolerance to a trial of demeclocycline (not required if the member is allergic to tetracyclines) (2) Samsca therapy has been initiated or reinitiated in the hospital no less than 2 days before the prior authorization request for continued outpatient therapy (hospital record must be provided) (3) No contraindications to therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 1 month |
| **Other Criteria** | Please note: Approval for coverage of Samsca will be limited to 1 month per treatment episode. |

# SANDIMMUNE SOLUTION

## Products Affected

- SANDIMMUNE ORAL SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Prophylaxis of Organ Rejection in Heart Transplant, Prophylaxis of Organ Rejection in Liver Transplant, Prophylaxis of Organ Rejection in Kidney Transplant, or Treatment of Graft Versus Host Disease. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PROPHYLAXIS OF ORGAN REJECTION IN HEART TRANSPLANT, PROPHYLAXIS OF ORGAN REJECTION IN LIVER TRANSPLANT, PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY TRANSPLANT, AND TREATMENT OF GRAFT VERSUS HOST DISEASE (1) Prescriber attests patient has diagnosis of Prophylaxis of Organ Rejection in Heart Transplant, Prophylaxis of Organ Rejection in Liver Transplant, Prophylaxis of Organ Rejection in Kidney Transplant, or Treatment of Graft Versus Host Disease (2) Clinical trial and failure, intolerance, or contraindication to both of the following: (i) Cyclosporine capsule (generic Sandimmune capsule) (ii) Gengraf Solution 100mg/mL |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SANDOSTATIN (OCTREOTIDE)

## Products Affected

- *octreotide acetate*
- SANDOSTATIN
- SANDOSTATIN LAR DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Carcinoid Tumors/Neuroendocrine Tumors, Diarrhea Associated with Vasoactive Intestinal Peptide Tumors, Acromegaly, Meningiomas (CNS Cancers), Thymic Carcinomas/Thymomas, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CARCINOID TUMORS/NEUROENDOCRINE TUMORS (1) Prescriber attests patient has diagnosis of carcinoid tumors/Neuroendocrine tumors (e.g. GI tract, Lung, Thymus, Pancreas, Adrenal) (2) One of the following: (i) Patient has severe diarrhea/flushing episode (carcinoid syndrome) (ii) Used to treat symptoms related to hormone hypersecretion in pancreatic tumors (iii) Primary treatment of unresected primary gastrinoma (iv) Used for the management of locoregionally advanced or metastatic disease of the bronchopulmonary, thymic, or GI tract (v) Used for the tumor control of unresectable and/or metastatic tumors of the pancreas B. DIARRHEA ASSOCIATED WITH VASOACTIVE INTESTINAL PEPTIDE TUMORS (1) Prescriber attests patient has diagnosis of Diarrhea associated with Vasoactive intestinal peptide tumors (VIPomas) (2) Patient has profuse watery diarrhea C. ACROMEGALY (1) Prescriber attests patient has diagnosis of Acromegaly (2) Baseline growth hormone (GH) and IGF-1 blood levels (renewal will require reporting of current levels) (3) One of the following: (i) Patient has documented inadequate response to surgery and/or radiotherapy (ii) Surgery and/or radiotherapy is not an option for this patient D. MENINGIOMAS (CNS CANCERS) (1) Prescriber attests patient has diagnosis of Meningiomas (CNS Cancers) (2) Patients disease is unresectable (3) Patients disease is recurrent or progressive meningioma (4) Radiation treatment is not possible for the patients disease E. THYMIC CARCINOMAS/THYMOMAS (1) Prescriber attests patient has diagnosis of Thymic Carcinomas/Thymomas (2) Must be used as second-line therapy with or without prednisone F. CONTINUATION OF THERAPY See Other Criteria |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | F. CONTINUATION OF THERAPY (1) Patient continues to meet criteria identified in initial (2) Absence of unacceptable toxicity from the drug (3) Prescriber attests to clinical improvement (4) ACROMEGALY ONLY: Disease response indicated by reduction of growth hormone (GH) and/or IGF-I blood levels from baseline (5) Neuroendocrine tumors of the pancreas (ONLY): Patient has had disease progression and therapy will be continued in patients with functional tumors in combination with systemic therapy. G. FOR SANDOSTATIN LAR: Patient must have responded to and tolerated octreotide injection |

# SAPHRIS

## Products Affected

- SAPHRIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Bipolar Disorder, Schizophrenia, Other Psychotic Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | BIPOLAR DISORDER, SCHIZOPHRENIA, AND OTHER PSYCHOTIC DISORDERS (1) Prescriber attests patient has diagnosis of bipolar disorder, schizophrenia, or other psychotic disorder (2) Patient is 10 years of age or older (3) Patient has clinical swallowing difficulties or one of the following: (i) Trial and failure, intolerance or contraindication of the formulary alternative risperidone (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) (ii) Trial and failure, intolerance or contraindication of quetiapine (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) (iii) Trial and failure, intolerance or contraindication of olanzapine (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) (iv) Trial and failure, intolerance or contraindication of ziprasidone (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) (4) Tried and failed, intolerance or contraindication to risperidone ODT (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history). (5) Not approvable if electronic claim history demonstrates swallowable orals used. |
| **Age Restrictions** | 10 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SAVELLA

## Products Affected

- SAVELLA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Fibromyalgia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. FIBROMYALGIA (1) Prescriber attests patient has diagnosis of Fibromyalgia (2) One of the following: (i) The diagnosis has been confirmed by a rheumatologist, physiatrist, neurologist, or pain management specialist (ii) The prescriber has conducted an evaluation confirming all of the following: (a) Physical exam indicating presence of 11 of 18 tender points (b) Widespread Pain Index (WPI) greater than or equal to7 and Symptom Severity (SS) scale score greater than or equal to5 (c) WPI is between 3 and 6 and SS scale score greater than or equal to9 (3) Symptoms have been present for at least 3 months (4) Other conditions mistaken for fibromyalgia have been ruled out (e.g. rheumatoid arthritis, peripheral neuropathies, infection ) (5) An inadequate response, intolerance or contraindication to a trial of a tricyclic antidepressant (i.e. amitriptyline) and duloxetine |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | See Required Medical Info |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SENSIPAR

## Products Affected

- *cinacalcet hcl*
- SENSIPAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Secondary Hyperparathyroidism, Hypercalcemia due to Parathyroid Carcinoma, Severe Hypercalcemia with Primary Hyperparathyroidism. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SECONDARY HYPERPARATHYROIDISM (1) Prescriber attests patient has diagnosis of secondary hyperparathyroidism due to chronic kidney disease (supported by documentation from the patients chart notes/medical records) on dialysis (2) iPTH levels must be greater than300pg/mL (biPTH greater than 160), Ca greater than or equal to 8.4 mg/dL, phosphate between 3.5-5.5 and serum levels of calcium x phosphate product greater than or equal to 55 mg2/DL2 in order to initiate therapy (3) Tried and failed, intolerant or contraindication to calcium acetate or a Non-calcium phosphate binder (i.e., Renagel, etc.) (medication usage must be supported by documentation from the patients chart notes/medical records) (4) Tried and failed, intolerant or contraindication to Vitamin D/Vitamin D analog (i.e., calcitriol, Hectorol, etc.) (medication usage must be supported by documentation from the patients chart notes/medical records B. HYPERCALCEMIA DUE TO PARATHYROID CARCINOMA (1) Prescriber attests patient has diagnosis of hypercalcemia due to parathyroid carcinoma (2) iPTH levels must be greater than300pg/mL (biPTH greater than 160) and Ca greater than or equal to8.4 mg/dL, phosphate between 3.5-5.5 and serum levels of calcium x phosphate product greater than or equal to 55 mg2/dL2 in order to initiate therapy C. SEVERE HYPERCALCEMIA WITH PRIMARY HYPERPARATHYROIDISM (1) Prescriber attests patient has diagnosis of severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy (2) iPTH levels must be greater than300 pg/mL (biPTH greater than 160) and Ca greater than or equal to 8.4 mg/dL, phosphate between 3.5-5.5 and serum levels of calcium x phosphate product greater than or equal to 55 mg2/dL2 in order to initiate therapy D. CONTINUATION OF THERAPY (1) iPTH levels must be greater than 150 pg/ml and calcium must be greater than or equal to8.4 mg/dL |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 3 months, First Renewal: 6 months, Additional Renewals: 12 months |
| **Other Criteria** | None |

# SEROMYCIN NON FORMULARY

## Products Affected

- *cycloserine oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Active Pulmonary/Extrapulmonary Tuberculosis or Urinary Tract Infection. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACTIVE PULMONARY/EXTRAPULMONARY TUBERCULOSIS (1) Prescriber attests patient has diagnosis of Active Pulmonary and Extrapulmonary tuberculosis (including renal disease) (2) Trial and failure, intolerance, or contraindication to primary treatment option streptomycin, isoniazid, rifampin, ethambutol B. URINARY TRACT INFECTION (1) Prescriber attests patient has diagnosis of urinary tract infection (2) Prescriber attests that infection caused by a causative organism (E. coli, Enterobacter sp.) (3) Patient has had a trial and failure, contraindication, intolerance, or resistance to at least two other antimicrobial agents indicated for treatment (i.e. ciprofloxacin, SMX/TMP, Nitrofurantoin) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SIGNIFOR

## Products Affected

- SIGNIFOR
- SIGNIFOR LAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cushings Disease or Acromegaly. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Severe Hepatic Impairment (i.e. Child-Pugh C) |
| **Required Medical Information** | A. CUSHINGS DISEASE (SIGNIFOR OR SIGNIFOR LAR) (1) Prescriber attests patient has diagnosis of Cushings disease and ONE of the following: (i) Patient has had a recurrence or persistence after pituitary surgical resection (ii) Patient is not a candidate for pituitary surgical resection (2) Patient is at least 18 years of age B. ACROMEGALY (SIGNIFOR LAR) (1) Prescriber attests patient has diagnosis of Acromegaly and ONE of the following: (i) Utilizing the requested agent as an adjunctive therapy with irradiation to alleviate acromegaly symptoms (ii) Patient has had an inadequate response to surgery or pituitary irradiation defined as one of the following: (a) Growth hormone level greater than 5 ng/mL (b) IGF-1 level greater than1.9 U/mL for males or greater than2.2 U/mL for females (iii)The patient is not a candidate for both surgical resection and pituitary irradiation (2) Patient is at least 18 years of age C. CONTINUATION OF THERAPY CUSHINGS DISEASE (1) The patient has had a 15% or greater decrease in urinary free cortisol levels (2) The patient has shown improvement in at least ONE of the following clinical signs and symptoms: (i) Fasting plasma glucose (ii) Hemoglobin A1c (iii) Hypertension (iv) Weight D. CONTINUATION OF THERAPY ACROMEGALY (1) Growth hormone level less than 5 ng/mL (2) IGF-1 level less than1.9 U/mL for males or less than2.2 U/mL for females (3) Clinical improvement (e.g. reduction in tumor size, decreased headaches, improved cardiovascular or respiratory symptoms) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Cushings: Initial: 3 months, Renewal 12 months, All Other: 12 months |
| **Other Criteria** | None |

# SILIQ NON FORMULARY

## Products Affected

- SILIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (Ps), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Crohns disease. Concurrent use with a biologic DMARD |
| **Required Medical Information** | A. FOR PLAQUE PSORIASIS: INITIAL: (1) Prescriber attests to a documented diagnosis of plaque psoriasis AND (2a) Prescriber attests that plaque psoriasis must involve greater than or equal to 5% of the body surface area (BSA) OR (2b) Patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (2c) Three of the following, Patient has had an inadequate response to 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA]) for psoriasis OR Patient has had an inadequate response to a 3-month trial of systemic therapy (i.e. MTX, cyclosporine, acitretin [Soriatane]) OR Patient has significant disability or impairment in physical or mental functioning, according to the treating physician. AND (3) Prescriber attests that patient must have a negative tuberculosis test or receive treatment if tested positive. AND (4) Prescriber and patient must be enrolled in the Siliq REMS program. AND (5) STEP ALERT: TRIAL AND FAILURE OF ENBREL AND HUMIRA<br>B. RENEWAL: (1) Prescriber attests that patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patient's condition AND (2) Prescriber attests that patient has disease stabilization or improvement as defined by standard monitoring for the patients condition |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | PS: prescribed by or in consultation with dermatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | Quantity Limit 3 mL per 28 days |

# SIMPONI

## Products Affected

- SIMPONI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Moderate to Severe Active Ulcerate Colitis (UC) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RA (1) Prescriber attests patient has diagnosis of RA (2) Patient tried one DMARD for at least 2 months (3) Patient to receive MTX in combination with Simponi (unless contraindicated) (4) One of the following: (i) Patient tried/failed/contraindicated to BOTH Humira and Enbrel (ii) Patient started on Simponi (5) Patient does not have any of the following: Simponi given in combination with a TNFa antagonist, anakinra, rituximab, abatacept, or tocilizumab, Plaque psoriasis without psoriatic arthritis, Asthma, or Ulcerative colitis B. PSA (1) Prescriber attests patient has diagnosis of PsA (2) Patient to receive Simponi alone or in combination with MTX or other non-biologic DMARD (3) One of the following: (i) Patient has tried/failed/contraindicated to BOTH Humira and Enbrel (ii) Patient started on Simponi (4) Patient does not have any of the following: Simponi given in combination with a TNFa antagonist, anakinra, rituximab, abatacept, or tocilizumab, Plaque psoriasis without psoriatic arthritis, Asthma, or Ulcerative colitis C. AS (1) Prescriber attests patient has diagnosis of AS (2) Patient to receive Simponi alone or in combination with MTX or other non-biologic DMARD (3) One of the following: (i) Patient has tried/failed/contraindicated to BOTH Humira and Enbrel (ii) Patient started on Simponi (4) Patient does not have any of the following: Simponi given in combination with a TNFa antagonist, anakinra, rituximab, abatacept, or tocilizumab, Plaque psoriasis without psoriatic arthritis, Asthma, or Ulcerative colitis D. UC (1) Prescriber attests patient has diagnosis of Moderate to Severe Active Ulcerative Colitis (2) Inadequate response, intolerance or contraindication to at least one conventional therapy indicated for the diagnosis, including but not limited to, azathioprine, corticosteroids, cyclosporine, sulfasalazine, mesalamine E. ALL DIAGNOSES (1) Prescriber attests patient must have a negative tuberculosis test or receive treatment if tested positive |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Humira and Enbrel are the preferred drugs. Member must have tried/failed Humira AND Enbrel first unless contraindicated. |

