

# **PRIOR AUTHORIZATION DETAIL**

# December 2021

**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, Tourette's 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

PA Criteria	Criteria Details
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.
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 MYCITE NON FORMULARY**

#### **Products Affected**

#### • ABILIFY MYCITE

• ABILIFY MYCITE STARTER KIT

• ABILIFY MYCITE MAINTENANCE KIT

PA Criteria	Criteria Details
Covered Uses	Schizophrenia, Bipolar I Disorder, including manic and mixed episodes associated with bipolar disorder, Major Depressive Disorder, FDA Approved indications will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	A. SCHIZOPHRENIA (1) Patient has a diagnosis of Schizophrenia, AND (2) Patient has a medical necessity for tracking medication ingestion (documentation and clinical reasoning must be provided) OR B. BIPOLAR I DISORDER (1) Patient has a diagnosis of bipolar I disorder AND (2) One of the following: (2a) Drug will be used for treatment of manic and mixed episodes as monotherapy or as an adjunct to lithium or valproate OR (2b) Drug will be used as maintenance treatment as monotherapy or as adjunct to lithium or valproate AND (3) Patient has a medical necessity for tracking medication ingestion (documentation and clinical reasoning must be provided) OR C. MAJOR DEPRESSIVE DISORDER (1) Patient has a diagnosis of Major Depressive Disorder, AND (2) Drug will be used as an adjunctive treatment AND (3) Patient has a medical necessity for tracking medication ingestion (documentation and clinical reasoning must be provided) OR C. MAJOR DEPRESSIVE
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

# **ABSORICA NON FORMULARY**

### **Products Affected**

ABSORICA

#### • ABSORICA LD

PA Criteria	Criteria Details
Covered Uses	Treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater who are unresponsive to conventional therapy, including systemic antibiotics
Exclusion Criteria	Known hypersensitivity to isotretinoin (vitamin A, given the chemical similarity to isotretinoin), Known or suspected pregnancy
Required Medical Information	A. RECALCITRANT NODULOCYSTIC ACNE (1) Patient has diagnosis of severe recalcitrant nodular acne characterized by multiple inflammatory nodules with a diameter of 5 mm or greater, AND (2) Patient has documented intolerance to, or treatment failure with, an adequate trial of ONE (1) systemic antibiotic AND (3) Patient has a documented intolerance to, or treatment failure with, an adequate trial of ONE (1) generic isotretinoin preparations (Amnesteem, Claravis, Myorisan) AND (4) Confirmation of the use 2 effective contraception methods or continuous abstinence for 1 month prior, during, and 1 month after isotretinoin therapy
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a dermatologist
Coverage Duration	12 months
Other Criteria	None

# ABSTRAL/FENTORA/LAZANDA/ONSOLIS/SUBSY S NON FORMULARY

### **Products Affected**

• *fentanyl citrate buccal* 

• LAZANDA

• FENTORA

• 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

PA Criteria	Criteria Details
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) NON FORMULARY

#### **Products Affected**

• ACTEMRA

• ACTEMRA ACTPEN

PA Criteria	Criteria Details
Covered Uses	Moderate to Severely active Rheumatoid Arthritis (RA), Giant Cell Arteritis (GCA), Systemic Juvenile Idiopathic Arthritis (SJIA), Polyarticular Juvenile Idiopathic Arthritis (PIJA), Cytokine Release Syndrome (CRS)
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Moderate to Severely Active Rheumatoid Arthritis (1) Patient has diagnosis of moderate to severe RA AND (2) Patient has documented trial and failure of or intolerance to or contraindication of trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of one DMARD agent (MTX, leflunomide, or sulfasalazine) AND (4) Patient has documented trial and failure of or intolerance to or contraindication of Enbrel, Humira, AND Kevzara B. Juvenile Idiopathic Arthritis/Polyarticular Juvenile Idiopathic Arthritis (1) Patient has diagnosis of SIJA or PIJA AND (2) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of one DMARD agent (MTX, leflunomide or sulfasalazine) AND (3) Patient has documented trial and failure of or intolerance to or contraindication of Enbrel AND Humira C. Giant Cell Arteritis (1) Patient has diagnosis of Giant Cell Arteritis AND (2) Patient has documented trial and failure of or contraindication of trial of one systemic corticosteroid D. Cytokine Release Syndrome (1)Patient has documented diagnosis of Cytokine Release Syndrome AND (2) Patient has received CAR T-cell therapy within the past 28 days AND (3) Actemra will be administered by IV infusion E. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Actemra.

PA Criteria	Criteria Details
Age Restrictions	PIJA/SIJA/CRS = 2 years of age or older, RA/GCA = 18 years of age and older
Prescriber Restrictions	RA/PIJA/SIJA= Prescribed by or in consultation with Rheumatologist, GCA/CRS-Prescribed by or in consultation with a specialist for the condition being treated
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

# **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 hypsarrythymia 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 an immunosuppressant. C. ULPUS 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 an immunosuppressant (e.g., azathioprine, cyclophosphamide, cyclosporine, mycopheolate). F. RHEUMATOID ARTHRITIS: (1) History of inadequate response to or intolerance to an IV corticosteroid AND hydroxychloroquine OR

PA Criteria	Criteria Details
	corticosteroid AND (2) Prior treatment with a non-biologic disease- modifying anti-rheumatic drug AND at least two biologic disease- modifying anti-rheumatic drugs.
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**

• ALYQ

• tadalafil (pah)

PA Criteria	Criteria Details
Covered Uses	Pulmonary Hypertension WHO group I, FDA approved 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) 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 RENEWAL CRITERIA: patient has shown improvement from baseline in the 6-minute walk distance test OR that the patient has a stable 6-minute walk distance test with a stable or improved WHO functional class
Age Restrictions	18 years of age or older
Prescriber Restrictions	Must be prescribed by a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	None

# **ADDYI NON FORMULARY**

### **Products Affected**

• ADDYI

PA Criteria	Criteria Details
Covered Uses	Lack or loss of sexual desire, in premenopausal women, FDA approved indications will also be considered for approval.
Exclusion Criteria	Concomitant use of moderate or strong CYP3A4 inhibitors, Hepatic impairment
Required Medical Information	A. HYPOACTIVE SEXUAL DESIRE DISORDER (1) Patient has a documented diagnosis of HSDD (i.e., evaluated by a complete clinical assessment, using DSM-5, interviews/questionnaires) which has persisted for a minimum of 6 months AND (2) Patient is premenopausal AND (3) Trial and failure of a 3 month trial of bupropion (supported by documentation from the patients chart notes/medical records) up to maximally indicated doses unless contraindicated or clinically significant adverse effects AND (4) Hypoactive sexual desire disorder (HSDD) is NOT caused by a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance B. RENEWAL (1) Patients HDD symptoms have improved after 8 weeks of therapy AND (2) Patient continues to be premenopausal
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	Initial= 8 weeks, Renewal= 12 months
Other Criteria	Dose does not exceed 100mg (1 tablet) per day

### 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	<ul> <li>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,</li> </ul>

PA Criteria	Criteria Details
	Revatio], tadalafil [Cialis, Adcirca], vardenafil [Levitra, Staxyn] dipyridamole or theophylline). AND (5) Creatinine clearance is greater than 15 ml/min AND
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**

• everolimus oral tablet

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 uresectable, 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

PA Criteria	Criteria Details
	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 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

### AIMOVIG

### **Products Affected**

• AIMOVIG

PA Criteria	Criteria Details
Covered Uses	Preventative treatment of migraines in adults
Exclusion Criteria	Concurrent use with another CGRP inhibitor; Concurrent use with Botox
Required Medical Information	A. Initial Migraine Prophylaxis (1) Patient has clinically diagnosed episodic migraine defined as 4 to 14 migraine days per month OR (2) Patient has clinically diagnosed chronic migraine defined as greater than or equal to 8 migraine days per month and greater than or equal to 15 headache days per month AND (3)Patient has no history of cluster headache or hemiplegic migraine AND (4) Patient has 2 month trial and failure of, had a contraindication to, or intolerance to at least 2 standard prophylactic pharmacologic therapies, each from a different class, used to prevent migraines or reduce frequency including a. Angiotensin receptor blockers b. Angiotensin Converting Enzyme Inhibitors c. Beta blockers (propranolol, metoprolol, atenolol) d. Calcium channel blockers (verapamil) e. Anti-epileptics (topiramate, divalproex) f. Antidepressants (venlafaxine, amitriptyline, nortriptyline) OR (5) (Patients who meet the chronic migraine definition only) Patient has tried and failed Botox (onabotulinumtoxina) for at least 2 quarterly injections (6 months)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	6 month initial; 1 year renewal
Other Criteria	B. Renewal (1) Positive response to therapy demonstrated by a 50% reduction in monthly migraine days AND (2) Patient use of acute migraine medications (NSAIDs, triptans) has decreased since starting Aimovig AND(3) Patient has overall improvement in function with therapy.

# 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

PA Criteria	Criteria Details
Covered Uses	Parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm. Cystic hadatid 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 hadatid 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 of intolerance to a full treatment 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

#### **Products Affected**

- ALINIA ORAL SUSPENSION RECONSTITUTED
- *nitazoxanide oral*

**Criteria Details PA** Criteria Diarrhea caused by Giardia lamblia, cryptosporidiosis. FDA approved **Covered Uses** indications will also be considered for approval None Exclusion Criteria Required A. GIARDIASIS (1) Prescriber attests patient has a diagnosis of diarrhea Medical caused by Giardia lambliaa (giardiasis) and (2) Patient is Information 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 None Restrictions Coverage Giardiasis or Cryptosporidiosis=3 days Duration **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

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by a neurologist
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 ORAL TABLET 50 MG

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 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

PA Criteria	Criteria Details
Prescriber Restrictions	None
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. FDA approved 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 the following: (i) Proctozone-HC rectal cream 2.5% OR (ii) hydrocortisone rectal suppository OR (iii) Procto-Pak rectal cream 1%
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 Memingitis, 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. fluconcazole, 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

### 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 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

PA Criteria	Criteria Details
	demonstrated a reduced seizure frequency with Aptiom 1200 mg daily. The seizure reduction with the 800 mg was not statistically significant (4) Drug interactions: inhibits CYP2C19 and induces CYP3A4

# **ARANESP NON FORMULARY**

#### **Products Affected**

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

ARANESP (ALBUMIN FREE)
 INJECTION SOLUTION PREFILLED

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	<ul> <li>(1) Anemia in patients with cancer who are not receiving chemotherapy</li> <li>(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)</li> </ul>
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-

1

PA Criteria	Criteria Details
	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 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 Autoinflammatory 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 Autoinflammatory 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 INHALATION CAPSULE 75 MCG

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

• azathioprine oral tablet 100 mg, 75 mg

PA Criteria	Criteria Details
Covered Uses	Atopic Dermatitis, Autoimmune Hepatitis, Bechets 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 Wegners Granulomatosis. Medically accepted indications will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	A. ATOPIC DERMATITIS, AUTOIMMUNE HEPATITIS, BECHETS 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, WEGNERS GRANULOMATOSIS (1) Prescriber attests patient has diagnosis of Atopic Dermatitis, Autoimmune Hepatitis, Bechets 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 Wegners 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 HBsAgpositive 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

# **BASAGLAR NON FORMULARY**

#### **Products Affected**

• BASAGLAR KWIKPEN

PA Criteria	Criteria Details
Covered Uses	Diabetes Mellitus. FDA approved indication will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	A. DIABETES MELLITUS (1) Patient has diagnosis of Diabetes Mellitus (2) Patient has had a previous trial and failure, intolerance, or contraindication to all the following: (i) Lantus (ii) Levemir (iii) Tresiba.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## BAXDELA

### **Products Affected**

• BAXDELA

PA Criteria	Criteria Details
Covered Uses	Community Acquired Pneumonia (CABP), Acute Infection of skin and/or subcutaneous tissue (ABSSSI),
Exclusion Criteria	None
Required Medical Information	A. ACUTE BACTERIAL SKIN OR SKIN STRUCTURE INFECTION (ABSSSI) (1) Confirmed diagnosis of ABSSSI AND (2) Continuation of IV Baxela therapy upon hospital discharge (must provide chart notes) OR (3) All of the following: (3a)Infection is caused by ONE of the following organisms (must provide culture): Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, or Pseudomonas aeruginosa AND 3(c) Culture and sensitivity report shows resistance of the isolated pathogen to all other formulary antibiotics FDA approved for members diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in conjunction with an Infectious Disease Specialist
Coverage Duration	See Other Criteria
Other Criteria	B. COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP) (1) Confirmed diagnosis of community-acquired bacterial pneumonia (CABP) AND (2) Continuation of IV Baxela therapy upon hospital discharge (must provide chart notes OR (3) Infection is caused by any of the following susceptible microorganisms (must provide culture): Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli,

PA Criteria	Criteria Details
	Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae AND (3a) Culture and sensitivity reports shows resistance to all other formulary antibiotics FDA approved for members diagnosis COVERAGE DURATION (ABSSSI): 450mg tablets 1x: 28 tablets per 14 days. (CABP): 450mg tablets 1x: 20 tablets per 10 days. Other indications: 450mg tablets 1x: 28 tablets per 14 days.

### **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

## BESIVANCE

### **Products Affected**

• BESIVANCE

PA Criteria	Criteria Details
Covered Uses	Bacterial conjunctivitis
Exclusion Criteria	None
Required Medical Information	A. BACTERIAL CONJUNCTIVITIS (1) Diagnosis of bacterial conjunctivitis AND (2) patient has had a trial (duration at least 3 days) and an inadequate response to two generic ophthalmic antimicrobial agents in the past 30 days: (ciprofloxacin, levofloxacin, ofloxacin, erythromycin, gentamycin, polymixin B/trimethoprin, etc.)
Age Restrictions	1 year of age and older
Prescriber Restrictions	Prescribed by or in conjunction with an optometrist or ophthalmologist
Coverage Duration	7 days
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

# **BEVYXXA NON FORMULARY**

#### **Products Affected**

BEVYXXA ORAL CAPSULE 40 MG, 80
MG

PA Criteria	Criteria Details
Covered Uses	Prophylaxis of venous thromboembolism (VTE), Medically accepted indications will also be considered for approval.
Exclusion Criteria	Patients with prosthetic heart valve, active pathological bleeding and severe hypersensitivity reaction to betrixaban, NOT to be used for prevention of thromboembolic events after total knee replacement, NOT to be used in patent with hepatic impairment.
Required Medical Information	A. PROPHYLAXIS OF VENOUS THROMBOEMBOLISM: (1) Prescriber attests to product being utilized for the prophylaxis of venous thromboembolism (VTE) AND (2) Patient must have been hospitalized (admitted) for an acute medical illness (including acutely decompensated heart failure with baseline Class II or greater, presenting as Class III or IV, acute respiratory failure in patients with chronic lung disease, acute infection without septic shock, acute rheumatic disorders, and acute ischemic stroke with lower extremity hemiparesis or hemiparalysis) who are severely immobilized for 24 hours during the current hospitalization, and are expected to remained immobilized for at least 4 days AND (3) Patient must have received loading dose 160mg once during hospitalization.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	42 days
Other Criteria	QUANTITY RESTRICTION: Total of 42 days of any combination of 40mg or 80 mg capsules

### BOSULIF

### **Products Affected**

• BOSULIF

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 cytogenic analysis, QPCR, or FISH.
Age Restrictions	18 years of age or older

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by, or in consultation with, a Hematologist or Oncologist
Coverage Duration	6 months
Other Criteria	None

# **BREZTRI NON FORMULARY**

### **Products Affected**

• BREZTRI AEROSPHERE

PA Criteria	Criteria Details
Covered Uses	Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
Exclusion Criteria	Treatment of asthma or status asthmaticus, Relief of acute bronchospasm, Hypersensitivity to budesonide, glycopyrrolate and/or formoterol
Required Medical Information	(1) Diagnosis of COPD AND (2) Patient has had trial and failure, intolerance, or contraindication to Trelegy Ellipta
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 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 SYMTPOMS 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

## BRIVIACT

### **Products Affected**

• BRIVIACT

PA Criteria	Criteria Details
Covered Uses	Adjunctive treatment of partial-onset seizures
Exclusion Criteria	Hypersensitivity to brivaracetam or any inactive ingredients in Briviact
Required Medical Information	A. PARTIAL ONSET SEIZURES (1) Confirmed diagnosis of partial- onset seizures AND (2) Must of tried and failed or intolerant to levetiracetam AND at least 1 other anticonvulsant indicated for partial- onset seizures RENEWAL: (1) Patient is responding to treatment as demonstrated by a reduction in the frequency of seizures AND (2) Patient is tolerating treatment
Age Restrictions	1 month and older
Prescriber Restrictions	Prescribed by or in conjunction with a neurologist
Coverage Duration	Initial: 12 months, Renewal: 12 months
Other Criteria	None

## BROVANA

#### **Products Affected**

• arformoterol tartrate

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 PULMONY 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*
- *buprenorphine hcl injection*

#### • BUTRANS TRANSDERMAL PATCH WEEKLY 10 MCG/HR, 15 MCG/HR, 20 MCG/HR, 5 MCG/HR

PA Criteria	Criteria Details
Covered Uses	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. All FDA approved indications.
Exclusion Criteria	Use as an as-needed (prn) analgesic. 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. Hypersensitivity to buprenorphine.
Required Medical Information	INITIAL: (1) Patient has a documented diagnosis of chronic, severe pain requiring long-term daily, around-the-clock opioid treatment; AND Patient has had a trial and failure, intolerance, or contraindication to alternative treatment options including non-opioid analgesics (e.g., NSAIDs) AND an immediate-release opioid/opioid combination product. RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria.
Age Restrictions	18 years of age or older prior to approval of Butrans. 2 years of age or older prior to approval of Buprenex
Prescriber Restrictions	Prescribed by, or in consultation with, a pain management specialist.
Coverage Duration	12 months
Other Criteria	None

## **BYDUREON/BYETTA NON FORMULARY**

#### **Products Affected**

• BYDUREON BCISE

- BYETTA 10 MCG PEN
- BYDUREON SUBCUTANEOUS PEN- BYETTA 5 MCG PEN INJECTOR 2 MG

PA Criteria	Criteria Details
Covered Uses	Type 2 Diabetes Mellitus
Exclusion Criteria	None
Required Medical Information	A. TYPE 2 DIABETES MELLITUS: (1) Patient has a diagnosis of Type 2 Diabetes Mellitus AND (2) Trial and failure of, intolerance to, or contraindication to metformin AND (3) Trial and failure, intolerance, or contraindication to all of the following: Ozempic, Victoza, Rybelsus AND Trulicity AND (4) Must have copies of recent Hgba1c labs that illustrate levels between 7.0 and 10.0.
Age Restrictions	
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **CABLIVI NON FORMULARY**

### **Products Affected**

• CABLIVI

PA Criteria	Criteria Details
Covered Uses	Acquired Thrombotic Thrombocytopenic Purpura (aTTP)
Exclusion Criteria	None
Required Medical Information	Chart notes documenting diagnosis, current therapy regimen, and date of plasma exchange therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a hematologist.
Coverage Duration	Approve for one course of treatment (up to 60 days following the last plasma exchange session).
Other Criteria	Approve for one course of treatment if the patient meets ALL of the following criteria: 1. First dose of Cablivi has been administered by a healthcare provider in combination with plasma exchange therapy; AND 2. Patient is currently receiving at least one immunosuppressive therapy. (e.g., systemic corticosteroids); AND 3. If previously treated with Cablivi, patient has not had more than two recurrences of aTTP while on Cablivi.

# **CABOMETYX NON FORMULARY**

### **Products Affected**

• CABOMETYX

PA Criteria	Criteria Details
Covered Uses	Advanced renal cell carcinoma (RCC), Hepatocellular carcinoma (HCC), Progressive metastatic, medullary thyroid carcinoma
Exclusion Criteria	None
Required Medical Information	A. Advanced renal cell carcinoma (RCC): documentation to support diagnosis is submitted. If Cabometyx will be used in combination with Opdivo (nivolumab), the patient has not received prior treatment for advanced renal cell carcinoma (first-line treatment). B. Hepatocellular carcinoma: documentation to support diagnosis is submitted AND Patient has had a trial and failure of Nexavar (sorafenib). C. Progressive metastatic medullary thyroid carcinoma : documentation to support diagnosis is submitted AND has progressed following VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible
Age Restrictions	HCC, RCC= 18 years of age or older, MTC= 12 years of age or older
Prescriber Restrictions	Prescribed by, or in conjunction with, an oncologist.
Coverage Duration	12 months
Other Criteria	None

## CANASA

#### **Products Affected**

• 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**

• 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

### **Products Affected**

• CIALIS ORAL TABLET 2.5 MG, 5 MG • tadalafil 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 STARTER KIT

• CIMZIA PREFILLED

PA Criteria	Criteria Details
Covered Uses	Moderate to severe Plaque Psoriasis, Psoriatic Arthritis, Moderately to Severely Active Rheumatoid Arthritis, Ankylosing Spondylitis, Non- radiographic Axial Spondylarthritis, and Crohns Disease. Only FDA Approved Indications will be considered for approval.
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Moderate to Severe Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) AND (4) Patient has documented trial and failure of Enbrel, Humira, Otezla, Skyrizi, Stelara, AND Cosentyx B. Psoriatic Arthritis (1) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (2) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (3) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Otezla, Stelara, AND Cosentyx C. Rheumatoid Arthritis (1) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (2) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Otezla, Stelara, AND Cosentyx C. Rheumatoid Arthritis (1) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (2) Patient has documented failure or intolerance to or contraindication to trial of DMARD (MTX, leflunomide, sulfasalazine) AND (3) Patient has documented failure or intolerance to or contraindication to trial of DMARD (MTX, leflunomide, sulfasalazine) AND (3) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Rinvoq, AND Kevzara CONT IN OTHER CRITERIA
Age Restrictions	18 years of age or older
Prescriber Restrictions	Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondylarthritis-prescribed by or in consultation with rheumatologist, Psoriatic arthritis-prescribed by or in consultation with rheumatologist or dermatologist, plaque psoriasis-prescribed by or in consultation with

PA Criteria	Criteria Details
	dermatologist, Crohns Disease-prescribed by or in consultation with gastroenterologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	D. Ankylosing Spondylitis (1) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (2) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel AND Cosentyx E. Non-Radiographic Axial Spondylarthritis (1) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy (for CO only: must t/f Cosentyx) F. Crohns Disease (1) Patient has diagnosis of Crohns Disease AND (2) Patient has documented failure or intolerance to or contraindication to trial of at least one form of conventional therapy including aminosalicylates (mesalamine and sulfasalazine), immunomodulators (azathioprine) or corticosteroids AND (3) Patient has documented failure or intolerance to or contraindication to Humira AND Stelara F. Renewal for all Indications (1)Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Cimzia

## **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 (100 MG DAILY DOSE) ORAL KIT 1 X 80 & 1 X 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 1 X 80 & 3 X 20 MG
- 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 NON FORMULARY**

### **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

# **CONTRACEPTIVE PRODUCTS NON FORMULARY**

### **Products Affected**

• norethin ace-eth estrad-fe oral tablet chewable

PA Criteria	Criteria Details
Covered Uses	Prevention of pregnancy, PMDD, Acne, PCOS, Endometriosis, Amenorrhea, Dysfunctional uterine bleeding
Exclusion Criteria	Pregnancy
Required Medical Information	A. Pregnancy Prevention (1) Prescriber indicates product is being used for contraception AND (2) Patient has 3 month trial and failure of, contraindication to, or intolerance to THREE formulary alternatives. B. All Other indications (1) Patient has FDA approved diagnosis AND (2) Patient has trial and failure of, contraindication to, or intolerance to THREE formulary alternatives.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 years
Other Criteria	None

## COPAXONE

### **Products Affected**

• glatiramer acetate

#### • GLATOPA

PA Criteria	Criteria Details
Covered Uses	Relapsing-remitting Multiple Sclerosis, FDA Approved 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) Brand Copaxone: Must have tried and failed or contraindication to generic Glatiramer. 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**

CORDRAN EXTERNAL LOTION
 NOLIX EX

#### • NOLIX EXTERNAL LOTION

• 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. CORTICOSTERIOD RESPONSIVE DERMATOSES (1) Prescriber attests patient has diagnosis of corticosteriod 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 0.05% cream and ointment, desoximetasone 0.025% cream and ointment, desoximetasone 0.05% cream and fluticasone 0.05% ointment. High potency: betamethasone diprop 0.05% 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 dipriop 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

PA Criteria	Criteria Details
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 thas 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

PA Criteria	Criteria Details
Coverage Duration	12 months
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

#### **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, Active Ankylosing Spondylitis, Active Non-radiographic Axial Spondylarthritis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Moderate to Severe Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication for at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) AND (4) TRIAL AND FAILURE OF 2 PREFERRED AGENTS: ENBREL, HUMIRA, OTEZLA, STELARA PRIOR TO COSENTYX B. Psoriatic Arthritis (1) Patient has diagnosis of psoriatic arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) TRIAL AND FAILURE OF 2 PREFERRED AGENTS: ENBREL, HUMIRA, OTEZLA, STELARA PRIOR TO COSENTYX C. Ankylosing Spondylitis (1) Patient has diagnosis of ankylosing spondylitis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy E. Renewal for all Indications (1) Patient has documented failure of intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy E. Renewal for all Indications (1) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Cosentyx
Age Restrictions	Ps= 6 years of age or older, AS, PsA, nr-axSpA =18 years of age or older

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with rheumatologist (AS, PsA, nr-axSpA) or dermatologist (PsA,PS)
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