# SIVEXTRO

## Products Affected

- SIVEXTRO ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute Bacterial Skin/Skin Structure Infection (ABSSI) or Methicillin Resistant Staphylococcus Aureus Infection. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACUTE BACTERIAL SKIN/SKIN STRUCTURE INFECTION (ABSSI) OR METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS INFECTION (1) Prescriber attests patient has diagnosis of Acute Bacterial Skin/Skin Structure Infection (ABSSI) caused by a susceptible bacteria or Methicillin Resistant Staphylococcus Aureus Infection (2) One of the following: (i) Prescriber attests that patient has had a clinical trial and failure to other antibiotics to which the organism is susceptible (ii) Patient is being released from a facility where they were receiving Sivextro (3) The medication is prescribed by, or in consultation with, an infectious disease specialist (4) The medication is being used for a 6 day treatment course |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an infectious disease specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SKELAXIN

## Products Affected

- *metaxalone oral tablet 800 mg*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute Painful Musculoskeletal Conditions. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACUTE PAINFUL MUSCULOSKELETAL CONDITIONS (1) Prescriber attests patient has diagnosis of Acute Painful Musculoskeletal Conditions (2) History of failure, contraindication, or intolerance to three of the following: (i) cyclobenzaprine (ii) orphenadrine (iii) chlorzoxazone (iv) methocarbamol |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SKLICE

## Products Affected

- SKLICE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pediculosis Capitis, Pediculosis Corporis, Pediculosis Pubis, Non-Adult Stage Onchocerca Volvulus, Intestinal Strongyloidiasis, or Rosacea with inflammatory lesions. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PEDICULOSIS CAPITIS, PEDICULOSIS CORPORIS, AND PEDICULOSIS PUBIS (1) Prescriber attests patient has diagnosis of Pediculosis Capitis, Pediculosis Corporis, or Pediculosis Pubis (2) Patient is greater than 6 months old (3) Patient has had an inadequate response or adverse reaction to malathion within the past 30 days B. NON-ADULT STAGE ONCHOCERCA VOLVULUS (1) Prescriber attests patient has diagnosis of Non-Adult Stage Onchocerca Volvulus C. INTESTINAL STRONGYLOIDIASIS (1) Prescriber attests patient has diagnosis of Intestinal Strongyloidiasis (2) Patient is 15 kg or more in body weight D. ROSACEA WITH INFLAMMATORY LESIONS (1) Prescriber attests patient has diagnosis of Rosacea with Inflammatory Lesions (2) Patient is 18 years of age or older |
| **Age Restrictions** | Rosacea: 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SKYRIZI NON FORMULARY

## Products Affected

- SKYRIZI (150 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate-to-severe plaque psoriasis in adults, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Skyrizi will not be used concomitantly with apremilast, tofacitinib, or other biologic DMARDs |
| **Required Medical Information** | A. FOR PLAQUE PSORIASIS: INITIAL: (1) Prescriber attests that patient has a documented diagnosis of plaque psoriasis AND (2a) Prescriber attests that patient has plaque psoriasis involving greater than or equal to 5% of the body surface area (BSA) OR (2b) Prescriber attests that patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (2c) Prescriber attests to three of the following, a. Patient has had an inadequate response to 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA]) for psoriasis OR b. Patient has had an inadequate response to a 3-month trial of systemic therapy (i.e. MTX, cyclosporine, acitretin [Soriatane]) OR c. Patient has significant disability or impairment in physical or mental functioning, according to the treating physician AND (3) STEP ALERT: PATIENT HAS TRIED AND FAILED BOTH ENBREL AND HUMIRA AND (4) Prescriber attests that patient has been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB. RENEWAL: (1) Prescriber attests that patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patient's condition AND (2) Prescriber attests that the patient has disease stabilization or improvement as defined by standard monitoring for the patients condition |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | 150mg (two 75mg injections) week 0, 4, and every 12 weeks thereafter |

# SOMATULINE

## Products Affected

- SOMATULINE DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly, Unresectable/Well- or Moderately Differentiated/Locally Advanced/Metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs), or Carcinoid Syndrome. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACROMEGALY (1) Prescriber attests patient has diagnosis of Acromegaly (2) Patient is at least 18 years of age or older (3) Has had an inadequate response to surgery or radiation therapy, or documentation that these therapies are not appropriate must be provided (4) Prescriber must provide the following baseline documentation from patients medical record: (i) Elevated serum IGF-1 level for patients age range and gender (ii) Elevated growth hormone level defined by a GH level greater than or equal to 1 ng/mL during oral glucose tolerance test (OGTT) B. UNRESECTABLE/WELL- OR MODERATELY DIFFERENTIATED/LOCALLY ADVANCED/METASTATIC GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS (GEP-NETS) (1) Prescriber attests patient has diagnosis of unresectable, well-or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (2) Patient is at least 18 years of age or older C. CARCINOID SYNDROME (1) Prescriber attests patient has diagnosis of Carcinoid Syndrome (2) Patient is at least 18 years of age or older |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SOMAVERT

## Products Affected

- SOMAVERT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACROMEGALY (1) Prescriber attests patient has diagnosis of Acromegaly (2) Patient is at least 18 years of age or older (3) Has had an inadequate response to surgery or radiation therapy, or documentation that these therapies are not appropriate must be provided (4) Prescriber must provide the following baseline documentation from patients medical record: (i) Elevated serum IGF-1 level for patients age range and gender (ii) Elevated growth hormone level defined by a GH level greater than or equal to 1 ng/mL during oral glucose tolerance test (OGTT) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SPORANOX (ITRACONAZOLE)

## Products Affected

- *itraconazole oral capsule*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Invasive Systemic Fungal Infection, Onychomycosis of the Finger Nails, Onychomycosis of the Toe Nails, Dermal Fungal Infections. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Congestive heart failure (2) Concomitant administration of itraconazole with drugs metabolized by CYP3A4: oral midazolam, pimozide, quinidine, dofetilide, tirazolam, lovastatin, and simvastatin |
| **Required Medical Information** | A. INVASIVE SYSTEMIC FUNGAL INFECTION (1) Prescriber attests patient has diagnosis of an Invasive, Systemic Fungal Infection B. ONYCHOMYCOSIS OF THE FINGER NAILS, ONYCHOMYCOSIS OF THE TOE NAILS (1) Prescriber attests patient has diagnosis of Clinically Documented Onychomycosis of the Finger Nails or Clinically Documented Onychomycosis of the Toe Nails (2) One of the following: (i) Patient is diabetic or immunosuppressed/immunocompromised (ii) Patient is in acute pain due to the onychomycosis with signs of associated soft tissue inflammation C. DERMAL FUNGAL INFECTIONS (1) Prescriber attests patient has diagnosis of Dermal Fungal Infections (not including onychomycosis) where topical antifungal agents are considered first line therapy (2) One of the following: (i) Patient must have failed or be intolerant to both an OTC and Rx topical antifungal agent used for an appropriate length of time (i.e. clotrimazole) (ii) Patient has an extensive infection involving areas too large to reasonably use a topical agent (iii) Patient has a chronic, recalcitrant infection (iv) Patient is immunocompromised |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Toenail Onychomycosis: 12 weeks Fingernail Onychomycosis: 5 weeks Other Diagnoses: 12 months |
| **Other Criteria** | None |

# SPRIX NON FORMULARY

## Products Affected

- *ketorolac tromethamine injection*
- *ketorolac tromethamine intramuscular*
- SPRIX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute Pain. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Patient is less than 18 years of age (2) Patient has high risk of GI bleed (3) Patient has any risk of bleed potential, including CVA and TIA (4) Patient needs medication for a longer period than 5 days |
| **Required Medical Information** | A. ACUTE PAIN (1) Prescriber attests patient has diagnosis of Acute Pain (2) Failed/intolerant to generic NSAIDs (3) Failed/intolerant to celecoxib (4) Failed/intolerant to preferred opioids including morphine sulfate, oxycodone (5) Failed/intolerant to generic ketorolac tromethamine tablets (6) Maximum combined duration of use of any form of ketorolac is not to exceed 5 days (7) Total daily dose of Sprix not to exceed 126mg (1 bottle per day) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 5 days |
| **Other Criteria** | None |

# SPRYCEL

## Products Affected

- SPRYCEL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Philadelphia Chromosome-Positive (Ph+) Chronic Myelogenous Leukemia, Acute Lymphoblastic Leukemia (ALL), Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PHILADELPHIA CHROMOSOME-POSITIVE (PH+) CHRONIC MYELOGENOUS LEUKEMIA (1) Prescriber attests patient has diagnosis of Philadelphia Chromosome-Positive (Ph+) Chronic Myelogenous Leukemia (2) Patients disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or BCR-ABL1 positive laboratory test result (3) One of the following: (i) Patient has chronic phase disease and is 1 year of age or older (ii) Patient is 18 years of age or older and has chronic or accelerated or blast phase disease and one of the following: (a) Patient has had a clinical trial and failure to prior therapy with Imatinib (b) Sprycel is being used as single agent for newly diagnosed disease in chronic phase (c) Sprycel is being used as single agent for myeloid blast phase or accelerated phase disease (d) Sprycel is being used In combination with steroids for lymphoid blast phase disease (e) Sprycel is being used in combination with induction chemotherapy for lymphoid or myeloid blast phase disease (4) Prescribed by, or in consultation with, an oncologist B. ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) (1) Prescriber attests patient has diagnosis of Acute Lymphoblastic Leukemia (2) Patients disease is Philadelphia chromosome-positive (Ph+) (3) Patient is 1 year of age or older (4) Patient has previous trial and failure or contraindication to therapy with imatinib (5) Prescribed by, or in consultation with, an oncologist C. CONTINUATION OF THERAPY (1) Patient is absent of any unacceptable toxicity from the drug (2) Prescriber attests that patient has been adherent to therapy (3) Prescriber attests to clinical response and disease stabilization with treatment |
| **Age Restrictions** | See Required Medical Info |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# STELARA

## Products Affected

- STELARA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque Psoriasis, Psoriatic Arthritis, Moderate to Severely Active Crohns Disease, Moderate to Severely Active Ulcerative Colitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Coverage of ustekinumab is NOT recommended in the following circumstances: (1) Ustekinumab should not be given in combination with a TNF antagonist (e.g., adalimumab [Humira], certolizumab pegol [Cimzia], etanercept [Enbrel], golimumab [Simponi], infliximab [Remicade]), anakinra (Kineret), or alefacept (Amevive): Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy (2) Children or adolescents less than or equal to 11 years of age: Safety and efficacy in pediatric patients have not been established (3) Multiple sclerosis: In a Phase II double-blind trial, 249 adult patients with relapsing-remitting multiple sclerosis were randomized to one of four different ustekinumab SC doses or placebo for 19 weeks. No statistically significant or clinically meaningful differences in the cumulative number of new lesions on serial cranial magnetic resonance imaging (MRI) through Week 23 between any of the ustekinumab dosage groups and placebo were observed. |
| **Required Medical Information** | A. PLAQUE PSORIASIS (1) Prescriber attests patient has diagnosis of Plaque Psoriasis AND (2) One of the following: (2a) Minimum BSA involvement of greater than or equal to 5% OR (2b) Plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (2c) Patient meets all of the following conditions: (a) Inadequate response to a 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light (PUVA) (b) Inadequate response to a 3-month trial of systemic therapy with one of the following: MTX, cyclosporine, or acitretin or has contraindications to all of these (c) Tried a tumor necrosis factor (TNF) antagonist [Humira, etanercept,] (d) Patient has significant disability or impairment in physical or mental functioning, according to the treating physician AND (3) Patient has tried systemic therapy or phototherapy for 3 months with one of the following: acitretin, cyclosporine, MTX, or phototherapy with UVB or PUVA AND (4) Patient has tried and failed ENBREL AND HUMIRA B. PSORIATIC ARTHRITS (1) Prescriber attests patient has diagnosis of Psoriatic Arthritis AND (2) Must have tried/failed/been intolerant to at |

| PA Criteria | Criteria Details |
|---|---|
| | least one non-biologic DMARD AND (3) Must have tried/failed/been intolerant to therapy with Humira and Enbrel or provide clinical rationale for use of the requested agent instead of Humira and Enbrel C. MODERATE TO SEVERELY ACTIVE ULCERATIVE COLITIS (1) Prescriber attests patient has diagnosis of Moderate to Severely Active Ulcerative Colitis AND (2) Must have tried and failed or been intolerant to therapy with at least 2 of the following: (2a) corticosteroids (2b) 5-Aminosalicylates (2c) 6-Mercaptopurine and/or azathioprine (2d) Immunosuppressants AND (3) Must have tried and failed or been intolerant to therapy with Humira |
| **Age Restrictions** | Plaque Psoriasis 6 years or older, Psoriatic Arthritis: 18 years or older, Crohns Disease: 18 years or older, Ulcerative Colitis: 18 years or older |
| **Prescriber Restrictions** | PsA: Prescribed by or in consultation with a rheumatologist, Ps: Prescribed by or in consultation with a dermatologist CD, UC: Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | C. MODERATE TO SEVERELY ACTIVE CROHNS DISEASE (1) Prescriber attests patient has diagnosis of Moderate to Severely Active Crohns Disease AND (2) Must have tried/failed/been intolerant to at least 2 of the following: (2a) Corticosteroids (2b) 5-Aminosalicylates (2c) 6-Mercaptopurine and/or azathioprine (2d) MTX AND (3) Must have tried and failed or been intolerant to therapy with Humira AND (4) Dosed within standard dosing limits: (i) Induction infusion is based on weight: (a) 55kg or LESS: 260 mg IV infusion as a single dose over 1 hour (b) 56kg to 85 kg: 390 mg IV infusion as a single dose over 1 hour (c) 86 kg or MORE: 520 mg IV infusion as a single dose over 1 hour (ii) Maintenance Therapy: 90 mg subcutaneously starting 8 weeks after the initial Intravenous induction dose, then given 90mg subcutaneously every 8 weeks thereafter OTHER USES WITH SUPPORTIVE EVIDENCE (1) Patient has been started on ustekinumab: Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications) (2) Other indications: Exceptions not recommended. Case reports have documented some efficacy in the treatment of pityriasis rubra pilaris and variable efficacy for treatment of palmoplantar pustulosis with ustekinumab. Controlled clinical trials are needed to evaluate the safety and efficacy of ustekinumab in conditions not mentioned in the authorization criteria. |

# STIMATE NON FORMULARY

## Products Affected

- STIMATE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Congenital Hemophilia A (factor VIII deficiency) or von Willebrand Disease (vWD) Type 1 or 2. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CONGENITAL HEMOPHILIA A (FACTOR VIII DEFICIENCY) (1) Prescriber attests patient has diagnosis of Congenital Hemophilia A (factor VIII deficiency) (2) Prescribed by, or in consultation with, a hematologist (3) Patient is 3 months of age or older (4) Drug is being requested for one of the following: (i) Control and prevention of bleeding episodes (ii) Perioperative management (iii) Routine prophylaxis to prevent or reduce the frequency of bleeding episodes (5) Patient does not have Factor VIII antibodies (6) Factor VIII coagulant activity levels are greater than 5% (7) Dose does not exceed 300mcg/day B. VON WILLEBRAND DISEASE (VWD) TYPE 1 OR 2 (1) Prescriber attests patient has diagnosis of von Willebrand disease (vWD), Type 1 or 2 (2) Prescribed by, or in consultation with, a hematologist (3) Patient is at least 3 months old or older (4) Factor VIII coagulant activity levels are greater than or equal to 5% (5) Drug is being requested for one of the following: (i) Control and prevention of bleeding episodes (ii) Perioperative management (iii) Routine prophylaxis to prevent or reduce the frequency of bleeding episodes (6) Dose does not exceed 300mcg per day |
| **Age Restrictions** | 3 months of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# STIVARGA

## Products Affected

- STIVARGA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Metastatic Colorectacl Cancer (CRC), Locally Advanced/Unresectable/Metastatic Gastrointestinal Stromal Tumor (GIST), Hepatocellular Carcinoma (HCC), Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. METASTATIC COLORECTAL CANCER (CRC) (1) Prescriber attests patient has diagnosis of Metastatic colorectral cancer (CRC) who has been previously treated with the following: (I) Fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (II) Anti-VEGF therapy - bevacizumab (III) If KRAS wild type, an anti-EGFR therapy - cetuximab, panitumumab (2) Prescriber is an Oncologist (3) Patient is 18 years of age or older (4) Liver function test baseline has been completed before initiation of treatment B. LOCALLY ADVANCED/UNRESECTABLE/METASTATIC GASTROINTESTINAL STROMAL TUMOR (GIST) (1) Prescriber attests patient has diagnosis of Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who has progressed after previous treatment with both of the following: (i) Imatinib (ii) Sunitinib (2) Prescriber is an Oncologist (3) Patient is 18 years of age or older (4) Liver function test baseline has been completed before initiation of treatment C. HEPATOCELLULAR CARCINOMA (HCC) (1) Prescriber attests patient has diagnosis of Hepatocellular carcinoma (HCC) patient who is Child-Pugh Class A who has progressed on or after previous treatment with sorafenib (2) Prescriber is an Oncologist (3) Patient is 18 years of age or older (4) Liver function test baseline has been completed before initiation of treatment D. CONTINUATION OF THERAPY (1) Patient continues to be seen by an Oncologist (2) Prescriber attests that patients condition has not worsened (i.e. disease progression) while on therapy (3) Prescriber attests patient has been adherent to therapy (4) The patient has not developed any contraindications to therapy or other significant adverse drug effects (i.e. Liver toxicity, Hemorrhage, GI perforation or fistula, Skin toxicity, Reversible posterior leukoencephalopathy syndrome (RPLS) |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by an Oncologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |

# SUMATRIPTAN INJ / NASAL SPRAY

## Products Affected

- *sumatriptan nasal*
- *sumatriptan succinate subcutaneous solution*
- *sumatriptan succinate subcutaneous solution auto-injector 6 mg/0.5ml*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Migraine. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MIGRAINE (1) Prescriber attests patient has diagnosis of Migraine (2) Tried and failed or intolerance to sumatriptan (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) (3) Tried and failed or intolerance to rizatriptan (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) (4) Tried and failed or intolerance to naratriptan (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) (5) Tried and failed or intolerance to almotriptan(medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) (6) Tried and failed or intolerance to the prior authorized alternative Sumatriptan Nasal Spray (before injection) (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SUTENT

## Products Affected

- SUTENT ORAL CAPSULE 12.5 MG, 25 MG, 50 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Gastrointestinal Stromal Tumor (GIST), Metastatic (advanced) renal cell carcinoma, Chordoma, Metastatic (advanced) thyroid cancer, Metastatic breast cancer, Neuroendocrine pancreatic tumor, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. METASTATIC (ADVANCED) RENAL CELL CARCINOMA, CHORDOMA, METASTATIC BREAST CANCER, NEUROENDOCRINE PANCREATIC TUMOR (1) Prescriber attests patient has diagnosis of Metastatic (advanced) renal cell carcinoma and the carcinoma is surgically unresectable, Chordoma, Metastatic breast cancer previously treated with an anthracycline and a taxane, or Neuroendocrine pancreatic tumor (2) All Information listed under ALL DIAGNOSES B. GASTROINTESTINAL STROMAL TUMOR (GIST) (1) Prescriber attests patient has diagnosis of Gastrointestinal Stromal Tumor (GIST) and GIST is unresectable and/or metastatic malignant (2) Disease progression while trying or intolerance to Gleevec drug regimen All Information listed under ALL DIAGNOSES C. METASTATIC (ADVANCED) THYROID CANCER (1) Prescriber attests patient has diagnosis of Metastatic (advanced) thyroid cancer (2) The patient has tried and failed or intolerant to vandetanib and carbozantinib All Information listed under ALL DIAGNOSES D. ALL DIAGNOSES (1) Prescribed by Oncologist (2) No clinical manifestations of congestive heart failure (3) Patient will NOT be treated with interferon alfa (Roferon-A, Pegasys, Intron-A, Peg-Intron) or interleukin-2 (Proleukin) therapy in combination with Sutent treatment (4) If the patient is female and of childbearing years (12 - 45 years of age), she is NOT pregnant, has NO plans for pregnancy and has been educated on the potential dangers of Sutent therapy in pregnancy E. CONTINUATION OF THERAPY (1) If the patient has received previous Sutent therapy, he/she has no evidence of disease progression (tumor growth) since initiating Sutent therapy |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by an Oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# SYMDEKO NON FORMULARY

## Products Affected

- SYMDEKO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Not to be used in conjunction with Kalydeco, Orkambi, or Trikafta |
| **Required Medical Information** | A. CYSTIC FIBROSIS, INITIAL : (1) Prescriber attests patient is homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence (refer to other criteria section) AND (2) Prescriber attests to monitoring baseline liver function tests (ALT/AST and bilirubin) AND (3) If less than 18 years of age, baseline ophthalmological exam completed. RENEWAL: (1) Documentation that patient is tolerating and responding to medication (i.e. improved FEV1, weight gain, decreased exacerbation etc.) AND (2) Adherence to therapy is confirmed (attested to by medical provider or patient chart notes or electronic claim history). AND (3) Prescriber attests to monitoring liver function tests (ALT/AST and bilirubin) with each renewal during first year of treatment and annually thereafter AND (4) Prescriber attests that ALT or AST does not exceed 5 times the upper limit of normal AND (5) Prescriber attests that ALT or AST does not exceed 3 times upper limit of normal with bilirubin greater than 2 times upper limit of normal AND (6) If less than 18 years of age, prescriber attests to appropriate follow up ophthalmological exam. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | List of CFTR gene mutations that produce CFTR protein and are responsive to Symdeko (arrows have been replaced with dashes in mutations) [note -if mutation given is not one of the following please verify package insert]): E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A-G, E831X, |

| PA Criteria | Criteria Details |
| --- | --- |
| | S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849+10kbC-T, F508del (2 copies) |

# SYMLIN

## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Type 1 Diabetes Mellitus or Type 2 Diabetes Mellitus. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TYPE 1 DIABETES MELLITUS AND TYPE 2 DIABETES MELLITUS (1) Prescriber attests patient has diagnosis of Type 1 Diabetes Mellitus or Type 2 Diabetes Mellitus (2) Prescribed by an Endocrinologist (3) One of the following: (i) Patient utilizes both basal and short-acting insulin (ii) Patient uses an insulin pump (4) Hgb A1C is greater than 7% but less than 9% or marked day-to day variability in blood glucose levels (5) The patient must not have gastroparesis |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by an Endocrinologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Note: Decrease pre-meal doses of short-acting insulin initially by 50% and inform the patient to perform frequent pre-and post-meal glucose monitoring upon approval. |

# SYNAGIS

## Products Affected

- SYNAGIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Prematurity, Chronic Lung Disease (CLD), Heart Disease, Neuromuscular Disease Congenital Airway Anomaly or Pulmonary Abnormality, Immunocompromised, Cystic Fibrosis (CF). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PREMATURITY (1) Prescriber attests patient has diagnosis of less than 12 months old at the start of RSV season and born before 29 weeks 0 days gestation B. CLD (1) Prescriber attests patient has diagnosis of less than 12 months old who develop CLD of prematurity (gestational age less than32 weeks, 0 days) and required greater than21% O2 for at least the first 28 days of life or between 12 and 24 months old who developed CLD of prematurity and require medical support (chronic corticosteroids, diuretics, supplemental O2 or bronchodilator) within 6 months of start of RSV season C. HEART DISEASE (1) Prescriber attests patient has diagnosis of 12 months old or younger with hemodynamically significant CHD or younger than 24 months who undergo cardiac transplantation during RSV season (2) Children with CHD most likely to benefit include those with: (i) acyanotic heart disease receiving medication to control CHF (documentation required) requiring cardiac surgical procedures (ii) moderate-severe pulmonary HTN (iii) cyanotic heart disease (if recommended by pediatric cardiologist) D. PULMONARY ABNORMALITY (1) Prescriber attests patient has diagnosis of under 12 months old with neuromuscular disease, congenital anomalies of the airway or pulmonary abnormalities that impair the ability to clear secretions from the upper airway due to ineffective cough E. IMMUNOCOMPROMISED (1) Prescriber attests patient has diagnosis of 24 months old or younger, profoundly immunocompromised due to chemotherapy or other conditions during RSV season F. CF (1) Prescriber attests patient has diagnosis of CF and less than 12 months old with clinical evidence of CLD and/or nutritional compromise or 12-24 months old with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest CT that persist when stable) or weight for length less than the 10th percentile |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | See Required Medical Info |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | October 1 - March 31 |
| **Other Criteria** | RSV Season: 10/1 through 3/31 (1) INDICATION and USAGE: Prevention of RSV for children less than2yo at high risk of RSV disease. Respiratory syncytial virus (RSV) prophylaxis with palivizumab (Synagis) may be considered medically necessary in infants and children meeting Required Medical Info to a maximum of five monthly doses (2) Immune prophylaxis for RSV is considered not medically necessary for infants and children with hemodynamically insignificant heart disease including but not limited to: (i) secundum atrial septal defect (ii) small ventricular septal defect (iii) pulmonic stenosis (iv) uncomplicated aortic stenosis (v) mild coarctation of the aorta (vi) patent ductus arteriosus (vii) Lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure (viii) Infants with mild cardiomyopathy who are not receiving medical therapy for the condition (3) Note: Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extra-corporeal membrane oxygenation for infants and children younger than 24 months (4) Dosage and Administration: The recommended dose of Synagis is 15mg/kg body weight administered intramuscularly. Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (greater than24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. Qualifying infants born during the RSV season may require fewer doses (5) Discontinuation of Synagis: If any infant or young child receiving monthly Synagis prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same |

| PA Criteria | Criteria Details |
| --- | --- |
| | season (less than0.5%) (6) Miscellaneous Information: The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis for these patients will be done on a case by case basis by the clinical reviewer |

# SYPRINE NON FORMULARY

## Products Affected

- CLOVIQUE
- SYPRINE
- *trientine hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Wilsons disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. WILSONS DISEASE: INITIAL: (1) Prescriber attests to a documented diagnosis of Wilsons disease confirmed by: genetic testing OR the presence of the following diagnostic features: a) If presence of Kayser-Fleisher rings, serum ceruloplasmin (CPN) less than 20 mg/dL AND 24-hour urine copper greater than 40 mcg b) If no presence of Kayser-Fleisher rings, serum ceruloplasmin (CPN) less than 20 mg/dL AND 24-hour urine copper greater than 100 mcg OR liver biopsy with copper dry weight greater than 250 mcg/g AND (2) Prescriber attests to a trial and failure, intolerance, or contraindication to Depen Titratabs (penicillamine) AND (3) Prescriber attests that patient must adhere to a low copper diet. RENEWAL: (1) Prescriber attest patient is tolerating and responding to therapy AND (2) Prescriber attest patient remains adherent to a low copper diet. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant prescriber |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | None |

# TABLOID

## Products Affected

- TABLOID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute Myelogenous Leukemia, Acute Lymphocytic Leukemia, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACUTE MYELOGENOUS LEUKEMIA AND ACUTE LYMPHOCYTIC LEUKEMIA (1) Prescriber attests patient has diagnosis of Acute Myelogenous Leukemia or Acute Lymphocytic Leukemia (2) Prescribed by, or in consultation with an oncologist or hematologist |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TAFINLAR

## Products Affected

- TAFINLAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Unresectable/Metastatic Melanoma, Anaplastic Thyroid Carcinoma in Combination with Trametinib, Non-Small Cell Lung Cancer in Combination with Trametinib, Other indication cited by NCCN as category 1, 2A, or 2B recommendation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. UNRESECTABLE/METASTATIC MELANOMA, ANAPLASTIC THYROID CARCINOMA IN COMBINATION WITH TRAMETINIB, NON-SMALL CELL LUNG CANCER IN COMBINATION WITH TRAMETINIB (1) Prescriber attests patient has diagnosis of Unresectable/Metastatic Melanoma, Anaplastic Thyroid Carcinoma in Combination with Trametinib, or Non-Small Cell Lung Cancer in Combination with Trametinib (2) Patient is at least 18 years old (3) Prescribed by an Oncologist or Hematologist (4) BRAF mutation V600E (or V600K for malignant melanoma unresectable or metastatic in combination with trametinib) (5) Confirmation of mutation by FDA-approved test (6) No Wild-BRAF mutation (7) Eastern Cooperative Oncology Group (ECOG) Performance Status 0 - 1 (7) Baseline ECG, electrolytes, & bilirubin assessed prior to initiation of therapy and within acceptable limits (8) Performed dermatologic evaluation (9) No concomitant BRAF-inhibitor or MEK-inhibitor, or ipilimumab therapy |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by an Oncologist or Hematologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TALTZ NON FORMULARY