## CRESEMBA

### **Products Affected**

• CRESEMBA ORAL

PA Criteria	Criteria Details
Covered Uses	Invasive aspergillosis species or other filamentous fungi, Invasive mucomycosis, 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 mucomycosis 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

PA Criteria	Criteria Details
Other Criteria	CONTINUED THERAPY A. ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT (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 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 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 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 D. PREVENTION OF PRETERM BIRTH (1) Currently receiving

# **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 Penicillamine 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- Fleisher 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

PA Criteria	Criteria Details
Coverage Duration	WD: Initial-6 months, Renewal- 1 year, Cystinuria, RA: Initial-3 months, Renewal- 6 months
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 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 a Androgen-dependent tumor AND (7) Must not have active thrombosis or thromboembolic disease and history of such events

PA Criteria	Criteria Details
Age Restrictions	None
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**

• pyrimethamine oral

PA Criteria	Criteria Details
Covered Uses	Treatment of severe acquired toxoplasmosis (including toxoplasmic encephalitis), congenital toxoplasmosis or secondary prophylaxis of toxoplasmic encephalitis. Primary Penumocystis Pneumonia (PCP) prophylaxis in HIV-infected patients or as secondary prophylaxis in HIV- infected patients who have been treated for an acute episode of Pneumocystis pneumonia.
Exclusion Criteria	Use of drug in patients with documented megaloblastic anemia due to folate deficiency
Required Medical Information	A. TOXOPLASMOSIS (1) Prescriber provides documented diagnosis of severe acquired toxoplasmosis (including toxoplasmic encephalitis), congenital toxoplasmosis or secondary prophylaxis of toxoplasmic encephalitis OR Primary Pneumocystis Pneumonia (PCP) prophylaxis in HIV-infected patients or as secondary prophylaxis in HIV infected patients who have been treated for an acute episode of Pneumocystis Pneumonia. AND (2) Primary prophylaxis must meet all (2a) Must be Toxoplasma-seropositive (IgG labs must be submitted) AND (2b) CD4 count less than 100 cells/mm3 for initiation of prophylaxis or CD4 less than 200 cells/mm3 if reinstituting prophylaxis AND (2c) Must have intolerance to trimethoprim-sulfamethoxazole TMP-SMX AND (2d) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and remains intolerant OR Patient has evidence of moderately server or life-threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (i.e. Stevens-Johnson syndrome, toxic epidermal necrolysis).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# 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 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

• desmopressin acetate pf

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 ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	Clostridium difficile-associated diarrhea, Additional FDA approved indications will also be considered for approval
Exclusion Criteria	None
Required Medical Information	A. CLOSTRIDIUM DIFFICILE- ASSOCIATED DIARRHEA (CDAD) (1) Patient has diagnosis of Clostridium difficile-associated diarrhea (CDAD) confirmed by a positive stool assay AND (2) The patient has intolerance to, contraindication to, or has experienced inadequate treatment response to oral vancomycin after a trial of at least 10 days, QTY LIMIT 20 per 10 day supply
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 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

## **DUEXIS NON FORMULARY**

### **Products Affected**

• DUEXIS

PA Criteria	Criteria Details
Covered Uses	The relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.
Exclusion Criteria	1. Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to ibuprofen or famotidine 2. History of asthma, urticaria or other allergic type reactions after taking aspirin or other NSAIDs 3. History of hypersensitivity to other H2-receptor antagonists. 4. In the setting of coronary artery bypass graft (CABG) surgery.
Required Medical Information	1. Diagnosis of rheumatoid arthritis and/or osteoarthritis, 2. Previous medications tried and failed 3. Previous medical history
Age Restrictions	19 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	1. Patient has a documented diagnosis of rheumatoid arthritis and/or osteoarthritis AND 2. Patient has had a documented adequate trial and therapeutic failure of at least TWO (2) generic oral NSAIDs AND 3. Patient has had a documented adequate trial and therapeutic failure of at least TWO (2) generic oral H2-receptor antagonists, AND 4. The patient has had a documented adequate trial and therapeutic failure of an NSAID taken WITH an H2-receptor antagonist, AND 5. Patient has history or current diagnosis of peptic ulcer (gastric or duodenal), gastrointestinal (GI) bleed, GI obstruction, or GI perforation.

### DUPIXENT

### **Products Affected**

• DUPIXENT

PA Criteria	Criteria Details
Covered Uses	Moderate to severe atopic dermatitis, Add-on maintenance treatment in patients with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). Additional FDA approved indications will be considered for approval.
Exclusion Criteria	Concurrent therapy with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
Required Medical Information	A. ATOPIC DERMATITIS: INITIAL: (1) Patient has documented diagnosis (supported by documentation from the patients chart notes/medical records) of moderate to severe atopic dermatitis AND (2) Prescriber attests that patient has greater than or equal to 10% body surface area (BSA) involvement AND (3) Must have tried and failed, have an intolerance or a contraindication to a 6 month trial of at least two of the three following options: a.) Very high or high potency topical steroid OR b.) Tacrolimus ointment or pimecrolimus cream OR c.) An immunosuppressive agent RENEWAL: (1) Documentation that the patient has responded to Dupixent therapy as determined by the prescribing physician (e.g., marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification, reduced pruritus, decreased requirement for other topical or systemic therapies, reduced body surface area affected with atopic dermatitis, or other responses observed) B. MODERATE TO SEVERE ASTHMA: INITIAL: (1) Patient has moderate to severe asthma (supported by documentation from the patients chart notes/medical records) defined as current drug therapy including a.) Medium, high-dose, or max-tolerated inhaled corticosteroid (ICS) AND one additional asthma controller medication (long-acting beta 2-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline) OR b.) Maximally tolerated ICS/LABA combination product AND (2) Patients peripheral blood eosinophil (EOS) count is greater than or equal to 150 cells per microliter AND (3) Patient has had one asthma exacerbation in

PA Criteria	Criteria Details
	previous 12 months (e.g. oral corticosteroid (OCS) burst, ER visit, hospital admission, urgent care visit) OR is dependent on chronic daily OCS for asthma control
Age Restrictions	ASTHMA, ATOPIC DERMATITIS: 6 years of age or older, RHINOSINUSITIS WITH NASAL POLYPS: 18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a pulmonologist, allergist, immunologist, asthma specialist, dermatologist or otolaryngologist.
Coverage Duration	CRSwNP, AD: Initial= 6 months, Asthma Initial=12 months, Renewal= 12 months (All indications)
Other Criteria	RENEWAL: Documentation that the treatment has resulted in clinical benefit defined as one or more of the following: a.) Decreased use of systemic corticosteroids b.) Increase in Forced Expiratory Volume (FEV1) from pretreatment baseline c.) Decreased use of inhaled corticosteroid use for at least 3 days d.) Decrease in hospitalizations e.) Decrease in ER visits OR f.) Decrease in unscheduled visits to healthcare provider. C. CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP): INITIAL: (1) Patient has a documented diagnosis (supported by documentation from the patients chart notes/medical records) of CRSwNP with the presence of nasal polyps AND (2) 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 AND (3) Patient is unable to achieve symptom relief after trial of intranasal corticosteroids AND (4) Patient will continue to use Dupixent in combination with intranasal corticosteroid therapy RENEWAL: Documentation that the patient has responded to Dupixent as determined by the prescribing physician.

### DYSPORT

### **Products Affected**

• DYSPORT

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= Benzaepril, 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**

• pimecrolimus

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	(1) Diagnosis of mild to moderate atopic dermatitis AND (2) Patient is not immunocompromised AND (3) Patient had a documented trial and failure, intolerance, or contraindication to at least ONE formulary topical corticosteroid (e.g., hydrocortisone, amcinonide, betamethasone, clobetasol, desoximetasone, fluocinolone, triamcinolone) OR (4) Elidel will be used on the face, body skin folds, genital area, armpit, or around the eyes AND (54) Patient has had a documented trial and failure, intolerance, or contraindication to tacrolimus ointment.
Age Restrictions	2 years of age or older
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 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

PA Criteria	Criteria Details
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

# EMGALITY

### **Products Affected**

• EMGALITY

#### • EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
Covered Uses	Preventative treatment of migraines in adults, Treatment of episodic cluster headache in adults
Exclusion Criteria	Concurrent use with another CGRP inhibitor; Concurrent use with Botox; Acute treatment of migraines
Required Medical Information	A. Migraine Prophylaxis (1) Patient has clinically diagnosed chronic migraine defined as greater than or equal to 8 migraine days per month and greater than or equal to 15 headache days per month OR (2) Patient has clinically diagnosed episodic migraine defined as 4 to 14 migraine days per month AND (3) Patient has 2 month trial and failure of, had a contraindication to, or intolerance to at least 2 standard prophylactic pharmacologic therapies, each from a different class, used to prevent migraines or reduce frequency including a. Angiotensin receptor blockers b. Angiotensin Converting Enzyme Inhibitors c. Beta-blockers (propranolol, metoprolol, atenolol) d. Calcium channel blockers (verapamil) e. Anti-epileptics (topiramate, divalproex) f. Antidepressants (venlafaxine, amitriptyline, nortriptyline) OR (4) (Patients who meet the chronic migraine definition only) Patient has tried and failed Botox (onabotulinumtoxina) for at least 2 quarterly injections (6 months) B. Episodic Cluster Headache (1) Patient has diagnosis of episodic cluster headache AND (2) Patient has between 1 headache every other day and 8 headaches per day
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	6 month initial; 1 year renewal
Other Criteria	B. Renewal (1) Positive response to therapy demonstrated by a 50% reduction in monthly migraine days AND (2) Patient use of acute migraine medications (NSAIDs, triptans) has decreased since starting

PA Criteria	Criteria Details
	Emgality AND (3) Patient has overall improvement in function with therapy.

### **ENBREL**

#### **Products Affected**

- ENBREL
  - ENBREL MINI

#### **PA** Criteria **Criteria Details Covered Uses** Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis Exclusion Concurrent use with a biologic DMARD Criteria Required A. Rheumatoid Arthritis/Psoriatic Arthritis/Juvenile Idiopathic Arthritis Medical (1) Patient has diagnosis of Rheumatoid Arthritis, Psoriatic Arthritis, or Information Juvenile Idiopathic Arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) B. Ankylosing Spondylitis (1) Patient has diagnosis of Ankylosing Spondylitis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 therapy C. Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND (2)Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) D. Renewal for all Indications (1) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Enbrel Juvenile Idiopathic Arthritis-2 years of age and older, Plaque Psoriasis-4 **Age Restrictions** years of age and older, Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis -18 years of age and older Prescriber Prescribed by or in consultation with rheumatologist or dermatologist Restrictions Initial= 3 months, Renewal = 3 yearsCoverage Duration **Other Criteria** None

ENBREL SURECLICK

### **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% 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. B. SYMPTOMATIC HEART FAILURE WITH SYSTEMIC LEFT VENTRICULAR SYSTOLIC DYSFUNCTION (FOR PEDIATRIC PATIENTS ONLY BETWEEN THE AGES OF 1-18) (1) Prescriber attests to a diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction RENEWAL: (1) 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**

• EPCLUSA ORAL TABLET

• sofosbuvir-velpatasvir

PA Criteria	Criteria Details
Covered Uses	Chronic Hepatitis C (GT 1, 2, 3, 4, 5, and 6)
Exclusion Criteria	If sofosbuvir/velpatasvir is administered with ribavirin, the contraindications to ribavirin also apply
Required Medical Information	A. CHRONIC HEPATITIS C (1) 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) History of previous HCV therapies documentation of dates of treatment required, AND (4) Presence/Absence of Cirrhosis. For patients with cirrhosis, cirrhosis must be documented by FibroScan, Fibrotest Actitest, liver biopsy, or radiological imaging. IF REQUESTING EPCLUSA MUST HAVE TRIED AND FAILED GENERIC sofosbuvir-velpatasvir.
Age Restrictions	3 years of age and older
Prescriber Restrictions	Prescribed by, or in conjunction with, a Gastroenterologist, Hepatologist, or Infections Disease Specialist
Coverage Duration	See Other Criteria
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 INTERFEREON-ALFA THERAPY , INTIAL (1) Prescriber attests to a diagnosis of anemia and concurrent use of ribavirin and interferon-alfa

PA Criteria	Criteria Details
	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 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 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 serum ferritin greater than or equal to 100 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 to 100 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 Colitits) AND (2)

PA Criteria	Criteria Details
	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 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

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	Initial= 6 months, Renewal= 12 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)
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

# **EVZIO NON FORMULARY**

#### **Products Affected**

• EVZIO INJECTION SOLUTION AUTO- • naloxone hcl injection solution auto-INJECTOR 2 MG/0.4ML

injector 2 mg/0.4ml

PA Criteria	Criteria Details
Covered Uses	Opiate dependency or addiction, Increased risk of opioid-induced respiratory depression, Medically accepted indications will also be considered for approval
Exclusion Criteria	None
Required Medical Information	A. OPIATE DEPENDENCY OR ADDICTION (1) Prescriber attests to diagnosis of opiate dependency or addiction AND (2) Patient is receiving addiction counseling services AND (3) Prescriber provides rationale as to why Narcan (naloxone) nasal spray cannot be used B. INCREASED RISK OF OPIOID-INDUCED RESPIRATORY DEPRESSION (1) Prescriber deems patient at increased risk of opioid-induced respiratory depression AND (2) The prescriber completes the Opioid Overdose Risk Assessment Checklist Form found at the following link: http://evzio.com/pdfs/Evzio- Opioid-Overdose-Risk-Assessment-Checklist.pdf AND (3) The medication is to be administered outside of a healthcare facility (such as a personal residence or school) AND (4) Prescriber provides rationale as to why generic naloxone injection rescue kit cannot be used AND (5) Prescriber provides rationale as to why Narcan (naloxone) nasal spray cannot be used
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

PA Criteria	Criteria Details
Prescriber Restrictions	None
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) 3 mg Fe/g dw or higher AND (2) Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC) 3 mg Fe/g dw or higher AND (2) Patient

PA Criteria	Criteria Details
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
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 (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 (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**

• 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 ORAL CAPSULE 10 MG, 20 MG

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 patient's 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 2ECOG 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

PA Criteria	Criteria Details
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

PA Criteria	Criteria Details
Other Criteria	None

# FASLODEX

#### **Products Affected**

• fulvestrant

DA Critaria	Critoria Dotoila
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 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, 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

PA Criteria	Criteria Details
Coverage Duration	12months
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) at least ONE IR opioid AND (2b) at least ONE ER opioid 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) at least ONE IR opioid AND (2b) at least ONE ER opioid 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) at least ONE IR opioid AND (2b) at least ONE ER
Age Restrictions	None
Prescriber Restrictions	None

PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	None

## FERRIPROX

### **Products Affected**

• deferiprone

#### • FERRIPROX ORAL SOLUTION

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

PA Criteria	Criteria Details
Other Criteria	None

## FINACEA

### **Products Affected**

• azelaic acid external

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

# FLECTOR PATCH NON FORMULARY

### **Products Affected**

 diclofenac epolamine transdermal patch 1.3 %

PA Criteria	Criteria Details
Covered Uses	Acute pain, due to minor strains, sprains and contusions. Medically accepted indications will also be considered for approval
Exclusion Criteria	None
Required Medical Information	A. ACUTE PAIN (1) Diagnosis of Acute pain, due to minor strains, sprains and contusions AND (2) An inadequate response or intolerance to a trial of oral diclofenac and two other covered oral prescription strength generic NSAIDs OR (2) Oral nsaid is not appropriate due to any one of the following- (2a) inability to swallow or absorb oral medications (2b) Current anticoagulant use (2c) History of a GI bleed (2d) History of Peptic Ulcer Disease (2e) Chronic heart failure AND (3) An inadequate response or intolerance to a trial of lidocaine 3% cream or capsaicin AND (4) An inadequate response or intolerance to a trial of diclofenac 1% gel.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 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

PA Criteria	Criteria Details
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **FORFIVO NON FORMULARY**

#### **Products Affected**

- *bupropion hcl er (xl) oral tablet extended* FLECTOR TRANSDERMAL PATCH release 24 hour 450 mg
  - 1.3 %
  - 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 corticosteriod, 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 HYPOGONODAL 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 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

PA Criteria	Criteria Details
Prescriber Restrictions	None
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 • *lanthanum carbonate* CHEWABLE

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 non LMWH* (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

PA Criteria	Criteria Details
Prescriber Restrictions	None
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

• GAMUNEX-C

 GAMMAKED INJECTION SOLUTION 10 GM/100ML, 20 GM/200ML, 5 GM/50ML

PA Criteria	Criteria Details
Covered Uses	<ul> <li>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.</li> </ul>
Exclusion Criteria	None
Required Medical Information	<ul> <li>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</li> </ul>

PA Criteria	Criteria Details
	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 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

## 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.

PA Criteria	Criteria Details
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## **GLEEVEC**

### **Products Affected**

• *imatinib mesylate* 

PA Criteria	Criteria Details	
Covered Uses	Criteria Details 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)	

PA Criteria	Criteria Details	
	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 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 Hodgkin's 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			
Exclusion Criteria	Known hypersensitivity to metformin HCL			
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		

### **GROWTH HORMONE**

#### **Products Affected**

- GENOTROPIN MINIQUICK
- GENOTROPIN SUBCUTANEOUS
   SOLUTION RECONSTITUTED 5 MG
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5
- OMNITROPE

- SAIZEN
- SAIZENPREP
- SEROSTIM SUBCUTANEOUS SOLUTION RECONSTITUTED 5 MG, 6 MG
- ZOMACTON
- ZOMACTON (FOR ZOMA-JET 10)
- ZORBTIVE

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
<b>Exclusion</b> <b>Criteria</b>	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 

PA Criteria	Criteria Details		
Required Medical Information	and failure of one preferred product OMNITROPE before a secondary		
Age Restrictions	No age restriction for Omnitrope only. 18 years of age and younger for all others.		
Prescriber Restrictions	Prescribed by, or in conjunction, with an Endocrinologist.		
Coverage Duration	Initial 6 months. Renewal 12 months		
Other Criteria	C. GROWTH FAILURE IN CHRONIC RENAL INSUFFICIENCY (CKD): (1) Documented diagnosis of CKD AND (2) non-fused epiphyses AND (3) Patient has not had a kidney transplant D. ADULT GH DEFICIENCY: (1) Documented diagnosis of Adult onset GH deficiency AND (2) Documented negative response to 1 of the standard growth hormone stimulation test listed , (2a)Arginine-GHRH, peak GH less than or equal to 11.0 ng/L if BMI less than 25 , peak GH less than or equal to		

PA Criteria Criter	ia Details
8.0 ng/I than or DOPA ( than or ng/ml) 0 Prescrib deficient (3b) Thy Gonado stimulat deficient docume lower li SHORT Docume specialit diet that AND (3 Patient 1 WASTI Docume patient 1 the follo 90% of to 20 kg parenter energy 1 limited growth doubles patient's RENEW parental range I0	La Details L if BMI greater than or equal to 25 and less than 30 , peak GH less equal to 4.0 ng/L if BMI greater than or equal to 30, Arginine-L- (less than 1.5 ng/ml) OR (2b) Insulin-induced Hypoglycemia (less equal to 5.0 mcg/ml)OR (2c) Glucagon (less than or equal to 3.0 OR (2d) Macrilen (macimorelin) and a BMI less than 40 OR (3) wer attests to 3 or more of the following pituitary hormone cies, (3a) Adrenocorticotropin hormone (ACTH) deficiency OR yroid stimulating hormone (TSH) deficiency OR (3c) tropin deficiency (luteinizing hormone [LH] and/or follicle ing hormone [FSH])OR (3d) Arginine vasopressin (AVP) cy [central diabetes insipidus] OR (4) Prescriber attests to a nted serum IGF-1 level lower than the gender and age-specific mit of normal (less than 2.5 percentile or less than -2 SDS) E. <sup>1</sup> BOWEL SYNDROME(SBS) (ZORBTIVE ONLY): INITIAL: ented diagnosis of SBS AND (2) Patient must be receiving zed nutritional support (defined as a high carbohydrate, low-fat <sup>1</sup> is adjusted for individual patient requirements and preferences) ) Therapy is limited to one 4 week course per year AND (4) is greater than or equal 18 years of age F. HIV ASSOCIATED NG OR CACHEXIA(SEROSTIM ONLY): INITIAL: ented diagnosis of HIV associated wasting or cachexia AND (2) has a documented unintentional weight loss as defined by one of owing, a. 10% weight loss from baseline OR b. Weight less than the lower limit of ideal body weight OR c. BMI less than or equal (m2 AND (3) Patient must be able to consume or be fed through al or enteral feedings greater than or equal to 75% of maintenance requirements based on current body weight AND (4) Therapy is to 24 weeks. RENEWAL IN CHILDREN: (1) Documented rate has must have increased significantly (height velocity at least by the end of the first year) AND (2) Documentation that the a height Velocity is greater than or equal 2.5cm per year. VAL IN ADULTS: (1) The patient has not reached the mid- height AND (2) Goal of therapy is to reach middle of the normal J

# **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 HYPERPARATHRYROIDISM (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 NON FORMULARY

### **Products Affected**

•	BERINERT	٠	KALBITOR
•	CINRYZE	•	ORLADEYO
•	FIRAZYR	•	RUCONEST
•	HAEGARDA	•	TAKHZYRO

PA Criteria	Criteria Details
Covered Uses	Hereditary Angioedema, FDA approved indications will also be considered for approval.
Exclusion Criteria	History of anaphylactic or life-threatening hypersensitivity reactions to human C1 inhibitor, Firazyr ecellantide or any component of the formulation. RUCONEST ONLY: known or suspected allergy to rabbits and rabbit derived products.
Required Medical Information	<ul> <li>A. HAE: PROPHYLAXIS INTIAL (CINRYZE, HAEGARDA, ORLADEYO OR TAKHZYRO) (1) The patient has a diagnosis of Type I or Type II hereditary angioedema (HAE) documented by chart notes/medical records by ONE of the following: (1a) BOTH of the following (there must be TWO separate low measurements for each test defined as below the testing laboratory's lower limit of the normal range):</li> <li>i. Low Serum complement factor 4 (C4) level AND ii. EITHER Low C1- INH antigenic level OR Low C1-INH functional level OR (1b) The patient has a mutation in the C1INH gene altering protein synthesis and/or function AND (2) The requested agent will be used for prophylaxis against HAE attacks AND (2a) The patient is receiving only ONE agent indicated for prophylaxis against HAE attacks OR (2b) The other agent being used for prophylaxis will be discontinued before starting the requested agent AND (2c) The patient has had at least 2 acute severe attacks per month (i.e. swelling of the throat, cutaneous or incapacitating abdominal swelling) AND</li> <li>(3) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, and estrogens) AND (4) Member has tried and failed, intolerant to, or has a contraindication to danazol PROPHYLAXIS RENEWAL (1) Prescriber attests to a</li> </ul>

PA Criteria	Criteria Details
	documented decrease in HAE attack frequency AND (2) Decrease in severity and duration of attacks B. HAE: ACUTE (BERINERT, FIRAZYR, , KALBITOR, OR RUCONEST) INITIAL (1) The patient has a diagnosis of Type I or Type II hereditary angioedema (HAE) documented by chart notes/medical records by ONE of the following: (1a) BOTH of the following (there must be TWO separate low measurements for each test defined as below the testing laboratory's lower limit of the normal range): i. Low Serum complement factor 4 (C4) level AND ii. EITHER Low C1-INH antigenic level OR Low C1-INH functional level OR (1b) The patient has a mutation in the C1INH gene altering protein synthesis and/or function AND CONT
Age Restrictions	Cinryze, Haegarda: 6 years of age or older, Ruconest: 13 years or older, Firazyr,: 18 years or older, , Kalbitor, Orladeyo, Takhzyro: 12 years or older, Berinert: None
Prescriber Restrictions	Prescribed by or in consultation with medical geneticist, allergist, immunologist, or hematologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	<ul> <li>(2) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, estrogens) AND (3)</li> <li>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 (4)</li> <li>Prescriber attests that patient is receiving only ONE agent indicated for treatment of acute HAE attack OR the other agent being used for acute HAE attacks will be discontinued before the starting requested agent AND (5) ONE of the following: (5a) Dose is within the program quantity limit (allows for 2 acute attacks/month)OR (5b) 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 FOR BERINERT, FIRAZYR, KALBITOR, OR RUCONEST (6) If Member is over 18 years of age, must have tried and failed generic icatibant RENEWAL: [BERINERT, FIRAZYR, KALBITOR, OR RUCONEST]: (1) Member has experienced a significant improvement in severity and duration of attacks, yet continues to have occurrence of acute attacks AND (2)The prescriber has communicated (via any means) with the</li> </ul>

PA Criteria	Criteria Details
	patient regarding frequency and severity of attacks and has verified patient does not have greater than 1 month supply (sufficient for 2 acute attacks) currently on-hand. Berinert 5,000 IU (10 vials)/30 days, Cinryze 10,000 units (20 vials)/30 days, Firazyr 6 syringes/30 days, Kalbitor 4 kits/30 days, Ruconest 8 vials/30 days, Takhzyro 2 vials/28 days, Haegarda 56,000 IU/28 days, Doses less than 2,000 IU, must use (1) 2,000IU vial, Doses greater than 2,000IU but less than 3,000IU, must use (1) 3,000IU vial, Doses greater than 3,000IU but less than 4,000IU, must use (2) 2,000IU vials, Doses greater than 4,000IU but less than 5,000IU must use (1) 2,000IU vial and (1) 3,000IU vial, Doses greater than 5,000 but less than 6,000IU can use either (3) 2,000IU vial OR (2) 3,000IU vial, Doses greater than 6,000IU but less than 8,000IU must use (2) 3,000IU vials AND (1) 2,000IU vial, Doses greater than 8,000IU must use (3) 3,000IU vials, Doses greater than 9,000IU must use (3) 3,000IU vials, Doses greater than 9,000IU must use (3) 3,000IU vials, Doses greater than 9,000IU must use (2) 2,000IU vials to a compare the for weight in adults and averaged for men and women to 238 lbs (108 kg), may be adjusted by CD pharmacists for higher patient weights