## Products Affected

- TALTZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque Psoriasis, Psoriatic Arthritis, Non-radiographic axial spondyloarthritis or Active Ankylosing Spondylitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients |
| **Required Medical Information** | A. MODERATE TO SEVERE PLAQUE PSORIASIS (1) Prescriber attests patient has diagnosis of Moderate to Severe Plaque Psoriasis AND (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records AND (3) Must be a candidate for phototherapy or systemic therapy AND (4) Must have tried and failed or intolerant to at least one corticosteroid AND (5) Must have tried and failed or intolerant to methotrexate AND (6) Must have tried and failed or intolerant to Enbrel and Humira AND (7) Must have a negative tuberculosis test or received treatment if tested positive B. PSORIATIC ARTHRITIS (1) Prescriber attests patient has diagnosis of Psoriatic Arthritis AND (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records AND (3) Must have tried and failed or intolerant to at least one corticosteroid AND (4) Must have tried and failed or intolerant to methotrexate AND (5) Must have tried and failed or intolerant to Enbrel and Humira AND (6) Must have a negative tuberculosis test or received treatment if tested positive C. ACTIVE ANKYLOSING SPONDYLITIS (1) Prescriber attests patient has diagnosis of Active Ankylosing Spondylitis AMD (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records AND (3) Must have tried and failed or intolerant to Enbrel and Humira AND (4) Inadequate response, intolerance or contraindication to at least two non-steroidal anti-inflammatory drugs (NSAIDS) AND (5) Must have a negative tuberculosis test or received treatment if tested positive |
| **Age Restrictions** | Plaque Psoriasis = 6 years of age or older, All others= 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 3 months Renewal: 12 months |
| **Other Criteria** | D. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSPA) (1) Prescriber attests patient has diagnosis of non-radiographic axial spondyloarthritis AND (2) Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as NSAIDs or nonbiological DMARDs such as sulfasalazine) AND (3) Individual has had an inadequate response to, is intolerant of, or has a contraindication to Humira. (4) Must have a negative tuberculosis test or received treatment if tested positive E. CONTINUATION OF THERAPY (1) Patient is responding to treatment AND (2) Patient tolerating treatment Caution: (1) Increased risk of serious infections. If a serious infection develops, discontinue Taltz until the infection resolves (2) Onset or exacerbation of inflammatory bowel disease (3) Hypersensitivity reactions: if an anaphylactic of other serious allergic reaction occurs, discontinue Taltz immediately and initiate appropriate therapy. Special Considerations: Patients may not receive live vaccinations. Usual dose: (1) Plaque Psoriasis - 160mg (two 80mg injections) SubQ week 0, followed by 80mg SubQ at weeks 2, 4, 6, 8, 10, 12 followed by 80mg SubQ every 4 weeks (2) Psoriatic Arthritis -160 mg (two 80 mg injections) SubQ week 0, followed by 80mg subQ every 4 weeks (3) Ankylosing spondylitis- 160 mg (two 80 mg injections) SubQ week 0, followed by 80mg subQ every 4 weeks |

# TARCEVA

## Products Affected

- *erlotinib hcl*
- TARCEVA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Locally Advanced/Metastatic Non-Small Cell Lung Cancer (NSCLS), Locally Advanced/Unresectable/Metastatic Pancreatic Cancer, Chordoma, Other indication cited by NCCN as category 1, 2A, or 2B recommendation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. LOCALLY ADVANCED/METASTATIC NON-SMALL CELL LUNG CANCER (NSCLS) (1) Prescriber attests patient has diagnosis of Locally advanced or metastatic NSCLC (2) Failure to at least one prior chemotherapy regimen B. LOCALLY ADVANCED/UNRESECTABLE/METASTATIC PANCREATIC CANCER (1) Prescriber attests patient has diagnosis of clinically documented locally advanced, unresectable, or metastatic pancreatic cancer (2) Must be used in combination with gemcitabine C. CHORDOMA (1) Prescriber attests patient has diagnosis of Chordoma |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Notes: Results from two multicenter, placebo controlled, randomized, Phase III trials conducted in first line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum based chemotherapy and its use are not recommended in this setting |

# TARGRETIN

## Products Affected

- *bexarotene*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cutaneous T-cell Lymphoma (CTCL), Mycosis Fungoides, Sezary Syndrome, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CUTANEOUS T-CELL LYMPHOMA (CTCL) (1) Prescriber attests patient has diagnosis of Cutaneous T-cell Lymphoma (CTCL) (2) Patient has received at least one prior therapy including but not limited to: (i) Topical mechlorethamine or topical carmustine (ii) Psoralen + ultraviolet A (PUVA) (iii) Methotrexate (iv) Bexarotene (v) Denileukin (vi) Isotretinoin (vii) Pentostatin (viii) Fludarabine (ix) Cladarabine (x) Photophoresis (extra-corporeal photochemotherapy) B. MYCOSIS FUNGOIDES (1) Prescriber attests patient has diagnosis of Mycosis Fungoides C. SEZARY SYNDROME (1) Prescriber attests patient has diagnosis of Sezary Syndrome |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TASIGNA

## Products Affected

- TASIGNA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Phase Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia (CML), Accelerated Phase Ph+ CML, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC PHASE PHILADELPHIA CHROMOSOME POSITIVE (PH+) CHRONIC MYELOGENOUS LEUKEMIA (CML), ACCELERATED PHASE PH+ CML (1) Prescriber attests patient has diagnosis of Chronic Phase Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia (CML), Accelerated Phase Ph+ CML (2) Prescribed by or in consultation with an oncologist (3) One of the following: (i) Trial and failure, intolerance to, or contraindication to therapy with imatinib (ii) Treatment of newly diagnosed chronic phase Ph+ CML B. CONTINUATION OF THERAPY (1) Patient is absent of any unacceptable toxicity from the drug (2) Prescriber attests that patient has been adherent to therapy (3) Prescriber attests to clinical response and disease stabilization with treatment |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TAZORAC

## Products Affected

- *tazarotene external*
- TAZORAC

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acne Vulgaris or Plaque Psoriasis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACNE VULGARIS (1) Prescriber attests patient has diagnosis of Acne Vulgaris (2) Tried/failed/intolerance to topical tretinoin (3) If female and able to bear children (e.g., no hysterectomy, not reached menopause, has achieved menses), patient has a negative pregnancy test prior to initiation of treatment, and prescriber confirmation that discussed with the patient the potential risks of fetal harm and importance of birth control while using Tazorac B. PLAQUE PSORIASIS (1) Prescriber attests patient has diagnosis of Plaque Psoriasis (2) Applied to less than 20% of Body Surface Area (3) Tried/failed/intolerance two topical corticosteroids (e.g., clobetasol, fluocinonide, mometasone, triamcinolone) (4) If female and able to bear children (e.g., no hysterectomy, not reached menopause, has achieved menses), patient has a negative pregnancy test prior to initiation of treatment, and prescriber confirmation that discussed with the patient the potential risks of fetal harm and importance of birth control while using Tazorac |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TECFIDERA

## Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack*
- TECFIDERA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing-Remitting Multiple Sclerosis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Severe Hepatic Impairment (2) Current Pregnancy (3) Leflunomide Treatment |
| **Required Medical Information** | A. RELAPSING-REMITTING MULTIPLE SCLEROSIS (1) Prescriber attests patient has diagnosis of relapsing-remitting multiple sclerosis supported by documentation from the patients medical records/most recent brain MRI. (Note: Relapsing forms of MS include relapsing-remitting, secondary progressive with relapses, and progressive relapsing) (2) Must be 18 years of age or older (3) Prescribed by a neurologist (4) Not approved if any contraindications: (i) Severe hepatic impairment (ii) Current Pregnancy (iii) leflunomide treatment |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Coverage of dimethyl fumarate is not recommended in the following circumstances: (1) Concurrent use of interferon beta-1a (subcutaneous) with interferon beta-1a (intramuscular) (Avonex), interferon beta-1b (Betaseron, Extavia) or glatiramer acetate (Copaxone) are not recommended (2) Patient is receiving natalizumab (Tysabri). Natalizumab is indicated as monotherapy for MS patients with relapsing forms of the disease (3) Patient is concurrently receiving fingolimod. Use of dimethyl fumarate with fingolimod has not been studied or established |

# TESTOSTERONE

## Products Affected

- *methyltestosterone oral*
- *testosterone cypionate intramuscular*
- *testosterone enanthate intramuscular*
- *testosterone transdermal gel*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary Hypogonadism or Secondary Hypogonadotropic Hypogonadism, Gender Dysphoria in female-to-male transgender. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Men with carcinoma of the breast or known or suspected carcinoma of the prostate (2) Female patients (3) Patients with known hypersensitivity to any of the products ingredients, including testosterone USP that is chemically synthesized from soy |
| **Required Medical Information** | A. PRIMARY HYPOGONADISM OR SECONDARY HYPOGONADOTROPIC HYPOGONADISM (1) Prescriber attests patient has diagnosis of Primary Hypogonadism or Secondary Hypogonadotropic Hypogonadism (congenital or acquired): Idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelters syndrome, or toxic damage from alcohol or heavy metals or radiation. These patients have low serum testosterone levels but have gonadotropins in the normal or low range. (2) NOT approved for erectile dysfunction or impotence (3) Must first try injectable testosterone for a minimum of two months (4) Men age 50 and older (or 40 and older for men with a family history or are African-American) should be screened for prostate cancer before starting therapy and routinely while on therapy |
| **Age Restrictions** | Gender dysphoria: 14 years of age and older, All other indications: None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | B. GENDER DYSPHORIA (Testosterone cypionate, enanthate and topical gel only) (1) Prescriber attests the drug is being prescribed for female-to-male gender reassignment in a patient who is 14 years of age or older and able to make informed, mature decision to engage in therapy. Not approved if: (1) Patient has any contraindications to testosterone (2) |

| PA Criteria | Criteria Details |
| --- | --- |
| | Patient is not testosterone-deficient (3) Male patients diagnosed with breast or prostate cancer or suspected of carcinoma of the prostate (4) Note that coverage for use in women, for impotence, or use in adolescents under the age of 17 is not approved and will be by appeal only. |

# THALOMID

## Products Affected

- THALOMID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL), multiple myeloma (including systemic light chain amyloidosis), AIDS-associated wasting syndrome, cancer cachexia, Recurrent Aphthous Ulcer and stomatitis in severely immunocompromised patients, Refractory Crohns disease, Waldenstroms Macroglobulinemia, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Pregnant women (2) Hypersensitivity to the use of thalidomide (3) ANC less than 750/mm3 |
| **Required Medical Information** | A. AIDS-ASSOCIATED WASTING SYNDROME, CANCER CACHEXIA, RECURRENT APHTHOUS ULCER AND STOMATITIS IN SEVERELY IMMUNOCOMPROMISED PATIENTS, AND REFRACTORY CROHNS DISEASE (1) Prescriber attests patient has diagnosis of AIDS-associated wasting syndrome, cancer cachexia, Recurrent Aphthous Ulcer and stomatitis in severely immunocompromised patients or Refractory Crohns disease (2) Patient must be 12 years of age or older since the safety and effectiveness has not been established in children under 12 years of age B. CUTANEOUS MANIFESTATIONS OF MODERATE TO SEVERE ERYTHEMA NODOSUM LEPROSUM (ENL), MULTIPLE MYELOMA (INCLUDING SYSTEMIC LIGHT CHAIN AMYLOIDOSIS), AND WALDENSTROMS MACROGLOBULINEMIA (1) Prescriber attests patient has diagnosis of Acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL), maintenance therapy for prevention and suppression of the cutaneous manifestations of erythema nodosum leprosum (ENL), multiple myeloma (including systemic light chain amyloidosis), or Waldenstroms Macroglobulinemia (2) Must be administered in compliance with all of the terms outlined in the S.T.E.P.S program under Other Criteria (3) Must be prescribed by a physician that is registered with the S.TE.P.S program C. CONTINUATION OF THERAPY (1) Women of childbearing age must have pregnancy testing done once weekly during the first 4 weeks of treatment and then once every 4 weeks if the menstrual cycle is regular and once every 2 weeks if the menstrual cycle is irregular and the result |

| PA Criteria | Criteria Details |
|---|---|
| | must be negative each time (2) White blood cell count and differential should be monitored. If ANC decreases to below 750/mm3 while on treatment, consideration should be given to discontinuing therapy if neutropenia persists |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 6 months |
| **Other Criteria** | Women of childbearing age must meet all of the following conditions: (i) Alternative therapies have failed or are considered inappropriate (ii) Understands and can reliably carry out instructions (iii) Must be capable of complying with the mandatory contraceptive measures, pregnancy testing, patient registration, and patient survey as described in the S.T.E.P.S. program (iv) Has received both oral and written warnings of the hazards of taking thalidomide during pregnancy and exposing a fetus to the drug (v) Has received both oral and written warnings about the need to use two forms of contraception or continuous abstinence from sexual contact and she acknowledges in written of her understanding of this (vi) Has a negative pregnancy test within 24 hours prior to beginning therapy (vii) For patients between 12 and 18 years of age, her parent or legal guardian must agree to the above. Men who are sexually mature must meet all of the following conditions: (i) Alternative therapies have failed or are considered inappropriate (ii) Understands and can reliably carry out instructions (iii) Must be capable of complying with the mandatory contraceptive measures, pregnancy testing, patient registration, and patient survey as described in the S.T.E.P.S. program (iv) Has received both oral and written warnings of the hazards of taking thalidomide and exposing a fetus to the drug (v) Has received both oral and written warnings about the presence of thalidomide in semen. The need to use a latex condom during any sexual contact with women of childbearing potential, even if he has undergone a vasectomy (vi) For patients between 12 and 18 years of age, his parent or legal guardian must agree to the above. Cautions: (1) The use of thalidomide in multiple myeloma results in an increased risk of venous thromboembolic events. This risk significantly increased when used in combination with standard chemotherapeutic agents including dexamethasone. Dosing/Regimen: (1) Erythema nodosum leprosum (ENL)- 100 mg up to a maximum of 400 mg once daily or in divided doses (2) Multiple myeloma-200 mg once daily with dexamethasone 40 mg daily on days 1-4, 9-12, and 17-20 every 28 days. Authorization and Limitations: (1) If the above criteria are met initial authorizations is 6 |

| PA Criteria | Criteria Details |
| --- | --- |
| | months. Physicians must provide updates on disease progression. If disease progression is noted therapy may not be continued (2) Based on the maximum daily dose the following quantities will be limited to: 1 capsule per day (3) The quantity is limited to a maximum of a 30 day supply per fill. |

# THYROGEN NON FORMULARY

## Products Affected

- THYROGEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Thyroid Cancer, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. THYROID CANCER (1) Prescriber attests patient has diagnosis of Thyroid Cancer (2) Patient requires one of the following: (i) Blood Thyroglobulin (Tg) testing (ii) Radioiodine ablation of remnant thyroid tissue after thyroidectomy (iii) One of the following: (a) Patient is unable to tolerate thyroid hormone withdrawal (ie, intolerable hypothyroid symptoms) (b) Thyroid hormone withdrawal is medically contraindicated (ie, exacerbation of comorbid conditions) (iii) Patient has inadequate thyroid stimulating hormone (TSH) response to thyroid hormone withdrawal (iv) Patient has an undetectable Tg on thyroid hormone suppressive therapy, to exclude the diagnosis of residual or recurrent thyroid cancer |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TOBRAMYCIN NEBULIZATION SOLUTION