### 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

### **HIV NON FORMULARY**

#### **Products Affected**

• DESCOVY

# TRUVADA ORAL TABLET 200-300 MG

PA Criteria	Criteria Details
Covered Uses	Treatment of HIV-1 infection, HIV-1 Pre-Exposure Prophylaxis (PrEP), HIV Post Exposure Prophylaxis (PEP)
Exclusion Criteria	None
Required Medical Information	A. Treatment of HIV-1 infection (1) Patient has diagnosis of HIV-1 AND (2) Patient has clinically significant trial and failure of emtricitabine- tenofovir disoproxil (must provide chart notes) AND (3) Patient has tried and failed, has a contraindication to, or has an intolerance to 2 additional formulary alternatives B. HIV-1 Prophylaxis (PrEP) OR (PEP) (1) Medication is being used for PrEP or PEP AND (2) Patient has clinically significant trial and failure of emtricitabine-tenofovir disoproxil (must provide chart notes) OR (4) For Descovy only: Patient has or is at risk for decreased bone mineral density, fracture or osteomalacia. Chart notes must be provided that indicate ONE of the following: a. previous fragility fracture OR b. diagnosis of osteomalacia OR c. T-score less than -2.5 at lumbar spine, total hip, femoral neck in men, OR d. T-score less than -2.5 to -1.0 AND 10-year risk of all osteoporotic fracture by FRAX greater than 20% or 10-year risk of all osteoporotic fracture by FRAX greater than 20% AND (5) For Descovy only: Not being utilized in patients at risk of infection from receptive vaginal sex
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 years
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	<ul> <li>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 (lgGless 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</li> </ul>

PA Criteria	Criteria Details
	diagnosis of Dermatomyositis (including juvenile) or Polymyositis AND (2) Tried/failed/intolerance to corticosteroids and adjuvant therapy (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

# 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
- HUMIRA PEDIATRIC CROHNS
   START
- HUMIRA PEN

- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS
   START
- HUMIRA PEN-PSOR/UVEIT STARTER
- HUMIRA PEN-CD/UC/HS STARTER

PA Criteria	Criteria Details
Covered Uses	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohns Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa, Uveitis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Rheumatoid Arthritis/Psoriatic Arthritis/Juvenile Idiopathic Arthritis (1) Patient has diagnosis of Rheumatoid Arthritis, Psoriatic Arthritis, or Juvenile Idiopathic Arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) B. Ankylosing Spondylitis (1) Patient has diagnosis of Ankylosing Spondylitis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 therapy C. Crohns Disease (1) Patient has diagnosis of Crohns Disease AND (2) Patient is experiencing a severe exacerbation AND (3) Patient has documented failure or intolerance to or contraindication to trial of at least one form of conventional therapy including aminosalicylates (mesalamine and sulfasalazine), immunomodulators (azathioprine) or corticosteroids D. Ulcerative Colitis (1) Patient has diagnosis of Ulcerative Colitis AND (2) Patient has an inadequate response to oral immunosuppressants such as corticosteroids, azathioprine, and 6-mercaptopurine. E. Plaque Psoriasis (1) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 1 year) plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-

PA Criteria	Criteria Details
	month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) CONT IN OTHER CRITERIA
Age Restrictions	Juvenile Idiopathic Arthritis, Uveitis-2 years of age and older; Crohns Disease-6 years of age and older; Rheumatoid arthritis/psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, ulcerative colitis-5 years of age and older; Hidradenitis suppura-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= 3 months, Renewal = 3 years
Other Criteria	F. Hidradenitis Suppurativa (1) Patient has diagnosis of Hidradenitis Suppurativa AND (2) Patient has documented trial and failure of at least one other therapy, such as intralesional or oral corticosteroids or systemic antibiotics G. Uveitis (1) Patient has diagnosis of non-infectious intermediate, posterior, and panuveitis AND (2) Patient has chronic, recurrent, treatment refractory or vision-threatening disease AND (3) Patient has documented failure or intolerance to or contraindication to trial of conventional therapy such as corticosteroids or immunosuppressive drugs (azathioprine, cyclosporine, or methotrexate) H. Renewal for all Indications (1) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Humira.

# HYDROXYPROGESTERONE NON FORMULARY

#### **Products Affected**

• hydroxyprogesterone caproate intramuscular

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- Immunoglbulin 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:

PA Criteria	Criteria Details
Age Restrictions	18 years of age or older
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) otolaryngologist (ENT physician) (iv) pulmonologist (v) infectious diseases 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) infectious diseases physician (iv) pulmonologist (v) infectious diseases physician the streament (cor 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 bel

PA Criteria	Criteria Details
	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 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

### **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.

# ICATIBANT

#### **Products Affected**

• *icatibant acetate* 

PA Criteria	Criteria Details
Covered Uses	Hereditary Angioedema, FDA approved indications will also be considered for approval
Exclusion Criteria	History of anaphylactic or life-threatening hypersensitivity reactions to human C1 inhibitor, icatibant, ecellantide or any component of the formulation.
Required Medical Information	B. HAE: ACUTE INITIAL (1) The patient has a diagnosis of Type I or Type II hereditary angioedema (HAE) documented by chart notes/medical records by ONE of the following: (1a) BOTH of the following (there must be TWO separate low measurements for each test defined as below the testing laboratory's lower limit of the normal range): i. Low Serum complement factor 4 (C4) level AND ii. EITHER Low C1-INH antigenic level OR Low C1-INH functional level OR (1b) The patient has a mutation in the C1INH gene altering protein synthesis and/or function AND (2) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, estrogens) AND (3) 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 (4) Prescriber attests that patient is receiving only ONE agent indicated for treatment of acute HAE attack OR the other agent being used for acute HAE attacks will be discontinued before the starting requested agent AND (5) ONE of the following: (5a) Dose is within the program quantity limit (allows for 2 acute attacks/month)OR (5b) 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 RENEWAL: (1) Member has experienced a significant improvement in severity and duration of attacks, yet continues to have occurrence of acute attacks AND (2)The prescriber has communicated (via any means) with the patient regarding frequency and severity of attacks and has verified patient does not have greater than 1 month supply (sufficient for 2 acute attacks) currently on-hand. icatibant 6 syringes/30 days

PA Criteria	Criteria Details
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with medical geneticist, allergist, immunologist, or hematologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None

### ICLUSIG

#### **Products Affected**

• ICLUSIG ORAL TABLET 15 MG, 45 MG

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

PA Criteria	Criteria Details
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 patient's 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

PA Criteria	Criteria Details
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
Coverage Duration	12 months
Other Criteria	None

# ILUMYA NON FORMULARY

#### **Products Affected**

• ILUMYA

PA Criteria	Criteria Details
Covered Uses	Plaque Psoriasis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) moderate to severe plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) AND (4) Patient has documented trial and failure of or intolerance to or contraindication of Enbrel, Humira, Otezla, Skyrizi, Stelara, AND Cosentyx B. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Ilumya.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

### **IMBRUVICA**

#### **Products Affected**

• IMBRUVICA ORAL CAPSULE 140 MG • IMBRUVICA ORAL TABLET 420 MG,

560 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

PA Criteria	Criteria Details
	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 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

PA Criteria	Criteria Details
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*

GONAL-F RFF REDIJECT

• ganirelix acetate

• 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

PA Criteria	Criteria Details
	cycles if other cause of infertility have been ruled out for ovarian failure or 12 months if prescriber attest to improvement in condition for 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,

PA Criteria	Criteria Details
	including but not limited to, azathioprine, methotrexate, NSAIDs, DMARDs, corticosteroids, sulfasalazine, mesalamine, etc. AND (3) 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 40 MG, 80 MG

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 isn't being used AND why switching to a 2nd generation antipsychotic if on a 1st generation isn't 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

# INTRAROSA

#### **Products Affected**

• INTRAROSA

PA Criteria	Criteria Details
Covered Uses	Moderate to Severe Dyspareunia
Exclusion Criteria	Undiagnosed abnormal genital bleeding, pregnant or breastfeeding, current or past history of breast cancer
Required Medical Information	A. MODERATE TO SEVERE DYSPAREUNIA (1) Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause AND (2) the patients has tried and failed two vaginal lubricants or vaginal moisturizers AND (3) Failure of greater than a 4 week trial of two vaginal estrogen (e.g., Estrace vaginal cream, Premarin vaginal cream, Vagifem, Estring) RENEWAL: (1) The patient meets all of the criteria for new starts AND (2) Patient has been evaluated and seen improvement on Intrarosa
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial=3 months, Renewal= 12 months
Other Criteria	Dose must not exceed 1 vaginal insert daily

### **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- HODKINS 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)

PA Criteria	Criteria Details
	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 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
- INVEGA TRINZA INTRAMUSCULAR SUSPENSION 273 MG/0.875ML, 410

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

•

MG/1.315ML, 546 MG/1.75ML, 819

MG/2.625ML

paliperidone er

# 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 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 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 con
Age Restrictions	None

PA Criteria	Criteria Details
Prescriber Restrictions	None
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, Chronic Graft- Versus-Host Disease, FDA Approved 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 D. CHRONIC GRAFT-VERSUS-HOST DISEASE (1) Prescriber attests patient has diagnosis of steroid-refractory acute graft-versus-host disease AND (2) Has had failure of 1 or 2 lines of systemic therapy E.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

PA Criteria	Criteria Details
	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
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

# **KALYDECO NON FORMULARY**

#### **Products Affected**

• KALYDECO

PA Criteria	Criteria Details
Covered Uses	Diagnosis of Cystic fibrosis.
Exclusion Criteria	Not to be used in conjunction with another cystic fibrosis transmembrane regulator (Symdeko, Orkambi, or Trikafta)
Required Medical Information	A. CYSTIC FIBROSIS (1) Documented diagnosis of Cystic fibrosis AND (2) Must have documentation of one of the following gating or residual function mutations in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data (arrows have been replaced with dashes in mutations [note - if mutation given is not one of the following please verify package insert])- refer to criteria section 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) Patient is not homozygous for the F508del mutation in the CFTR gene B. CONTINUATION OF THERAPY (1) Documentation patient is tolerating and responding to medication (i.e. improved FEV1 (only for patients 6 and older), weight gain, decreased exacerbations, etc.) (2) Adherence to therapy is confirmed (supported by documentation from patients chart notes or electronic claim history)
Age Restrictions	Member is 4 months of age or older
Prescriber Restrictions	Prescribed by an appropriate specialist such as pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None

### **KEVZARA**

#### **Products Affected**

• KEVZARA

PA Criteria	Criteria Details
Covered Uses	Rheumatoid Arthritis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Rheumatoid Arthritis (1) Patient has clinically diagnosed moderate to severe active rheumatoid arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to 2 of the following: Humira, Enbrel, or Rinvoq B. Renewal for all Indications (1) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Kevzara
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
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,

PA Criteria	Criteria Details
	test results, or clinical markers supporting the diagnosis and or continuing treatment.
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 NON FORMULARY**

#### **Products Affected**

• KINERET

PA Criteria	Criteria Details
Covered Uses	Rheumatoid Arthritis, Cryopyrin-Associated Periodic Syndromes- Neonatal Onset Multisystem Inflammatory Disease
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Moderate to Severely Active Rheumatoid Arthritis (1) Patient has diagnosis of moderate to severe RA AND (2) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of one DMARD agent (MTX, leflunomide, or sulfasalazine) AND (3) Patient has documented trial and failure of or intolerance to or contraindication of Enbrel, Humira, AND Kevzara B. Cryopyrin- Associated Periodic Syndromes (1) Patient has diagnosis of Neonatal Onset Multisystem Inflammatory Disease C. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Kineret.
Age Restrictions	RA-18 years of age and older
Prescriber Restrictions	RA-Prescribed by or in consultation with Rheumatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

# KISQALI

# **Products Affected**KISQALI (200 MG DOSE)

- KISQALI (600 MG DOSE)
- KISQALI (400 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 fulvestrantwill 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	When prior authorization is approved, up to 21 capsules may be authorized per 28 days. Authorization may be reviewed at least annually

PA Criteria	Criteria Details
	to confirm that current medical necessity criteria are met and that the medication is effective?

# **KORLYM NON FORMULARY**

#### **Products Affected**

• KORLYM

PA Criteria	Criteria Details
Covered Uses	Hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushings syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. FDA approved indications will also be considered for approval.
Exclusion Criteria	Pregnancy, Coadministration with simvastatin, lovastatin, and CYP3A substrates with narrow therapeutic ranges (eg, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus), Concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses (eg, immunosuppression after organ transplantation), History of unexplained vaginal bleeding, Endometrial hyperplasia with atypia or endometrial carcinoma.
Required Medical Information	A. HYPERGLYCEMIA- INITIAL : (1) Patient has a documented diagnosis (supported by documentation from the patients chart notes/medical records) of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial: 12 months, Renewal: 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 NON FORMULARY**

#### **Products Affected**

• KUVAN ORAL PACKET

- sapropterin dihydrochloride oral tablet soluble 100 mg
- KUVAN ORAL TABLET SOLUBLE 100
   MG

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 tetrahydrobterin- (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% 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 Macrgloblinemia/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 MACRGLOBLINEMIA/LYMPHOPLASMACYTIC LYMPHOMA (1)

PA Criteria	Criteria Details
	Prescriber attests to diagnosis of Waldenstroms Macrgloblinemia/Lymphoplasmacytic Lymphoma AND (2) Requested 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.

### LABA-LAMA INHALERS NON FORMULARY

#### **Products Affected**

• BEVESPI AEROSPHERE

DUAKLIR PRESSAIR

PA Criteria	Criteria Details
Covered Uses	Chronic obstructive pulmonary disease (COPD).
Exclusion Criteria	Severe hypersensitivity to milk proteins, Treatment of asthma or acute bronchospasms
Required Medical Information	1. Patient has a diagnosis of chronic obstructive pulmonary disease (COPD), AND 2. Patient has a documented tolerance to, or treatment failure, of an adequate trial to BOTH Anoro Ellipta AND Stiolto Respimat.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# 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	<ul> <li>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</li> <li>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</li> </ul>
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

PA Criteria	Criteria Details
Covered Uses	Pulmonary hypertension WHO group I, WHO Class II or III. FDA approved indications will also be considered
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) patient has a diagnosis of Pulmonary hypertension WHO group I, WHO Class II or III (documented by chart notes/medical records with diagnosis based on right heart catheterization with the following parameters: mean pulmonary artery pressure (PAP) greater than or equal to 25mmHg, pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg or pulmonary vascular resistance (PVR) > 3 Wood units) AND (3) Patient does not have idiopathic pulmonary fibrosis (IPF). RENEWAL CRITERIA (1) Patient has diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1 WHO CLASS II OR III) AND (2) Patient has shown improvement from baseline in the 6-minute walk distance test OR Patients WHO functional class remained stable or has improved
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 myelosupressive 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

PA Criteria	Criteria Details
	(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 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 myelosupressive 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 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

PA Criteria	Criteria Details
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

PA Criteria	Criteria Details
Other Criteria	None

## LUCEMYRA NON FORMULARY

#### **Products Affected**

• LUCEMYRA

PA Criteria	Criteria Details
Covered Uses	Indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.
Exclusion Criteria	None
Required Medical Information	A. Chart notes/documentation supporting indication AND B. Provider attestation that if the patient is taking methadone, baseline electrocardiogram (ECG) has been performed AND C. Provider attestation that patient is not concurrently using opioid medication without explanation (verified by state opioid database, if available) AND D. Provider attestation Lucemyra is used in conjunction with other withdrawal symptom management medications (i.e. stool softeners, sleep aides) and psychosocial support to help prevent relapse.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	None

### LUPANETA

#### **Products Affected**

• LUPANETA PACK COMBINATION KIT 11.25 & 5 MG, 3.75 & 5 MG

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 (4-MONTH)

• LUPRON DEPOT (6-MONTH)

- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-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 as defined by DSM-5 criteria 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)

PA Criteria	Criteria Details
	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. Endometriosis/Uterine Leiomyomata: females greater than or equal to 18 years of age.
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. medroprogesterone 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). **this prior authorization does not apply to leuprolide acetate 1mg/0.2ml daily injection kits. E. GENDER DYSPHORIA (1) Patient has diagnosis of gender dysphoria as defined by DSM-5 criteria AND (2) Provider has documentation that the patient has the capacity to make fully informed decisions and consents to treatment 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 are supported toxicity D. PANCREATIC CANCER (1) Prescriber attests to a diagnosis of deleterious or suspected deleterious deleterious deleterious deleterious attests to a diagnosis of deleterious or suspected deleterious or a diagnosis of deleterious or suspected deleterious delet
Age Restrictions	18 years of age or older
Prescriber Restrictions	None

PA Criteria	Criteria Details
Coverage Duration	Initial: 3months, Renewal: 6 months
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**

• pregabalin

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.
Exclusion Criteria	None
Required Medical Information	A. NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC NEUROPATHY OR POST-HERPETIC NEURALGIA (1) The 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 of ONE of the following (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claims history) (2a) Tricyclic antidepressants (amitriptyline, desipramine, imipramine, and nortriptyline) (2b) A traditional anticonvulsant (e.g. carbamazepine, sodium valproate) (2c) venlafaxine (2d) gabapentin (2e) duloxetine B. SEIZURE DISORDER (1) The 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 ONE of the following-(2a) Dilantin (2b) Depakote (2c) Depakene (2d) Lamictal OR C. FIBROMYALGIA (1) The 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	(3) Symptoms have been present for at least 3 months AND (4) Conditions mistaken for fibromyalgia have been ruled out (e.g. rheumatoid arthritis, peripheral neuropathies, infection) AND (5) Tried and failed or intolerance to a 30 day trial with ONE of 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 ONE 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

# MAKENA NON FORMULARY

### **Products Affected**

hydroxyprogesterone caproate
 intramuscular
 MAKENA

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 ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	Diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5, or 6.
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) 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) For treatment experienced patients: History of previous HCV therapies documentation of dates of treatment required, AND (4) Presence/Absence of Cirrhosis. For patients with cirrhosis, cirrhosis must be documented by FibroScan, Fibrotest Actitest, liver biopsy, or radiological imaging.
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
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, 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
- raloxifene hcl

• ergoloid mesylates oral

• sirolimus oral

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 ifosfamine-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**

• 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

• XATMEP

• RASUVO

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 patient's 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 patient's 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

PA Criteria	Criteria Details
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 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

# MIACALCIN

#### **Products Affected**

• calcitonin (salmon) injection

PA Criteria	Criteria Details
Covered Uses	Hypercalcemia, Pagets Disease, Postmenopausal osteoporosis
Exclusion Criteria	Hypersensitivity of calcitonin-salmon or any component of the product
Required Medical Information	A. HYPERCALCEMIA (1) Documented diagnosis of hypercalcemia AND (2) Corrected total serum calcium of greater than or equal to 12 mg/dl (must provide documentation) OR (3) Greater than or equal to corrected total serum calcium of 6 mEq/L (must provide documentation) B. PAGETS DISEASE (1) Documented diagnosis of Pagets disease AND (2) patient has a history of failure or intolerance to two oral bisphosphonates (e.g. alendronate) C. POSTMENOPAUSAL OSTEOPOROSIS (1) Chart notes indicates patient has diagnosis of postmenopausal osteoporosis AND (2) has had a trial and failure to a bisphosphonate or selective estrogen- receptor modulator (SERM) AND (3) History or intolerance to calcitonin(salmon) nasal spray (4) has a history of vertebral compression fractures, or fractures of the hip or distal radius resulting from minimal trauma, or T score of -2.5 or less
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Hypercalcemia= 1month, all others= 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

#### • MYORISAN

• CLARAVIS

- ZENATANE
- isotretinoin oral capsule 10 mg, 20 mg, 30 mg, 40 mg

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

PA Criteria	Criteria Details
Covered Uses	Tinea corporis, Tinea cruruis, 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	Alzheimer's 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 Alzheimer's 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

# NARCOLEPSY NON FORMULARY

#### **Products Affected**

• WAKIX

#### • XYREM

PA Criteria	Criteria Details
Covered Uses	Narcolepsy with Cataplexy or Narcolepsy with Excessive Daytime Sleepiness. Additional FDA approved indications will be considered for approval. No non-FDA approved indications will 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 the requested drug (5) Patient does not meet above criteria (6) Concomitant use of narcotics
Required Medical Information	A. NARCOLEPSY WITH CATAPLEXY (1)Patient has diagnosis of Narcolepsy with cataplexy substantial enough to warrant treatment (2) Must have tried and failed or have intolerance to a one month trial of two formulary tricyclic antidepressants AND two formulary SSRIs (3) Must be prescribed by a neurologist or a sleep specialist (4) Patients are to be evaluated by physician no less frequently than every 3 months (5) Xyrem 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 two formulary/preferred stimulant treatments, such as methylphenidate or dextroamphetamine AND (3) Must have tried and failed or have an intolerance to at least a one month trial of armodafinil AND modafinil at maximally tolerated doses AND (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) Xyrem Quantity limit of 540 mL/ 30 days
Age Restrictions	18 years of age or older
Prescriber Restrictions	Must be prescribed by a neurologist or a sleep specialist

PA Criteria	Criteria Details
Coverage Duration	Initial: 1 month Renewal: 6 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**

- FULPHILA
- NEULASTA
- NEULASTA ONPRO

#### • NYVEPRIA

- UDENYCA
- ZIEXTENZO

PA Criteria	Criteria Details
Covered Uses	FULPHILA, NEULASTA, NYVEPRIA, UDENYCA, and ZIEXTENZO: Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia NEULASTA ONLY: Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).
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	A. DECREASE THE INCIDENCE OF INFECTION AS MANIFESTED BY FEBRILE NEUTROPENIA: STEP ALERT: MUST HAVE TRIED, FAILED, OR INTOLERANT TO PREFERRED AGENT: ZIEXTENZO PRIOR TO USE OF NON-PREFERRED AGENTS: FUPHILA, NEULASTA, NYVEPRIA OR UDENYCA. NEULASTA ONPRO: MUST HAVE TRIED, FAILED, OR INTOLERANT TO ZIEXTENZO FIRST AND THEN NEULASTA (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, Recent surgery g. Poor performance status h. Poor renal function i. Liver dysfunction (i.e. elevated bilirubin) j. 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

PA Criteria	Criteria Details
	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. B. HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME: [NEULASTA ONLY NOT NEULASTA ONPRO] (1) Used for hematopoietic sub syndrome of acute radiation syndrome
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), 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

PA Criteria	Criteria Details
	transplantation OR (1g) Prescriber attests that use is for mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis SEE OTHER CRITERIA
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	Parkinson's 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

# **NEUROTOXINS NON FORMULARY**

#### **Products Affected**

• BOTOX COSMETIC

• BOTOX

#### • MYOBLOC

• XEOMIN

DYSPORT

PA Criteria	Criteria Details
Covered Uses	FDA approved indications (excluding cosmetic)
Exclusion Criteria	Hypersensitivity to botulinum toxin or any component of the formulation. Infection at the proposed injection site, Treatment of cosmetic indications, and treatment of the following conditions that is not considered medically necessary: biliary dyskinesia, irritable bowel, pain conditions not associated with spasticity/dystonia (i.e. myofascial pain and fibromyalgia), plantar hyperhidrosis and wrinkles.
Required Medical Information	A. FOR AXILARY HYPERHIDROSIS:INITIAL (Botox only): (1) Prescriber provides documented diagnosis of severe primary axillary hyperhidrosis (chart notes/medical records) AND (2) Prescriber attests to a documented trial and failure of topical antiperspirants (e.g. prescription strength aluminum chloride) B. FOR OVERACTIVE BLADDER AND URINARY INCONTIENCE DUE TO DETRUSOR OVER ACTIVITY: INITIAL (Botox only): (1a) Prescriber provides documented diagnosis of overactive bladder (chart notes/medical records) OR (1b) Prescriber provides documented diagnosis of urinary incontinence due to detrusor over activity associated with a neurologic condition (chart notes/medical records) AND (2) Prescriber attests to a documented trial and failure of TWO anticholinergic medications (e.g. oxybutynin, tolterodine, etc.) C. FOR CHORNIC MIGRAINE: INITIAL (Botox only): (1) Prescriber provides documented diagnosis of chronic migraine (chart notes/medical records) AND (2) Prescriber attests to documentation of more than 15 migraine headache days per month lasting more than 4 hours per day AND (3a) Patient is utilizing standard abortive medications, intolerance or failure to standard abortive medications AND (4) Prescriber attests to a documented trial and failure of TWO prophylactic agents from different therapeutic classes (e.g. propranolol, amitriptyline, topiramate, valproic acid, diltiazem, verapamil etc.) D. FOR ALL OTHER FDA APPROVED INDICATIONS: INITIAL: (1) Prescriber provides documented diagnosis

PA Criteria	Criteria Details
	of a FDA approved indication (chart notes/medical records) AND (2) Members age is appropriate for the requested indication AND (3) Prescriber attests that indication is not for cosmetic purpose (verify plan design) CONT.
Age Restrictions	See FDA approved indications
Prescriber Restrictions	None
Coverage Duration	Initial= 6 months, Renewal= 6 months
Other Criteria	(4) Prescriber attests to a documented trial and failure of the currently accepted standard therapies used to treat the member's condition as described in the medical compendium 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 member's condition. E. RENEWAL FOR ALL INDICATIONS: (1) Prescriber provides documentation of applicable diagnoses via chart notes or medical records and that patient continues to meet the initial criteria for the specific indication AND (2a) Prescriber attests to documentation of a clinically significant reduction in severity or frequency of symptoms OR (2b) Prescriber attests to documentation of an improvement of functional ability.