## Products Affected

- *tobramycin inhalation nebulization solution 300 mg/5ml*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis or Non-Cystic Fibrosis Bronchiectasis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CYSTIC FIBROSIS (1) Prescriber attests patient has diagnosis of Cystic Fibrosis (2) Must have Pseudomonas aeruginosa in the lungs (3) Must NOT have any of the following: (i) FEV1 less than 25% predicted (KITABIS,TOBI) (ii) FEV1 less than 40% (BETHKIS ONLY) (iii) Colonization with Burkholderia cepacia (4) Must have 28 days off tobramycin therapy (5) Trial, failure, or intolerance to Bethkis, Kitabis Pak, tobramycin neb PRIOR to Tobi Neb or Podhaler B. NON-CYSTIC FIBROSIS BRONCHIECTASIS (1) Prescriber attests patient has diagnosis of Non-Cystic Fibrosis Bronchiectasis (2) Experiencing chronic bronchial infection with Pseudomonas Aeruginosa |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TOLCAPONE

## Products Affected

- TASMAR
- *tolcapone*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Parkinsons Disease. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PARKINSONS DISEASE (1) Prescriber attests patient has diagnosis of Parkinsons Disease (2) Patient will be taking tolcapone concurrently with levodopa/carbidopa (3) Patient has tried and failed therapy with the preferred catechol-o-methyltransferase (COMT) inhibitor agent, entacapone |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TRACLEER

## Products Affected

- *bosentan*
- TRACLEER ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Arterial Hypertension WHO Group 1. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PULMONARY ARTERIAL HYPERTENSTION WHO GROUP 1 (1) Prescriber attests patient has diagnosis of Pulmonary Arterial Hypertension WHO Group 1 as defined by pulmonary artery pressure greater than 25 mmHg at rest or greater than 30 mmHg with exertion (2) Prescribed by or in conjunction with a cardiologist or pulmonologist (3) Symptoms of PAH have progressed despite medical or surgical treatment of the underlying disorder (4) Chronic thromboembolic pulmonary hypertension (5) A negative acute vasoreactivity testing, or a treatment failure/contraindication with calcium channel blockers (6) Not utilizing Flolan or Remodulin |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a cardiologist or pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TRELSTAR

## Products Affected

- TRELSTAR MIXJECT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Prostate Cancer, Metastatic Prostatic Carcinoma or Stage B2-C Prostatic Cancer, Endometriosis, Uterine Leiomyoma (Uterine Fibroids), Central Precocious Puberty, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PROSTATE CANCER (1) Prescriber attests patient has diagnosis of Prostate Cancer (2) Tried and failed, intolerant to, or documented as unacceptable for orchiectomy or estrogen B. METASTATIC PROSTATIC CARCINOMA OR STAGE B2-C PROSTATIC CANCER (1) Prescriber attests patient has diagnosis of Metastatic Prostatic Carcinoma or Stage B2-C Prostatic Cancer C. ENDOMETRIOSIS (1) Prescriber attests patient has diagnosis of Endometriosis (2) Tried and failed or intolerant to at least two of the following: (i) oral contraceptive (ii) medroxyprogesterone (iii) danazol (3) Tried and failed or intolerant to Leuprolide D. UTERINE LEIOMYOMA (UTERINE FIBROIDS) AND CENTRAL PRECOCIOUS PUBERTY (1) Prescriber attests patient has diagnosis of Uterine Leiomyoma (Uterine Fibroids) or Central Precocious Puberty (2) Tried and failed or intolerant to Leuprolide |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TREMFYA NON FORMULARY

## Products Affected

- TREMFYA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (Ps), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Used in combination with a biologic DMARD |
| **Required Medical Information** | A. PLAQUE PSORIASIS,: INITIAL: (1) Prescriber attests that patient has a documented diagnosis of plaque psoriasis AND (2a) Prescriber attests: patients with plaque psoriasis involving greater than or equal to 5% of the body surface area (BSA) OR (2b)Patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR (2c) Three of the following, Patient has had an inadequate response to 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA]) for psoriasis AND (3) Patient has had an inadequate response to a 3-month trial of systemic therapy (i.e.MTX, cyclosporine, acitretin [Soriatane]) AND (4) Prescriber attests that patient must have a negative tuberculosis test or receive treatment if tested positive AND (5) STEP ALERT: TRIAL AND FAILURE OF ENBREL AND HUMIRA (1) Prescriber attests that patient has been evaluated within the last 12 months, unless an evaluation is not clinically appropriate for patient's condition AND (2) Prescriber attests that patient has had disease stabilization or improvement as defined by standard monitoring for the patients condition |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Ps: Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None |

# TREXALL NON FORMULARY

## Products Affected

- TREXALL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis, Severe/Recalcitrant/Disabling Psoriasis, Breast Cancer, Epidermoid Cancers of the Head and Neck, Advanced Mycosis Fungoides, Lung Cancer, Non-Hodgkins Lymphoma, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RHEUMATOID ARTHRITIS, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS, SEVERE/RECALCITRANT/DISABLING PSORIASIS, BREAST CANCER, EPIDERMOID CANCERS OF THE HEAD AND NECK, ADVANCED MYCOSIS FUNGOIDES, LUNG CANCER, NON-HODGKINS LYMPHOMA (1) Prescriber attests patient has diagnosis of one of the following: (i) Severe, active rheumatoid arthritis or polyarticular juvenile idiopathic arthritis, who are intolerant of or had an inadequate response to first-line therapy (ii) Severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy (iii) Treatment of breast, epidermoid cancers of the head and neck, advanced mycosis fungoides, lung cancer, or non-Hodgkins lymphoma (2) Trial and failure of methotrexate tablet (3) Trial and failure of methotrexate given intravenously or intramuscularly |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TRIAMCINOLONE AEROSOL SOLUTION

## Products Affected

- KENALOG EXTERNAL
- *triamcinolone acetonide external aerosol solution*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pruritus and Topical Inflammation Associated with Moderate to Severe Corticosteroid-Responsive Dermatoses. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRURITUS AND TOPICAL INFLAMMATION ASSOCIATED WITH MODERATE TO SEVERE CORTICOSTEROID-RESPONSIVE DERMATOSES (1) Prescriber attests patient has diagnosis of Pruritus and Topical Inflammation Associated with Moderate to Severe Corticosteroid-Responsive Dermatoses (2) Has tried and failed at least THREE of the following: (i) mometasone 0.1$% solution (ii) fluocinonide 0.05% solution (iii) fluocinolone 0.01% solution (iv) clobetasol 0.05% shampoo (v) clobetasol 0.05% solution |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TRIKAFTA NON FORMULARY

## Products Affected

- TRIKAFTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of cystic fibrosis (CF) in patients who have at least one F508del mutation in the CFTR gene, medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | Severe hepatic impairment (Child-Pugh Class C) |
| **Required Medical Information** | A. CYSTIC FIBROSIS, INITIAL : (1) Prescriber attests patient has cystic fibrosis with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene AND (2) Prescriber attests to monitoring baseline liver function tests (ALT/AST and bilirubin) and will monitor liver function at least every three months for the first year AND (3) If patient is less than 18 years of age, baseline ophthalmological exam has been completed AND (4) Prescriber attests Trikafta will not be used concurrently with Kalydeco, Orkambi, or Symdeko. RENEWAL: (1) Documentation that patient is tolerating and responding to medication (i.e. improved FEV1, weight gain, decreased pulmonary exacerbation or infections, etc.) AND (2) Adherence to therapy is confirmed (attested to by medical provider or patient chart notes or electronic claim history) AND (3) Prescriber attests to monitoring liver function tests (ALT/AST and bilirubin) at least annually after the first year of treatment AND (4) Prescriber attests that ALT or AST does not exceed 5 times the upper limit of normal AND (5) Prescriber attests that ALT or AST does not exceed 3 times upper limit of normal with bilirubin greater than 2 times upper limit of normal AND (6) If patient is less than 18 years of age, prescriber attests to appropriate follow up ophthalmological exam. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None |

# TRINTELLIX

## Products Affected

- TRINTELLIX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Major Depressive Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Hypersensitivity to vortioxetine or any components of the Brintellix formulation (2) Must not be used concomitantly with an MAOI or within 14 days of stopping an MAOI. Do not use MAOIs within 21 days of stopping treatment with Trintellix (3) Do not start Trintellix in a patient who is being treated with linezolid or IV methylene blue |
| **Required Medical Information** | A. MAJOR DEPRESSIVE DISORDER (1) Prescriber attests patient has diagnosis of Major Depressive Disorder (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records (3) Must be 18 years of age or older (4) Failed or intolerant to all of the following: (i) At least one generic SSRI (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine HCl immediate-release, sertraline) (ii) At least one SNRI (duloxetine, venlafaxine, desvenlafaxine, Fetzima) (iii) Viibryd B. CONTINUATION OF THERAPY (1) Patient is tolerating and responding to medication and there continues to be a medical need for the medication |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Description: Brintellix (vortioxetine) inhibits reuptake of serotonin (5-HT). It also has agonist activity at the 5-HT1A receptor and antagonist activity at the 5-HT3 receptor. The mechanism of the antidepressant effect of vortioxetine is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS through inhibition of the reuptake of serotonin (5-HT). It also has several other activities including 5-HT3 receptor antagonism and 5-HT1A receptor antagonism. The contribution of these activities to vortioxetines antidepressant effect has |

| PA Criteria | Criteria Details |
| --- | --- |
| | not been established. Quantities will be limited to 1 tablet per day (30 tablets per month) |

# TRULANCE NON FORMULARY

## Products Affected

- TRULANCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe Chronic Idiopathic Constipation or Irritable Bowel Syndrome with Constipation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SEVERE CHRONIC IDIOPATHIC CONSTIPATION AND IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (1) Prescriber attests patient has diagnosis of Severe Chronic Idiopathic Constipation or Irritable Bowel Syndrome with Constipation (2) Patient is 18 years or older (3) An inadequate response to at least one agent from within each of the following laxative types: (i) Fiber laxatives (psyllium, methylcellulose, calcium polycarbophil) (ii) Stimulant laxatives (bisacodyl, Senna) (iii) Osmotic laxatives (polyethylene glycol, milk of magnesia, sorbitol, lactulose) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TYKERB

## Products Affected

- *lapatinib ditosylate*
- TYKERB

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | HER2-Positive Breast Cancer, EGFR Positive Recurrent Bone Cancer (Chordoma), Central Nervous System Cancers with Activity Against Primary Tumor From Breast, Other indication cited by NCCN as category 1, 2A, or 2B recommendation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HER2-POSITIVE BREAST CANCER (1) Prescriber attests patient has diagnosis of Breast Cancer, Human Epidermal Growth Factor Receptor 2 (HER2)-Positive (2) The member meets ONE of the following criteria: (i) Patient has advanced or metastatic breast cancer and meets the following criteria (a) Tykerb will be used in combination with capecitabine OR Herceptin (b) Patient has received prior therapy with Herceptin (ii) Patient has hormone receptor positive metastatic breast cancer and the following criteria are met (a) Patient is postmenopausal (b) Tykerb will be used in combination with aromatase inhibitor (Femara, generics) (iii) Patient has early breast cancer and the following criterion is met (a) Tykerb will be used in combination with Herceptin B. EGFR POSITIVE RECURRENT BONE CANCER (CHORDOMA) (1) Prescriber attests patient has diagnosis of Bone Cancer (Chordoma) for EGFR positive recurrent disease C. CENTRAL NERVOUS SYSTEM CANCERS WITH ACTIVITY AGAINST PRIMARY TUMOR FROM BREAST (1) Prescriber attests patient has diagnosis of Central Nervous System Cancers with Activity Against Primary Tumor From Breast |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# TYVASO NON FORMULARY

## Products Affected

- TYVASO
- TYVASO REFILL
- TYVASO STARTER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Arterial Hypertension WHO Group 1. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Smoking Cigarettes |
| **Required Medical Information** | A PULMONARY ARTERIAL HYPERTENSION WHO GROUP 1 (1) Prescriber attests patient has diagnosis of Pulmonary Arterial Hypertension WHO Group 1. (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records (3) Patients has NYHA class III or IV (4) Prescribed by a pulmonologist or cardiologist (5) Patient is not smoking cigarettes (6) Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test. (7) Must have tried and failed sildenafil (8) Must have tried and failed Letairis (9) Must have baseline 6 minute walking distance B. CONTINUATION OF THERAPY (1) Patient is tolerating treatment (2) By 12 weeks the patient must show an increase in exercise ability, demonstrated by a 20 meter improvement in 6 minute walking distance |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a pulmonologist or cardiologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# UCERIS NON FORMULARY

## Products Affected

- *budesonide er*
- UCERIS ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mild to Moderate Ulcerative Colitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MILD TO MODERATE ULCERATIVE COLITIS (1) Prescriber attests patient has diagnosis of mild to moderate ulcerative colitis (supported by documentation from the patients chart notes/medical records) (2) Prescribed by or in conjunction with a Gastroenterologist (3) Tried and failed, intolerance, or contraindication to trial of budesonide SR and another oral corticosteroid (i.e., hydrocortisone, prednisolone, prednisone) (medication usage must be supported by documentation from the patients chart notes/medical records) (4) Tried and failed, intolerance, or contraindication to a 30-day trial of all of the following (medication usage must be supported by documentation from the patients chart notes/medical records): (i) sulfasalazine (immediate-release/delayed-release) (ii) balsalazide (iii) mesalamine tablet DR 800mg (iv) mesalamine tablet DR 1.2gm |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a Gastroenterologist |
| **Coverage Duration** | 8 weeks |
| **Other Criteria** | Note: This medication is utilized at a maximum duration of 8 weeks, after which time remission is maintained with another (formulary) medication. |

# UPTRAVI

## Products Affected

- UPTRAVI ORAL TABLET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Arterial Hypertension WHO Group 1. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Severe Hepatic Impairment, Currently Breastfeeding |
| **Required Medical Information** | A. PULMONARY ARTERIAL HYPERTENSTION WHO GROUP 1 (1) Prescriber attests patient has diagnosis of Pulmonary Arterial Hypertension WHO Group 1 (2) NYHA Functional Class II-III (3) Prescribed by or in conjunction with a cardiologist or pulmonologist (4) 18 years of age or older (5) Must have trial and failure or intolerance to Sildenafil (Revatio) or Adcirca (tadalafil) AND Letairis (ambrisentan) (6) Patient does not have severe hepatic impairment and must not be currently breastfeeding (if applicable) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a cardiologist or pulmonologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VALCYTE