# NEXAVAR

#### **Products Affected**

• NEXAVAR

PA Criteria	Criteria Details
Covered Uses	Advanced renal cell carcinoma (RCC), Unresectable hepatocellular carcinoma, Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC)
Exclusion Criteria	None
Required Medical Information	A. Advanced renal cell carcinoma (RCC): documentation to support diagnosis is submitted. B. Unresectable hepatocellular carcinoma: documentation to support diagnosis is submitted. C. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC): documentation to support diagnosis is submitted AND patients disease is refractory to radioactive iodine treatment
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in conjunction with, an oncologist.
Coverage Duration	12 months
Other Criteria	None

# Nexium Granules et al NON FORMULARY

#### **Products Affected**

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

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 three (3) 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 INTRAVENOUS

• posaconazole

• NOXAFIL ORAL SUSPENSION

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 hematopoetic 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

PA Criteria	Criteria Details
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), Hypereosinophilic syndrome (HES), Chronic rhinosinusitis with nasal polyps. FDA approved indications will also be considered for approval.
Exclusion Criteria	Nucala will not be used in conjunction with benralizumab (Fasenra), dupilumab (Dupixent), omalizumab (Xolair) or reslizumab (Cinqair). NOT to be used for the relief of acute bronchospasm or status asthmaticus
Required Medical Information	A. EOSINOPHILLIC ASTHMA: INITIAL: (1) Patient has 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. RENEWAL: (1) Documentation 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 attests that member continues to take at least a medium dose inhaled corticosteroid with either a LABA, leukotriene modifier, or theophylline. B. EOSINOPHILIC GRANULOMATOSIS WITH POLYANGITIS (EGPA): INITIAL: (1) Patient has 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) Documentation that the member has experienced ONE of the following: improved symptom control, disease remission, decrease hospitalizations, decreased rescue medication use, and/or decreased oral corticosteroids). RENEWAL: (1) Documentation that the member has experienced ONE of the following: improved symptom control, disease remission, decrease hospitalizations, decreased oral corticosteroids). RENEWAL: (1) Documentation that the member has experienced ONE of the following: improved symptom control, disease remission, decrease hospitalizations, decreased oral corticosteroids). RENEWAL: (1) Documentation that the member has experienced ONE of the following: impr

PA Criteria	Criteria Details
Age Restrictions	Eosinophilic asthma: 6 years of age or older. EGPA: 18 years of age or older. HES: 12 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	C. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS: INITIAL: (1) Documented diagnosis of Chronic rhinosinusitis with nasal polyps AND (2) Patient has had an inadequate response to nasal corticosteroids (must be supported by documentation from the patients chart notes/medical records/electronic claim history) AND (3) Patient has had a trial and failure of Dupxient AND mometasone (must be supported by documentation from the patients chart notes/medical records/electronic claim history) RENEWAL: (1) Documentation that the member has experienced ONE of the following: improved symptom control, disease remission, decrease hospitalizations, decreased exacerbations. D. HYPEREOSINOPHILIC SYNDROME (HES): INITIAL: (1) Documented diagnosis of HES for greater than or equal to 6 months AND (2) Prescriber attests to no identifiable non hematologic secondary cause (e.g drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) AND (3) Prescriber attests that patient has had HES flare while on stable HES therapy (such as chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy) AND (4) Prescriber reports eosinophil count greater than or equal to 1000cell/mcL RENEWAL: (1) Documented disease stabilization or improvement with medication (i.e. reduction in number of HES flares, reduction in eosinophil count)

# 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

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by, or in conjunction with, a pulmonologist
Coverage Duration	Initial= 6 months, Renewal= 12 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.

## **OLUMIANT NON FORMULARY**

### **Products Affected**

• OLUMIANT

PA Criteria	Criteria Details
Covered Uses	Rheumatoid Arthritis
Exclusion Criteria	Use with potent immunosuppressants such as azathioprine and cyclosporine, Concurrent use with a biologic DMARD
Required Medical Information	A. Rheumatoid Arthritis (1) Patient has diagnosis of moderate to severely active rheumatoid arthritis AND (2) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, or leflunomide) AND (3) Patient has documented trial and failure of or intolerance to or contraindication of Enbrel, Humira, AND Kevzara B. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Olumiant.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with Rheumatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

# **ONCOLOGY**

### **Products Affected**

- ALIMTA
- busulfan
- dacarbazine
- ERBITUX INTRAVENOUS SOLUTION 100 MG/50ML
- gemcitabine hcl intravenous solution 1 gm/26.3ml, 2 gm/52.6ml, 200 mg/5.26ml
- gemcitabine hcl intravenous solution reconstituted
- 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
- temsirolimus
- 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

PA Criteria	Criteria Details
	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
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

### **Products Affected**

• clobazam

#### • 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/medication usage must be supported by documentation from the patients chart notes/medication usage must be supported by documentation from the patients chart notes/medication (medication usage must be supported by documentation from the patients chart notes/medication (medication usage must be supported by documentation from the patients chart notes/medication (medication usage must be 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 ORAL TABLET 10 MG, 5 MG • oxymorphone hcl er

**PA** Criteria **Criteria Details Covered Uses** Chronic Pain, Medically accepted indications will also be considered for approval Exclusion Moderate and severe hepatic impairment, Paralytic ileus Criteria A. CHRONIC PAIN (1) Prescriber attests to a diagnosis of chronic pain Required Medical requiring an opioid analgesic AND (2) used for management of moderate-Information 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 None Prescriber Restrictions 12 months Coverage **Duration** None **Other Criteria** 

### **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 patient's 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, hepatoxicity
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 STARTER PACK
- ORALAIR ADULT SAMPLE KIT SUBLINGUAL TABLET SUBLINGUAL 300 IR
- 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 NON FORMULARY**

#### **Products Affected**

#### ORENCIA

#### • ORENCIA CLICKJECT

PA Criteria	Criteria Details
Covered Uses	Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis, Adult Psoriatic Arthritis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Rheumatoid Arthritis (1) Patient has diagnosis of Rheumatoid Arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Enbrel, Humira, Rinvoq, AND Kevzara B. Psoriatic Arthritis (1) Patient has diagnosis of Psoriatic Arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Enbrel, Humira, Otezla, Stelara, AND Cosentyx C. Polyarticular Juvenile Idiopathic Arthritis (1) Patient has diagnosis of Juvenile Idiopathic Arthritis AND (2) Patient has documented failure or intolerance to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Humira and Enbrel D. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Orencia
Age Restrictions	Psoriatic Arthritis, Rheumatoid Arthritis- 18 years of age and older; Juvenile Idiopathic Arthritis-2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist

PA Criteria	Criteria Details
Coverage Duration	Initial= 3 months, Renewal = 3 years
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 patient's 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

# **ORILISSA NON FORMULARY**

### **Products Affected**

• ORILISSA

PA Criteria	Criteria Details
Covered Uses	Moderate to severe pain associated with endometriosis All FDA approved indications.
Exclusion Criteria	Pregnancy. Known osteoporosis. Severe hepatic impairment (Child-Pugh C). Patients taking inhibitors of organic anion transporting polypeptide (OATP)1B1 (a hepatic uptake transporter) that are known or expected to significantly increase elagolix plasma concentrations
Required Medical Information	(1) Patient had a documented diagnosis of moderate to severe pain due to endometriosis; AND (2) Patient has had a previous trial, intolerance, or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen, meloxicam, etc.); AND (3) Patient has had a previous trial, intolerance, or contraindication to a progestin-containing preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy); AND (4) Patient meets one of the following criteria: (a) For Orilissa 150mg: Patient has normal liver function or mild hepatic impairment (Child-Pugh Class A) OR Patient have moderate hepatic impairment (Child-Pugh Class B) OR (b) For Orilissa 200mg: Patient has normal liver function or mild hepatic impairment (Child-Pugh Class B) OR (b) For Orilissa 200mg: Patient has normal liver function or mild hepatic impairment (Child-Pugh Class B) OR (b) For Orilissa 200mg:
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an obstetrician/gynecologist.
Coverage Duration	See Other Criteria
Other Criteria	Initial: 6 months. Renewal (150 MG): 18 months, maximum of 24 months. Renewal (200 MG): No renewal allowed

### 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 B. CONTINUATION OF THERAPY (1) Documentation patient is tolerating and responding to medication (i.e. improved FEV1 (only for patients 6 and older), weight gain, decreased exacerbations, etc.) (2) Adherence to therapy is confirmed (supported by documentation from patients chart notes or electronic claim history)
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	Moderate to Severe Plaque Psoriasis, Psoriatic Arthritis, Oral Ulcers associated with Behcets Disease
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Moderate to Severe Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) B. Psoriatic Arthritis (1) Patient has diagnosis of psoriatic arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) C. Behcets Disease (1) Patient has diagnosis of Behcets Disease AND (2) Patient has at least two active oral ulcers AND (3) Patient has documented trial and failure of or intolerance to or contraindication to one nonbiologic Behcets Disease medication (corticosteroid, immunosuppressants, azathioprine, cyclosporine, cyclophosphamide, or colchicine) D. Renewal for all Indications (1) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Otezla
Age Restrictions	18 years of age or older
Prescriber Restrictions	Psoriatic Arthritis= Prescribed by or in consultation with a rheumatologist or dermatologist, Psoriasis= Prescribed by or in consultation with a dermatologist, Behcets Disease= prescribed by or in consultation with a rheumatologist, dermatologist, or physician who specialize in the treatment of Bechets Disease.
Coverage Duration	Initial= 3 months, Renewal = 3 years

PA Criteria	Criteria Details
Other Criteria	None

# **OXANDRIN (OXANDROLONE)**

### **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	<ul> <li>(1) Known or suspected carcinoma of the prostate or the male breast (2)</li> <li>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</li> </ul>
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

### OXAYDO

### **Products Affected**

• oxycodone hcl er

#### • OXYCONTIN

PA Criteria	Criteria Details
Covered Uses	Severe Pain that Requires an Opioid Analgesic or 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. SEVERE PAIN THAT REQUIRES AN OPIOID ANALGESIC OR CHRONIC SEVERE PAIN IN OPIOID-TOLERANT PATIENTS REQUIRING A LONG-TERM DAILY AROUND-THE-CLOCK OPIOID ANALGESIC (1) Prescriber attests patient has diagnosis of Severe pain that requires an opioid analgesic or Chronic, severe pain in opioid-tolerant patients requiring a long-term daily around-the-clock opioid analgesic (2) One of the following: (i) Member has had a trial and inadequate clinical response or intolerance to two preferred short acting agent (Oxycodone tablet, morphine sulfate tablet, oxycodone/APAP, hydromorphone) (ii) Patient has a need for an abuse-deterrent formulation based upon a history of substance abuse disorder by dissolving in order to inject or snorting (iii) Patient has a need for an abuse-deterrent formulation based upon household resident has active substance abuse disorder or a history of substance use disorder
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **OXBRYTA NON FORMULARY**

### **Products Affected**

• OXBRYTA

PA Criteria	Criteria Details
Covered Uses	Sickle cell disease. FDA approved indications will also be considered for approval.
Exclusion Criteria	(1) Severe Hepatic Impairment (2) Current Pregnancy (3) Leflunomide Treatment
Required Medical Information	A. SICKLE CELL DISEASE INTIAL: 1. Patient has a diagnosis of sickle cell disease AND 2. Patient has a hemoglobin of less than 10.5 g/dL AND 3. Patient is having symptoms of anemia with are interfering with activities of daily living AND 4. Patient has had a trial and failure to, contraindication to, or intolerance to hydroxyurea B. RENEWAL: 1. Patient has diagnosis of sickle cell disease AND 2. Patient has maintained an improvement in symptoms associated with anemia.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	12 months
Other Criteria	None