## Products Affected

- VALCYTE
- *valganciclovir hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of Cytomegalovirus (CMV) Retinitis in Patients with Acquired Immunodeficiency Syndrome (AIDS), Prevention of CMV Disease in High Risk Adult Patients (Donor CMV Seropositive/Recipient CMV Seronegative) Undergoing Kidney, Heart, or Kidney/Pancreas Transplantation, Prevention of CMV Disease in High-Risk Pediatric Patients Undergoing Kidney or Heart Transplant. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Breastfeeding or pregnant females, males or females trying to conceive within 30 days of treatment, neutrophil count less than 500 cells per microliter, platelet count less than 25,000 per microliter, or hemoglobin is less than 8 g per dL |
| **Required Medical Information** | A. TREATMENT OF CYTOMEGALOVIRUS (CMV) RETINITIS IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS), PREVENTION OF CMV DISEASE IN HIGH RISK ADULT PATIENTS (DONOR CMV SEROPOSITIVE/RECIPIENT CMV SERONEGATIVE) UNDERGOING KIDNEY, HEART, OR KIDNEY/PANCREAS TRANSPLANTATION (1) Prescriber attests patient has diagnosis of Treatment of Cytomegalovirus (CMV) Retinitis in Patients with Acquired Immunodeficiency Syndrome (AIDS) or Prevention of CMV Disease in High Risk Adult Patients (Donor CMV Seropositive/Recipient CMV Seronegative) Undergoing Kidney, Heart, or Kidney/Pancreas Transplantation B. PREVENTION OF CMV DISEASE IN HIGH-RISK PEDIATRIC PATIENTS UNDERGOING KIDNEY OR HEART TRANSPLANT (1) Prescriber attests patient has diagnosis of Prevention of CMV Disease in High-Risk Pediatric Patients Undergoing Kidney (4 months to 16 years of age) or Heart Transplant (1 month to 16 years of age) C. CONTINUATION OF THERAPY (1) Continues to meet initial criteria |
| **Age Restrictions** | Pediatric kidney transplant: 4 months to 16 years, Pediatric heart transplant: 1 month to 16 years |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VANTAS NON FORMULARY

## Products Affected

- VANTAS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced Prostate Cancer, Other indication cited by NCCN as category 1, 2A, or 2B recommendation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADVANCED PROSTATE CANCER (1) Prescriber attests patient has diagnosis of Advanced Prostate Cancer (2) 18 years of age or older (3) Male B CONTINUATION OF THERAPY (1) Testosterone continues below castration level |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VECTICAL OINTMENT

## Products Affected

- *calcitriol external*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mild to Moderate Plaque Psoriasis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. MILD TO MODERATE PLAQUE PSORIASIS (1) Prescriber attests patient has diagnosis of Mild to Moderate Plaque Psoriasis (2) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic topical steroid (e.g. betamethasone dipropionate, clobetasol propionate, desoximetasone, or fluocinonide) (3) Patient has experienced an inadequate response, intolerance, or contraindication to topical Calcipotriene (4) Patient is at least 18 years of age or older |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VELPHORO NON FORMULARY

## Products Affected

- VELPHORO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Kidney Disease in Patient on Dialysis with Hyperphosphatemia. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC KIDNEY DISEASE IN PATIENT ON DIALYSIS WITH HYPERPHOSPHATEMIA (1) Prescriber attests patient has diagnosis of Chronic Kidney Disease and patient is on dialysis with hyperphosphatemia (greater than or equal to 5.5 mg/dL) (2) Patient is 18 years of age or older (3) One of the following: (i) Evidence of bone disease (ii) Individual with vascular and/or other soft tissue calcification (iii) Elevated corrected serum calcium of greater than or equal to 10.2 mg/dL OR two consecutive low iPTH levels of less than 150 pg/mL with normal or elevated corrected serum calcium (4) Clinical trial and failure, contraindication, or intolerance to at least TWO of the following: (i) calcium acetate (ii) lanthanum carbonate (iii) sevelamer carbonate B. CONTINUATION OF THERAPY (1) Prescriber attests to a clinical response while on therapy, defined as one of the following: (i) Serum phosphorous levels between 3.5-5.5 mg/dL (1.13-1.78 mmol/L) (ii) Serum levels of corrected total calcium between 8.4-9.5 mg/dL (2.1-2.37 mmol/L) (iii) Intact parathyroid hormone (iPTH, second-generation PTH assay) levels are between 150-300 pg/mL (or 80-160 pg/mL using bio-intact PTH assay) (2) Prescriber attests that the patient has been adherent to therapy with the requested medication and is still requiring dialysis |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VENTAVIS

## Products Affected

- VENTAVIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary Arterial Hypertension WHO Group 1. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A PULMONARY ARTERIAL HYPERTENSION WHO GROUP 1 (1) Prescriber attests patient has diagnosis of Pulmonary Arterial Hypertension WHO Group 1. (2) The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records (3) Patients has NYHA class III or IV (4) Prescribed by a pulmonologist or cardiologist (5) Patient is not smoking cigarettes (6) Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test. (7) Must have tried and failed sildenafil (8) Must have tried and failed either bosentan or ambrisentan B. CONTINUATION OF THERAPY (1) Patient is tolerating and responding to medication and there continues to be a medical need for the medication (2) Patient has improved exercise capacity or a delay in clinical worsening |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by a pulmonologist or cardiologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Ventavis is primarily an outpatient therapy initially administered under the care of a healthcare professional |

# VEREGEN NON FORMULARY

## Products Affected

- VEREGEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | External Genital Warts or Perianal Warts. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. EXTERNAL GENITAL WARTS OR PERIANAL WARTS (1) Prescriber attests patient has diagnosis of External Genital Warts or Perianal Warts (2) Must be age 18 years or older (3) Must have a trial and failure of Imiquimod (16 week trial) or Podofilox (28 day trial) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VERSACLOZ NON FORMULARY

## Products Affected

- VERSACLOZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Bipolar Disorder, Schizophrenia, Other Psychotic Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. BIPOLAR DISORDER, SCHIZOPHRENIA, OTHER PSYCHOTIC DISORDER (1) Prescriber attests patient has diagnosis of Bipolar Disorder, Schizophrenia, or Other Psychotic Disorder (2) Clinical swallowing difficulties (supported by documentation from the patients chart notes/medical records/electronic claim history). Not approvable if electronic claim history demonstrates swallowable orals used (3) One of the following: (i) Trial and failure, intolerance or contraindication of the prior authorized alternative Fazaclo (clozapine ODT) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) (ii) Trial and failure, intolerance or contraindication of the formulary alternative clozapine tablets (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VFEND

## Products Affected

- *voriconazole oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Invasive Aspergillosis, Fungal Infections due to Scedosporium Apiospermum or Fusarium Spp, Esophageal Candidiasis, Candidemia in Non-Neutropenic Patients, Disseminated Candida Infections in the Skin or Abdomen, Candida Kidney Infections, Candida Bladder Wall Infections, Candida Infected Wounds. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Hypersensitivity to voriconazole or its excipients (2) Coadministration with terfenadine, astemizole, cisapride, pimozide, or quinidine can lead to QT prolongation or Torsade de Pointes (3) Coadministration with sirolimus can lead to increased sirolimus levels (4) Coadministration with rifampin, carbamazepine and long acting barbiturates can lead to decreased voriconazole levels (5) Coadministration with rifabutin can increase rifabutin levels and voriconazole levels can be decreased (6) Coadministration with ergot alkaloids can result in ergotism |
| **Required Medical Information** | A. INVASIVE ASPERGILLOSIS AND FUNGAL INFECTIONS DUE TO SCEDOSPORIUM APIOSPERMUM OR FUSARIUM SPP (1) Prescriber attests patient has diagnosis of clinically documented fungal infection invasive aspergillosis, Scedosporium apiospermum, or Fusarium spp that is susceptible to voriconazole (2) Fungal culture and other relevant laboratory studies (including histopathology) need to be obtained to isolate and identify causative organisms (3) Failed/intolerant to at least one other antifungal therapy B. ESOPHAGEAL CANDIDIASIS, CANDIDEMIA IN NON-NEUTROPENIC PATIENTS, DISSEMINATED CANDIDA INFECTIONS IN THE SKIN OR ABDOMEN, CANDIDA KIDNEY INFECTIONS, CANDIDA BLADDER WALL INFECTIONS, AND CANDIDA INFECTED WOUNDS (1) Prescriber attests patient has diagnosis of Esophageal Candidiasis, Candidemia in Non-Neutropenic Patients, Disseminated Candida Infections in the Skin or Abdomen, Candida Kidney Infections, Candida Bladder Wall Infections, or Candida Infected Wounds (2) Failed/intolerant to oral fluconazole |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | Not approved if: (1) The patient has any contraindications to the use of voriconazole (2) The patient does not meet the above stated guidelines for approval |

# Viagra

## Products Affected

- *sildenafil citrate oral tablet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Erectile Dysfunction. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Nitrate Therapy |
| **Required Medical Information** | A. ERECTILE DYSFUNCTION (1) Prescriber attests patient has diagnosis of Erectile Dysfunction confirmed by one of the following: (i) Organic (an identifiable, non-correctable direct physical cause to the condition) (Examples: Diabetes, peripheral vascular disease, spinal cord injuries, surgery, prostate cancer) (ii) Medication-induced (antiandrogens, anticonvulsants, antidepressants, antipsychotics, etc.) (iii) Psychogenic with chart note documentation, Idiopathic with documentation of work-up for organic and psychogenic causes (2) The patient is male (3) The patient is not currently on nitrates, including intermittent nitrate therapies B. CONTINUATION OF THERAPY (1) Patient continues to meet initial criteria |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Verify plan coverage of erectile dysfunction medications |

# VIIBRYD

## Products Affected

- VIIBRYD
- VIIBRYD STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Major Depressive Disorder. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Patient has any contraindication to the use of Viibryd (2) Used concomitantly with a MAOI or within 14 days of stopping MAOI (3) The indicated diagnosis (including any applicable labs and /or tests) and medication usage is not supported by documentation from the patients medical records and/or electronic claim history |
| **Required Medical Information** | A. MAJOR DEPRESSIVE DISORDER OR SEASONAL AFFECTIVE DISORDER (1) Prescriber attests patient has diagnosis of Major Depressive Disorder (2) Must be 18 years of age or older (3) Failed or intolerant to at least one generic SSRI (4) Failed or intolerant to at least one SNRI (5) Failed or intolerant to at least one other anti-depressant from a different class |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Note: Allow 7 days after stopping Viibryd before starting a MAOI |

# VIMOVO NON FORMULARY

## Products Affected

- VIMOVO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing Spondylitis, Osteoarthritis, Rheumatoid Arthritis, or Juvenile Rheumatoid Arthritis all in Patients at Risk for NSAID-Induced Gastric Ulcers. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ANKYLOSING SPONDYLITIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, OR JUVENILE RHEUMATOID ARTHRITIS ALL IN PATIENTS AT RISK FOR NSAID-INDUCED GASTRIC ULCERS (1) Prescriber attests patient has diagnosis of Ankylosing Spondylitis, Osteoarthritis, Rheumatoid Arthritis, or Juvenile Rheumatoid Arthritis all in Patients at Risk for NSAID-Induced Gastric Ulcers (2) Persistent GI intolerance as documented by chart notes/medical records (3) Tried and failed, intolerance or contraindication to a 28-day trial of all of the following, each in combination with prescription strength naproxen (medication usage must be supported by documentation from the patients chart notes/medical records): (i) omeprazole product (OTC or RX) (ii) lansoprazole (OTC or RX) (iii) pantoprazole (iv) Nexium 20mg OTC 24 HR (v) Dexilant (Prior Authorization) (4) Tried and failed, intolerance or contraindication to Mobic (meloxicam), Voltaren (diclofenac) and Relafen (nabumetone) (supported by documentation from the patients chart notes/medical records/electronic claim history) (5) Tried and failed, intolerance or contraindication with the prior authorized alternative Celebrex (supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VIMPAT

## Products Affected

- VIMPAT ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Partial-Onset Seizures Requiring Adjunct Therapy. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PARTIAL-ONSET SEIZURES REQUIRING ADJUNCT THERAPY (1) Prescriber attests patient has diagnosis of Partial-Onset Seizures and requires adjunct therapy (2) 17 years of age or older (3) An inadequate response, intolerance to, or contraindication to a trial of at least two alternative anticonvulsants |
| **Age Restrictions** | 17 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VIVITROL

## Products Affected

- VIVITROL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Alcohol Dependence or Opioid Dependence. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ALCOHOL DEPENDENCE (1) Prescriber attests patient has diagnosis of Alcohol Dependence (2) Patient must be 18 years old or over (3) Patient must have already abstained from drinking alcohol (4) Must be part of a comprehensive treatment program for alcohol dependence that should include a psychosocial support system (5) Failed/intolerant to oral naltrexone (6) Failed/intolerant to Campral B. OPIOID DEPENDENCE (1) Prescriber attests patient has diagnosis of Opioid Dependence (2) Patient must be 18 years old or over (3) Patient must be opioid free for a minimum of 7-10 days (4) Patient must not have a current need for opioid analgesics (5) Must be part of a comprehensive treatment program for opioid dependence that should include a psychosocial support system (6) Failed/intolerant to oral naltrexone (7) Failed/intolerant to Suboxone and Subutex |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# VOSEVI

## Products Affected

- VOSEVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Hepatitis C Infection Genotype 1b, 2, 4, 5, or 6, Chronic Hepatitis C Infection Genotype 1a or 3. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Chronic hepatitis C treatment naive patients (2) Patients with severe renal impairment (GFR less than 30 mL/min/1.73 m2) (3) End stage renal disease requiring dialysis (4) Patients with moderate or severe hepatic impairment (Child-Pugh B or C) (5) Patient concurrently taking rifampin or amiodarone |
| **Required Medical Information** | A. CHRONIC HEPATITIS C INFECTION GENOTYPE 1B, 2, 4, 5, OR 6 (1) Prescriber attests patient has diagnosis of HCV genotype 1b,2,4,5, or 6 (2) Patient has previously been treated with a HCV regimen containing an NS5A inhibitor (Harvoni, Technivie, Viekira, Zepatier, Daklinza, Epclusa, Mavyret) (3) All criteria listed under ALL INDICATIONS B. CHRONIC HEPATITIS C INFECTION GENOTYPE 1A OR 3 (1) Prescriber attests patient has diagnosis of Chronic Hepatitis C (HCV) infection genotype (GT) 1a or 3 (2) Patient has previously been treated with a HCV regimen containing sofosbuvir WITHOUT an NS5A (3) All criteria listed under ALL INDICATIONS C. ALL INDICATIONS (1) Must provide HCV RNA level dated within last 6 months (2) Must provide the following lab values dated within 12 weeks of initiating therapy: (i) CBC with Platelets (ii) AST/ALT (iii) Total Bilirubin (iv) Serum Albumin (v) PT/INR (vi) Serum Creatinine (vii) GFR (3) The member does not have end stage renal disease requiring dialysis or a glomerular filtration rate less than 30 mL/minute/1.73m2 (4) The member does not have evidence or known diagnosis of malignancy of any body organ diagnosed within the last 12 months, or currently receiving or planning to receive chemotherapy or radiation therapy (exceptions will be made for hepatocellular carcinoma if the member is on a liver transplant waiting list) (5) The member is not currently enrolled in hospice (6) The member has not been denied Hepatitis C treatment by another insurance carrier for an acceptable cause. If approved for coverage by another carrier (7) Patient must have had hepatitis B testing (HBsAg, anti-HBc, anti-HBs) prior to starting hepatitis C treatment. |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Must be prescribed by, or in conjunction with, a Gastroenterologist, Hepatologist, or Infectious Disease Specialist |
| **Coverage Duration** | 12 weeks (84 day supply per approval) |
| **Other Criteria** | None |

# VOTRIENT

## Products Affected

- VOTRIENT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced/Metastatic Renal Cell Carcinoma, Advanced Soft Tissue Sarcoma, Uterine Sarcoma, Other indication cited by NCCN as category 1, 2A, or 2B recommendation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADVANCED/METASTATIC RENAL CELL CARCINOMA (1) Prescriber attests patient has diagnosis of Advanced/Metastatic Renal Cell Carcinoma B. ADVANCED SOFT TISSUE SARCOMA (1) Prescriber attests patient has diagnosis of Advanced Soft Tissue Sarcoma (2) One of the following: (i) Being used as palliative therapy for cancers of the extremity/superficial trunk, head/neck, or retroperitoneal/intra-abdominal (ii) Being used as palliative therapy for angiosarcoma or rhabdomyosarcoma (iii) For disease progression of Gastrointestinal Stromal Tumors after single-agent therapy with imatinib, sunitinib, and regorafenib C. UTERINE SARCOMA (1) Prescriber attests patient has diagnosis of Uterine Sarcoma |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# WELCHOL NON FORMULARY

## Products Affected

- WELCHOL ORAL PACKET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypercholesterolemia of Adjunct Therapy to Diet and Exercise to Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPERCHOLESTEROLEMIA (1) Prescriber attests patient has diagnosis of Hypercholesterolemia (2) Trial and failure of all of the following: (i) cholestyramine (ii) colestipol (3) Documented allergic response to generic colesevelam B. ADJUNCT THERAPY TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (1) Prescriber attests patient has diagnosis of adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus (2) Documented allergic response to generic colesevelam |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# XADAGO NON FORMULARY

## Products Affected

- XADAGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Parkinson Disease. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Concurrent use of MAOI therapy, including linezolid |
| **Required Medical Information** | A. PARKINSON DISEASE (1) Prescriber attests patient has diagnosis of Parkinson disease (2) Must have tried and failed or have a contraindication or intolerance to rasagiline or selegiline (3) 18 years of age or older (4) Prescribed by or in consultation with a neurologist |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# XALKORI

## Products Affected

- XALKORI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-Small Cell Lung Cancer, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NON-SMALL CELL LUNG CANCER (1) Prescriber attests patient has diagnosis of non-small cell lung cancer (2) Patients disease is metastatic or recurrent (3) One of the following: (i) Patients cancer is anaplastic lymphoma kinase (ALK) positive as detected by an FDA approved test (ii) Patients cancer is ROS-1 positive as detected by an FDA approved test (iii) Patient has high level MET amplification or MET exon 13 skipping mutation B. Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# XELJANZ

## Products Affected

- XELJANZ
- XELJANZ XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid Arthritis, Psoriatic Arthritis (PsA), or Moderately to Severely Active Ulcerative Colitis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Used in combination with OTHER biologic DMARDs than requested therapy, concurrent use with other potent immunosuppressants (i.e. azathioprine, cyclosporine, etc.), plaque psoriasis. |
| **Required Medical Information** | INITIAL FOR ALL INDICATIONS: (1) Prior to therapy initiation, tuberculin skin test results or chest x-ray within the previous six months are required to evaluate for latent tuberculosis infection (note, If there is evidence of latent tuberculosis infection, treatment should be initiated prior to therapy with Xeljanz) A. RA, PsA (1) Prescriber attests patient has diagnosis of Rheumatoid Arthritis or Psoriatic Arthritis (2) A failed trial or current use of methotrexate (3) A failed trial of at least one non-biologic DMARD therapy (4) A failed response, intolerance, or contraindication to Enbrel AND Humira (5) Patient has moderate disease activity and features of a poor prognosis (6) Xeljanz will not be used in combination with biologic DMARDs or with potent immunosuppressants (e.g. azathioprine, cyclosporine) (7) Absolute lymphocyte count is greater than 500 cells/mm3, and absolute neutrophil count (ANC) is greater than 1000 cells/mm3, and hemoglobin is greater than9 g/dL (8) Xeljanz is not being co-administered with a potent CYP3A4 inducer (e.g. rifampin) B. UC (1) Prescriber attests patient has diagnosis of Moderately to Severely Active Ulcerative Colitis (2) Prescriber attests that patient has had an inadequate response or contraindication to a first line agent such as a corticosteroid, 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, etc. (3) A failed response, intolerance, or contraindication to Humira (4) Patient has moderate disease activity and features of a poor prognosis (5) Xeljanz will not be used in combination with biologic DMARDs or with potent immunosuppressants (e.g. azathioprine, cyclosporine) (6) Absolute lymphocyte count is greater than 500 cells/mm3, and absolute neutrophil count (ANC) is greater than 1000 cells/mm3, and hemoglobin is greater than9 g/dL (7) Xeljanz is not being co-administered with a potent CYP3A4 inducer (e.g. rifampin) |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | PsA, RA: Prescribed by or in consultation with a rheumatologist UC: Prescriber by or in consultation with gastroenterologist |
| **Coverage Duration** | Initial= 12 months, Renewal= 12 months |
| **Other Criteria** | RENEWAL FOR ALL INDICATIONS: (1) Prescriber attests to documentation of response to therapy using quantitative measures (e.g., RA/PsA: reduction in ESR, CRP, and reduction in duration of morning stiffness and/or number of swollen/painful joints, or fatigue, UC: maintained remission, decrease in stool frequency, rectal bleeding, improved endoscopy findings, improvement in physician global assessment, etc.) AND (2) Prescriber attests to documentation of ALL of the following, along with date performed, absolute neutrophil count (ANC) at least 1000 cell/mm3, lymphocyte count at least 500 cells/mm, hemoglobin level at least 9 g/dL. |

# XELODA

## Products Affected

- *capecitabine*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dukes C Stage II or III Colon Cancer, Metastatic Colorectal Carcinoma (Colon Cancer or Rectal Cancer), Adenocarcinoma of the Distal Esophagus or Gastroesophageal Junction, Advanced/Metastatic Gastric Cancer, Locoregional Disease as Capecitabine-Based Chemoradiation for Unresectable Disease in Medically Fit Patients, Hepatobiliary Cancer, Islet Cell Tumors Requiring Management of Bone Metastases or Unresectable Liver and Lung Metastases, Pancreatic Adenocarcinoma, Metastatic or Recurrent Breast Cancer, Brain Metastases if Active Against Primary Breast Tumor, or Ovarian Cancer, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. DUKES C STAGE II OR III COLON CANCER, METASTATIC COLORECTAL CARCINOMA (COLON CANCER OR RECTAL CANCER), ADENOCARCINOMA OF THE DISTAL ESOPHAGUS OR GASTROESOPHAGEAL JUNCTION, LOCOREGIONAL DISEASE AS CAPECITABINE-BASED CHEMORADIATION FOR UNRESECTABLE DISEASE IN MEDICALLY FIT PATIENTS, ISLET CELL TUMORS REQUIRING MANAGEMENT OF BONE METASTASES OR UNRESECTABLE LIVER AND LUNG METASTASES, PANCREATIC ADENOCARCINOMA, METASTATIC OR RECURRENT BREAST CANCER, BRAIN METASTASES IF ACTIVE AGAINST PRIMARY BREAST TUMOR, OR OVARIAN CANCER (1) Prescriber attests patient has diagnosis of Dukes C Stage II or III Colon Cancer, Metastatic Colorectal Carcinoma (Colon Cancer or Rectal Cancer), Adenocarcinoma of the Distal Esophagus or Gastroesophageal Junction, Locoregional Disease as Capecitabine-Based Chemoradiation for Unresectable Disease in Medically Fit Patients, Islet Cell Tumors Requiring Management of Bone Metastases or Unresectable Liver and Lung Metastases, Pancreatic Adenocarcinoma, Metastatic or Recurrent Breast Cancer, Brain Metastases if Active Against Primary Breast Tumor, or Ovarian Cancer B. ADVANCED/METASTATIC GASTRIC CANCER (1) Prescriber attests patient has diagnosis of Advanced/Metastatic Gastric Cancer (2) Xeloda is being used as a |

| PA Criteria | Criteria Details |
|---|---|
| | component of modified ECF (epirubicin, cisplatin, or oxaliplatin, and capecitabine) protocol C. HEPATOBILIARY CANCER (1) Prescriber attests patient has diagnosis of Hepatobiliary Cancer (2) One of the following: (i) Extrahepatic Cholangiocarcinoma (ii) Gallbladder Cancer (iii) Intrahepatic Cholangiocarcinoma |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# XENAZINE

## Products Affected

- *tetrabenazine*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chorea Associated with Huntingtons Disease. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHOREA ASSOCIATED WITH HUNTINGTONS DISEASE (1) Prescriber attests patient has diagnosis of Chorea Associated with Huntingtons Disease (2) Required information is needed to complete review which includes clinical notes from the patient medical records including any applicable labs and/or tests supporting the diagnosis (3) Must have tried and failed at least two of the following: (i) amantadine (ii) an antipsychotic (fluphenazine, haloperidol, risperidone, ziprasidone, quetiapine, or olanzapine) (iii) riluzole (iv) a benzodiazepine (4) Must be prescribed by a neurologist that treats Huntingtons Disease (5) For doses greater than 50 mg/day, CYP2D6 genotyping is required (6) No contraindications to therapy including: (i) actively suicidal (ii) untreated or inadequately treated depression (iii) impaired hepatic function (iv) concomitant use of monoamine oxidase inhibitors (v) concomitant use of reserpine or within 20 days of discontinuing reserpine B. CONTINUATION OF THERAPY (1) Signs and symptoms of chorea must be decreased (2) Patient must not show signs of worsening depression |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Must be prescribed by a neurologist that treats Huntingtons Disease |
| **Coverage Duration** | 3 months |
| **Other Criteria** | None |

# XIAFLEX NON FORMULARY

## Products Affected

- XIAFLEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dupuytrens Contracture, Peyronies disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Peyronies plaques that involve the penile urethra |
| **Required Medical Information** | A. DUPUYTRENS CONTRACTURE (1) Prescriber attests patient has diagnosis of Dupuytrens Contracture with palpable cords that significantly impairs daily function fixed-flexion contractures of the metacarpophalangeal joint or proximal interphalangeal joint of 20 degrees or more (excluding the thumb) (2) A contraindication, treatment failure, or intolerance to a trial of alternative treatments appropriate for the patients clinical condition and disease state (3) Xiaflex should only be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytrens contracture (orthopedic surgeon, hand surgeon, general surgeon, plastic surgeon, or rheumatologist) (4) Only one cord per session should be injected. If patient has other cords with contractures, treat each in sequential order (5) Must not have had surgery on the primary joint within the past 90 days CONTINUATION OF THERAPY (1) Injection may be repeated up to a maximum of 3 sessions per cord at 4 week intervals if reduction in primary joint contracture is not 0-5 degrees of full extension (2) Patient must follow-up within 24 hours following an injection for finger extension procedure if a contracture persists in order to qualify for more injections (3) If after the second injection there is no improvement the 3rd injection may not be approved |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Xiaflex should only be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytrens contracture (orthopedic surgeon, hand surgeon, general surgeon, plastic surgeon, or rheumatologist) OR Must be administered by a healthcare provider experienced in the treatment of male urological diseases, who has completed required training for use of Xiaflex in the treatment of Peyronies disease |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | DC= Max 3 injections per cord at 4 week intervals PD= 2 injections at 6 week intervals up to 4 times |
| **Other Criteria** | B. PEYRONIES DISEASE (1) Prescriber attests patient has diagnosis of Peyronies disease AND (2) is an adult male AND (3) Has palpable plaque and curvature deformity of at least 30 degrees at the start of therapy AND (4) Peyronies disease symptoms must have persisted for at least 12 months AND (5) Request must be for 1 treatment cycle consisting of 2 Xiaflex injection procedures and one penile modeling procedure CONTINUATION OF THERAPY (1) Must provide clinical documentation of all previous treatment cycles AND (2) Maximum of 4 treatment cycles are approvable per plaque (each cycle consists of 2 Xiaflex injection procedures and one penile modeling procedure) AND (3) Must be at least 6 weeks since last treatment cycle AND (4) Curvature deformity must be at least 15 degrees after most recent treatment cycle AND (5) Request must be for 1 treatment cycle consisting of 2 Xiaflex injection procedures and one penile modeling procedure |

# XIIDRA NON FORMULARY

## Products Affected

- XIIDRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dry Eye Disease. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. DRY EYE DISEASE (1) Prescriber attests patient has diagnosis of Dry Eye Disease (2) Age is 17 years or older (3) Prescribed by or in collaboration with an ophthalmologist, optometrist, or rheumatologist (4) An inadequate response or intolerance to a trial of at least 2 artificial tears or ocular lubricant products in the past 120 days B. CONTINUATION OF THERAPY (1) Prescriber attests patient has diagnosis of Dry Eye Disease requiring continued treatment (2) There has been a clinical response without adverse events |
| **Age Restrictions** | 17 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in collaboration with an ophthalmologist, optometrist, or rheumatologist |
| **Coverage Duration** | Initial: Maximum of 6 months. Continuation: Maximum of 12 months. |
| **Other Criteria** | None |

# XOLAIR

## Products Affected

- XOLAIR SUBCUTANEOUS SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to Severe Persistent Asthma with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms inadequately controlled with inhaled corticosteroids, Moderate to Severe Refractory Chronic Idiopathic Urticaria. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | When the criteria is not met and when Xolair is contraindicated (Severe hypersensitivity reaction to Xolair or any ingredient of Xolair) , Concurrent use of IgE targeted monoclonal antibodies. |
| **Required Medical Information** | A. MODERATE TO SEVERE ASTHMA: INITIAL: (1) Prescriber attests to a documented diagnosis of moderate to severe persistent asthma AND (2) Prescriber attests this medication is not being used for acute bronchospasm or status asthmaticus. AND (3) Prescriber attests that the member must still be symptomatic despite being compliant to a trial of a combination of at least a medium dose inhaled corticosteroid with either a long-acting beta agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene modifier, or theophylline AND (4) Prescriber attests to documented positive skin test or in vitro reactivity to a perennial aeroallergen AND (5) Prescriber attests to documentation that the source of the allergenic asthma-triggers has been removed or addressed AND (6a) For patients 12 years of age or older: Prescriber attests to documented serum IgE level between 30-700 IU/mL AND Body weight between 66 and 330 lbs OR (6b) For patients 6 to less than 12 years of age: Prescriber attests to documented serum IgE level between 30-1300 IU/mL AND Body weight between 44 and 330 lbs. AND (7) Prescriber attests that the medication will be administered in a setting by a healthcare professional prepared to manage anaphylaxis AND (8) Prescriber attests that Xolair will not be used in conjunction with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala) or resilizamab (Cinqair) B. CHRONIC IDIOPATHIC URTICARIA (CIU): INITIAL: (1) Prescriber attests to a documented diagnosis of moderate to severe chronic idiopathic urticaria AND (2) Prescriber attests that medication is not being used to treat other allergic conditions besides chronic idiopathic urticaria. CONTINUED IN OTHER CRITERIA |
| **Age Restrictions** | Asthma: 6 years of age or older. CIU: 12 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Asthma: Prescribed by or in consultation with a Pulmonologist, Immunologist, or Allergist. CIU: Prescribed by an Allergist, Immunologist, or Dermatologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | (3) Prescriber attests to documentation that the member is symptomatic despite being compliant with: Two (2) or more H1 antihistamines OR One (1) H1 antihistamine and one (1) or more of the following: H2 antihistamine, oral corticosteroids, and leukotriene modifiers. AND (4) Prescriber attests that Xolair will not be used in conjunction with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala) or resilizamab (Cinqair). RENEWAL FOR ALL INDICATIONS: (1) Patient continues to meet initial criteria AND (2) Prescriber attests to documentation that the member has experienced improved symptom control and/or decreased exacerbations on physician reevaluation at 4-6 months after last approval AND (3a) FOR ASTHMA: Prescriber attests that patient has continued to use inhaled corticosteroid OR (3b) FOR CIU: Prescriber attests that patient continues to used H1 antihistamine AND (4) Prescriber attests that Xolair will not be used in conjunction with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala) or resilizamab (Cinqair). |

# XULTOPHY

## Products Affected

- XULTOPHY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diabetes Mellitus Type 2. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. DIABETES MELLITUS TYPE 2 (1) Prescriber attests patient has diagnosis of Diabetes Mellitus Type 2 (2) Patient is at least 18 years of age or older (3) Patient has had a previous trial and failure, intolerance, or contraindication to therapy with metformin (4) Patient has had an inadequate treatment response to the use of a GLP-1 agonist (Ozempic, Victoza, Trulicity) and long acting insulin (Lantus, Toujeo, Levemir, Tresiba) used as separate agents concurrently (5) Prescriber attests to monitor for signs and symptoms of thyroid tumors (6) Patients Hemoglobin A1c must be greater than 7.0% B. CONTINUATION OF THERAPY (1) Prescriber attests that patient has had a documented clinical response to the medication (2) Prescriber attests to continued monitoring for signs and symptoms of thyroid tumors |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# XYREM NON FORMULARY

## Products Affected

- XYREM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Narcolepsy with Cataplexy or Narcolepsy with Excessive Daytime Sleepiness. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | (1) Patient is being treated with sedative hypnotic agents, other CNS depressants, or using alcohol. (2) Patient has succinic semialdehyde dehydrogenase deficiency (This rare disorder is an in-born error of metabolism and variably characterized by mental retardation, hypotonia, and ataxia.) (3) Patient has a history of drug abuse. (4) Patient has any contraindications to the use of Xyrem (5) Patient does not meet above criteria. |
| **Required Medical Information** | A. NARCOLEPSY WITH CATAPLEXY (1) Prescriber attests patient has diagnosis of Narcolepsy with cataplexy substantial enough to warrant treatment (2) Must have tried and failed or have intolerance to tricyclic antidepressants or SSRIs (3) Must be older than 16 (4) Patient and physician must adhere to all regulations of the XYREM REMS Program (4) Must be prescribed by a neurologist or a sleep specialist (5) Patients are to be evaluated by physician no less frequently than every 3 months (6) Quantity limit of 540 mL/ 30 days B. NARCOLEPSY WITH EXCESSIVE DAYTIME SLEEPINESS (1) Prescriber attests patient has diagnosis of Narcolepsy with daytime sleepiness substantial enough to warrant treatment (2) Must have tried and failed or have intolerance to at least one formulary/preferred stimulant treatment, such as methylphenidate or dextroamphetamine (3) Must be older than 16 (4) Patient and physician must adhere to all regulations of the XYREM REMS Program (4) Must be prescribed by a neurologist or a sleep specialist (5) Patients are to be evaluated by physician no less frequently than every 3 months (6) Quantity limit of 540 mL/ 30 days |
| **Age Restrictions** | Older than 16 years of age |
| **Prescriber Restrictions** | Must be prescribed by a neurologist or a sleep specialist |
| **Coverage Duration** | Initial: 1 month Renewal: 3 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem Success= Program(R), using a centralized pharmacy. Prescribers and individuals must enroll in the program, call 1866XYREM88. |

# ZEGERID NON FORMULARY

## Products Affected

- ZEGERID ORAL CAPSULE 20-1100 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | GERD, Hypersecretory GI disease, Duodenal ulcers, On high dose steroids or NSAID and having failed therapy with H2 antagonists. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. GERD, HYPERSECRETORY GI DISEASE, DUODENAL ULCERS, AND ON HIGH DOSE STEROIDS OR NSAID AND HAVING FAILED THERAPY WITH H2 ANTAGONISTS. (1) Prescriber attests patient has diagnosis of GERD symptoms and disease, Hypersecretory GI disease, Duodenal ulcers, or the patient is on high dose steroids or NSAID and having failed therapy with H2 antagonists (2) Tried and failed, intolerance or contraindication to a 4 week trial of two of the following (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history): (i) omeprazole product (OTC or Rx) (ii) lansoprazole (OTC) (iii) pantoprazole (iv) Nexium 20 mg OTC 24 HR (3) Tried and failed, intolerance or contraindication to a 4 week trial of Zegerid OTC (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) B. CONTINUATION OF THERAPY (1) Clinical benefit outweighs risk of chronic PPI use evidenced by chart notes/medical records documenting medical evaluation (office visit) within the past 90 days |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | GERD: 3 months. All other indications: 6 months |
| **Other Criteria** | None |

# ZEMPLAR

## Products Affected

- *paricalcitol oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Secondary Hyperparathyroidism. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SECONDARY HYPERPARATHYROIDISM (1) Prescriber attests patient has diagnosis of Secondary hyperparathyroidism (2) Intact Parathyroid Hormone (iPTH) greater than 240 pg/mL (3) Corrected serum calcium less than10.5 mg/dL (4) Corrected Serum Ca x(times) Serum Phosphorus less than70 (5) Trail/failure/intolerance to calcitriol/Hectorol oral or injection therapy by demonstrating iPTH level greater than 180 pg/mL (6) Development of hypercalcemia (serum calcium greater than11.5 mg/dL) despite adequate therapy and discontinuance of calcium based phosphate binders B. CONTINUATION OF THERAPY (1) iPTH greater than120 pg/mL (or 2 times the upper limit of normal) (2) Corrected Serum calcium less than11.5 mg/dL (3) Corrected Serum Ca x (times) Serum Phosphorus less than 75 |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ZOLADEX NON FORMULARY

## Products Affected

- ZOLADEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hormone-receptor positive breast cancer in men and pre-menopausal women, Advanced breast cancer in pre- and perimenopausal women, Prostatic carcinoma, Endometrial ablation or hysterectomy (preoperative adjunct), Endometriosis (Stage III or IV), Uterine fibroids (preoperative adjunct to surgical treatment), Precocious puberty, or Dysfunctional uterine bleeding. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HORMONE-RECEPTOR POSITIVE BREAST CANCER IN MEN AND PRE-MENOPAUSAL WOMEN, ADVANCED BREAST CANCER IN PRE- AND PERIMENOPAUSAL WOMEN, PROSTATIC CARCINOMA, ENDOMETRIAL ABLATION OR HYSTERECTOMY (PREOPERATIVE ADJUNCT), ENDOMETRIOSIS (STAGE III OR IV), UTERINE FIBROIDS (PREOPERATIVE ADJUNCT TO SURGICAL TREATMENT), PRECOCIOUS PUBERTY, AND DYSFUNCTIONAL UTERINE BLEEDING (1) Prescriber attests patient has diagnosis of Hormone-Receptor Positive Breast Cancer in Men and Pre-Menopausal Women, Advanced Breast Cancer in Pre- and Peri-Menopausal Women, Prostatic Carcinoma, Endometrial Ablation or Hysterectomy (Preoperative Adjunct), Endometriosis (Stage III or IV), Uterine Fibroids (Preoperative Adjunct to Surgical Treatment), Precocious Puberty, or Dysfunctional Uterine Bleeding |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ZOLINZA

## Products Affected

- ZOLINZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cutaneous T-cell Lymphoma (CTCL), Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CUTANEOUS T-CELL LYMPHOMA (CTCL) (1) Prescriber attests patient has diagnosis of Cutaneous T-cell Lymphoma (CTCL) (2) Patient must have a medical oncology consult (3) Strict diagnostic criteria and demonstration of a T cell clonality or mutation (4) Progressive, persistent or recurrent disease on or following two systemic therapies B. CONTINUATION OF THERAPY (1) Patient must have a follow up with medical oncology (2) Must have a clinical response to treatment within 3 to 6 months of beginning treatment |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | Approved for 3 months initially: If a response is seen, Zolinza will be approved each time for an additional 3 months (A response is defined as: Objective measures for disease activity and may include pruritis or decrease plaques or erythema) If no response is seen, may be approved for an additional 3 months (No response is defined as: Disabling pruritis and diffuse erythema and may warrant a treatment change). Zolinza will not be re approved if no response after 6 months of treatment. Cautions: (1) Pulmonary Embolism and deep vein thrombosis have been reported (2) Dose related thrombocytopenia have occurred and may require dose modification or discontinuation (3) Gastrointestinal disturbances (nausea, vomiting, and diarrhea). Patients may require antiemetics, antidiarrheals and fluid and electrolyte replacement to prevent dehydration. Monitoring: Blood cell counts and chemistry tests, including electrolytes, glucose and |

| PA Criteria | Criteria Details |
| --- | --- |
| | serum creatinine, every 2 weeks during the first 2 months of therapy and monthly thereafter. |

# ZORTRESS

## Products Affected

- *everolimus*
- ZORTRESS ORAL TABLET 0.25 MG, 0.5 MG, 0.75 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Liver Transplant Rejection or Renal Transplant Rejection. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. LIVER TRANSPLANT REJECTION AND RENAL TRANSPLANT REJECTION (1) Prescriber attests patient has diagnosis of a solid organ transplant (2) Prescribed by, or in consultation with, a transplant specialist (3) At least ONE of the following: (i) Has had a trial and failure on an anti-rejection regiment containing at least two of the following: (a) cyclosporine (b) tacrolimus (c) azathioprine (d) mycophenolate mofetil/sodium (ii) has renal dysfunction (iii) patient has a coronary allograft vasculopathy following heart transplant (iv) patient is seronegative for cytomegalovirus (CMV) with donor organ seropositive for CMV (v) symptomatic CMV disease |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a transplant specialist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ZOVIRAX OINTMENT

## Products Affected

- *acyclovir external ointment*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Genital Herpes. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. GENITAL HERPES (1) Prescriber attests patient has diagnosis of Genital Herpes caused by the herpes simplex virus (2) Patient has had a clinical trial and failure, intolerance, or contraindication to oral acyclovir |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 3 months |
| **Other Criteria** | None |

# ZYDELIG

## Products Affected

- ZYDELIG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Lymphocytic Leukemia, Follicular B-cell Non-Hodgkin Lymphoma, Small Lymphocytic Lymphoma (SLL), Gastric and Nongastric MALT Lymphoma, Marginal Zone Lymphoma, Other indication cited by NCCN as category 1, 2A, or 2B recommendation. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC LYMPHOCYTIC LEUKEMIA, FOLLICULAR B-CELL NON-HODGKIN LYMPHOMA, SMALL LYMPHOCYTIC LYMPHOMA (SLL), GASTRIC AND NONGASTRIC MALT LYMPHOMA, AND MARGINAL ZONE LYMPHOMA (1) Prescriber attests patient has diagnosis of Chronic Lymphocytic Leukemia, Follicular B-cell Non-Hodgkin Lymphoma, Small Lymphocytic Lymphoma (SLL), Gastric and Nongastric MALT Lymphoma, or Marginal Zone Lymphoma (2) Trial and failure, intolerance, or contraindication to one prior systemic therapy |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ZYFLO / ZYFLO CR (ZILEUTON / ZILEUTON ER)

## Products Affected

- *zileuton er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Asthma. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ASTHMA (1) Prescriber attests patient has diagnosis of Asthma (2) Tried and failed, intolerance or contraindication to montelukast, theophylline, Arnuity Ellipta, Serevent, zafirlukast, and Flovent HFA (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history) |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 12 months |
| **Other Criteria** | None |

# ZYKADIA

## Products Affected

- ZYKADIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-Small Cell Lung Cancer, Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NON-SMALL CELL LUNG CANCER (1) Prescriber attests patient has non-small cell lung cancer AND (2) Patients NSCLC is metastatic and anaplastic lymphoma kinase (ALK)-positive AND (3) Patient meets one of the following (3a) The patient has progressed on Xalkori OR (3b) The patient is intolerant to Xalkori OR (3c) Patient is using Zykadia as first-line therapy B. Other diagnoses as cited by the National Comprehensive Cancer Network (NCCN) guidelines as 1, 2A, or 2B will be considered for approval |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an Oncologist |
| **Coverage Duration** | Initial 12 months, Renewal 12 months |
| **Other Criteria** | None |

# ZYTIGA

## Products Affected

- *abiraterone acetate*
- ZYTIGA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Metastatic castration resistant prostate cancer , locally advanced or metastatic, castration sensitive prostate cancer, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.METASTATIC CASTRATION RESISTENT PROSTATE CANCER (1) Prescriber attests the patient has a diagnosis of castration resistant prostate cancer AND (2) medication will be used in combination with prednisone OR B. LOCALLY ADVANCED OR METASTATIC, CASTRATION SENSITIVE PROSTATE CANCER (1) Prescriber attests the patient has a diagnosis of locally advanced or metastatic, castration sensitive prostate cancer AND (2) medication will be used in combination with prednisone |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with , an Oncologist or Urologist |
| **Coverage Duration** | Initial 12 months, Renewal 12 months |
| **Other Criteria** | None |

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