## **PAXIL SUSPENSION**

### **Products Affected**

• paroxetine hcl 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

### PCSK9

#### **Products Affected**

- PRALUENT
- REPATHA

#### • REPATHA PUSHTRONEX SYSTEM

• REPATHA SURECLICK

PA Criteria	Criteria Details
Covered Uses	To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease, As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C), As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C, FDA approved indications.
Exclusion Criteria	None
Required Medical Information	A. HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH), INITIAL: (1) Patient has diagnosis of HeFH confirmed by Simon Broome criteria listed below, a. Prescriber reports Total cholesterol greater than 290mg/dL in adults or greater than 260mg/dL in children less than 16yo or LDL cholesterol greater than 190mg/dL in adults or greater than 155mg/dL in children less than 16yo PLUS ONE OF THE FOLLOWING,(i)1st degree or 2nd degree relative similarly affected or with premature CAD or with positive genetic testing for an LDL-C raising gene defect (LDL receptor, apoB or PCSK9) OR (ii) Genetic evidence of an LDL receptor mutation, familial defective apo B- 100, or a PCSK9 mutation OR (iii) Tendon xanthoma in the patient or 1st degree relative AND (2a) Prescriber attests that PCSK-9 will be used in combination with a maximally tolerated statin OR (2b) Prescriber attests that member is statin intolerant and can provide rationale to intolerance or contraindication. B.HOMOZYGOUS FAMILIAL HYPERCHOLESTSEROLEMIA (HoFH) INITIAL: (1) Prescriber attests to a diagnosis of HoFH confirmed by clinical diagnosis based ANY one the following, (i) Patient has a documented history of untreated LDL-C greater than 400 mg/dL and 1 or both parents having clinical diagnosed familial hypercholesterolemia (FH) or (ii). Prescriber attests to genetic

PA Criteria	Criteria Details
	evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation or autosomal recessive FH or (iii). Prescriber attests to documented history of untreated LDL-C greater than 560 mg/dL or (iv). LDL-C greater than 400mg/dL with aortic valve disease or (v). LDL-C greater than 400mg/dL with xanthomata at less than 20 years of age AND (2a) Prescriber attests that PCSK-9 will be used in combination with a maximally tolerated statin OR (2b) Prescriber attests that member is statin intolerant and can provide rationale to intolerance or contraindication. SEE OTHER CRITERIA
Age Restrictions	CVD: 18 years of age or older, HeFH: 18 years of age or older (Praluent); 10 years of age or older (Repatha), HoFH: 13 years of age or older (Praluent); 10 years of age or older (Repatha)
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or lipid specialist
Coverage Duration	Initial: 12 months, Renewal: 12 months
Other Criteria	C. CLINICAL ASCVD OR PRIMARY HYPERLIPIDEMIA AT HIGH RISK FOR ASCVD: INITIAL:(1a) Patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) as defined as one of the following, a. History of or current acute coronary syndrome b. myocardial infarction (MI) c. coronary or other arterial revascularization d. stroke e. transient ischemic stroke (TIA) f. stable/unstable angina g. peripheral arterial disease presumed to be atherosclerotic region OR (1b) Patient is at high risk for ASCVD or CV event based on 10-year risk score use by one of the following tools: i. ASCVD pooled cohort risk assessment: score greater than or equal to 7.5 percent OR ii. Framingham Risk Score: score greater than or equal to 20 percent AND (3) Prescriber reports: baseline and current LDL-C AND (4) One of the following, (a) baseline LDL-C is between 70-189mg/dL OR (b) patient requires greater than 25 percent additional lowering of LDL-C AND (5) (a) Prescriber attests PCSK-9 will be used in combination with a maximally tolerated high-intensity statin OR (b) Prescriber attests that member is statin intolerant, as demonstrated by experiencing, i. Documented statin-associated rhabdomyolysis OR ii Documented myositis or myalgia related symptoms with either, rosuvastatin, atorvastatin OR another maximally tolerated statin AND (7) Requires LDL-C reduction after at least a 960 day trial of BOTH of the following: (a) high-intensity statin (atorvastatin 40- 80mg OR rosuvastatin 20-40mg) or documentation of maximally tolerated statin AND (b) in

PA Criteria	Criteria Details
	combination with ezetimibe FOR ALL INDICATIONS: RENEWAL:(1) Documented response, defined as ONE of the following, (a) Prescriber reports percentage reduction of LDL is greater than or equal to 40 percent compared to pre- PCSK-9 treatment OR (b) Prescriber reports absolute LDL is less than 70 mg/dL AND (2) Patient is tolerating the medication AND (3) Patient will continue to be used in combination with a maximally tolerated statin or is statin intolerant demonstrated by experiencing (a) Documented statin-associated rhabdomyolysis OR (b) Documented myositis or myalgia related symptoms with either, rosuvastatin, atorvastatin OR another maximally tolerated statin.

### **PEGASYS/PEGINTRON**

#### **Products Affected**

- PEGASYS
- PEGASYS PROCLICK SUBCUTANEOUS SOLUTION 180 MCG/0.5ML
- PEGASYS PROCLICK
   SUBCUTANEOUS SOLUTION AUTO INJECTOR 180 MCG/0.5ML
- PEGINTRON SUBCUTANEOUS KIT 50 MCG/0.5ML

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

## **PENNSAID SOLUTION NON FORMULARY**

#### **Products Affected**

- diclofenac sodium external solution
- PENNSAID
- diclofenac sodium transdermal solution 1.5 %
- PENNSAID TRANSDERMAL SOLUTION 2 %

PA Criteria	Criteria Details
Covered Uses	Osteoarthritis. Medically accepted indications will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	A. OSTEOARTHRITIS (1) Prescriber attests patient has diagnosis of Osteoarthritis (2) An inadequate response or intolerance to a trial of oral diclofenac and two other covered oral prescription strength generic NSAIDs (2) Oral NSAID is not appropriate due to any one of the following: (i) Inability to swallow or absorb oral medications (ii) Current anticoagulant use (iii) History of a GI bleed (iv) History of Peptic Ulcer Disease (v) Chronic heart failure (3) An inadequate response or intolerance to a trial of lidocaine 3% cream or capsaicin (4) An inadequate response or intolerance to a trial of Diclofenac 1% gel (5) An inadequate response or intolerance to a trial of diclofenac 1.5% solution (for Pennsaid 2% solution only)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
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 patient's 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

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

# **PREPOPIK NON FORMULARY**

#### **Products Affected**

• PREPOPIK ORAL PACKET 10-3.5-12 MG-GM-GM

PA Criteria	Criteria Details
Covered Uses	Colonoscopy Preparation. Medically accepted indications will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	A. COLONOSCOPY PREPARATION (1) Prescriber attests patient has diagnosis of Colonoscopy Preparation (2) Patient is 18 years of age or older (3) Prescribed by, or in consultation with, a Gasteroenterologist (4) Patient has a documented intolerance to, or treatment failure of Suprep and Moviprep
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

## **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

PA Criteria	Criteria Details
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 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

PA Criteria	Criteria Details
	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 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	Hypersensitivity to modafinil or the related compound armodafinil or any of their inactive ingredients
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) Patient has cataplexy, accompanied by irresistible attacks of refreshing sleep that occur daily over at least 3 months 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	17 years of age and older
Prescriber Restrictions	None

PA Criteria	Criteria Details
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**

• 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. John's wort)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### RAPAFLO

#### **Products Affected**

• 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**

• 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

# **RAYOS NON FORMULARY**

### **Products Affected**

• RAYOS

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	Patients who have known hypersensitivity to prednisone.
Required Medical Information	1. Patient has had a documented a prior trial and inadequate response to one generic immediate-release oral prednisone agent AND 2. Patient has had a documented a prior consecutive trial and inadequate response to TWO (2) additional generic oral corticosteroids (e.g., prednisolone, methylprednisolone, hydrocortisone) AND (3) Documentation has been provided for why the delayed-release agent is clinically necessary and NOT for convenience.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 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

PA Criteria	Criteria Details
Prescriber Restrictions	None
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

PA Criteria	Criteria Details
	least one agent from within each of the following laxative types: (i) Fiber laxatives (ii) Stimulant laxatives (iii) Osmotic laxatives
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# RENVELA/ RENAGEL (SEVELAMER CARBONATE)

#### **Products Affected**

• RENVELA

• sevelamer hcl

• sevelamer carbonate

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

# **REVATIO (SILDENAFIL CITRATE)**

#### **Products Affected**

• sildenafil citrate oral tablet

PA Criteria	Criteria Details
Covered Uses	Pulmonary Hypertension WHO Group 1. FDA approved 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) Concomitant use with HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine (3) Concomitant use with riociguat or any other guanylate cyclase stimulator (4) Hypersensitivity reaction or contraindication to sildenafil
Required Medical Information	A. PULMONARY HYPERTENSION WHO GROUP 1 (1) 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 patient's medical records
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

### 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. FDA approved 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) Must be receiving concurrent treatment with dexamethasone OR (3) being used for maintenance therapy following autologous hematopoietic stem cell transplantation (4) Absolute neutrophil count (ANC) of at least 500/mL (5) Platelet count of at least 50,000/mL (5) 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	Prescribed by or in conjunction with an oncologist or hematologist
Coverage Duration	None
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 diagnosis of Tuberculosis In 10 Prescriber attests patient has diagnosis of Tuberculosis 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

PA Criteria	Criteria Details
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# RINVOQ

#### **Products Affected**

• RINVOQ

PA Criteria	Criteria Details
Covered Uses	Rheumatoid arthritis
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) 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) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after 3 months of therapy with Rinvoq.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist
Coverage Duration	Initial= 3 months, Renewal = 3?years
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 (2) 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

PA Criteria	Criteria Details
	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
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 patient's condition RENEWAL FOR RA and PV: (1) Prescriber attests patient has been evaluated on is not clinically appropriate for patient's condition AND (2) Prescriber attests that the 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 patient's 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, Infantil spasms greater than/= 1 month to less than/= 2 years of age
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **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 LAR DEPOT

SANDOSTATIN

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 gastrinomal (iv) Used for the management of locorgional advanced or metastatic disease of the bronchopulmoary, 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

PA Criteria	Criteria Details
	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
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**

• asenapine maleate

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) (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

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 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 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

PA Criteria	Criteria Details
	must be greater than 150 pg/ml and calcium must be greater than or equal to8.4 mg/dL
Age Restrictions	None
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 than 2.2 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

PA Criteria	Criteria Details
Other Criteria	None

# SILIQ NON FORMULARY

### **Products Affected**

• SILIQ

PA Criteria	Criteria Details
Covered Uses	Plaque Psoriasis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) moderate to severe plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) AND (4) Patient has documented trial and failure of Enbrel, Humira, Otezla, Skyrizi, Stelara, AND Cosentyx B. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Siliq
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with dermatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

### **SIMPONI NON FORMULARY**

#### **Products Affected**

• SIMPONI

• SIMPONI ARIA

PA Criteria	Criteria Details
Covered Uses	Ankylosing spondylitis (AS), Active polyarticular Juvenile Idiopathic Arthrisit (pJIA) [SIMPONI ARIA], Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC)
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Psoriatic Arthritis (1) Patient has diagnosis of psoriatic arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3- month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Otezla, Stelara, AND Cosentyx B. Rheumatoid Arthritis (1) Patient has diagnosis of rheumatoid arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Rinvoq, AND Kevzara C. Ankylosing Spondylitis (1) Patient has diagnosis of ankylosing spondylitis AND (2) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Rinvoq, AND Kevzara C. Ankylosing Spondylitis (1) Patient has diagnosis of ankylosing spondylitis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel AND Cosentyx D. Ulcerative Colitis (1) Patient has diagnosis of ulcerative colitis AND (2) Patient has documented failure or intolerance to or contraindication to trial of at least one form of conventional therapy including aminosalicylates (mesalamine and sulfasalazine), immunomodulators (azathioprine) or corticosteroids AND (3) Patient has documented failure or intolerance to or contraindication to Humira AND Stelara E. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS(PJIA) (SIMPONI ARIA ONLY) (1) A documented diagnosis of a PJIA AND (2) Must have a tried and failed one conventional therapy indicated for the diagnosis, including but not limited to, a

PA Criteria	Criteria Details
	(3) STEP ALERT: TRIAL AND FAILURE OF BOTH ENBREL AND HUMIRA
Age Restrictions	AS, RA, UC: 18 years of age or older , PsA/pJIA [SIMPONI ARIA ONLY]: 2 years of age or older
Prescriber Restrictions	Rheumatoid arthritis, ankylosing spondylitis-prescribed by or in consultation with rheumatologist; Psoriatic arthritis-prescribed by or in consultation with rheumatologist or dermatologist; Ulcerative colitis- prescribed by or in consultation with gastroenterologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	E. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Simponi

### SIRTURO

### **Products Affected**

• SIRTURO ORAL TABLET 100 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved Indications
Exclusion Criteria	Latent infection due to Mycobacterium tuberculosis, Drug-sensitive tuberculosis, Extra-pulmonary tuberculosis, Infections caused by non- tuberculous mycobacteria, treatment of HIV infected patients with multi- drug resistant tuberculosis (MDR-TB)
Required Medical Information	(1) Patient has a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) AND (2) patient will be using Sirturo in combination with at least three (3) other drugs to which the patients MDR-TB isolate has been shown to be susceptible in vitro; OR (4) patient will be using Sirturo in combination with at least 4 other drugs to which patients MDR-TB isolate is likely to be susceptible, if in vitro testing results are unavailable; AND (5) for pediatric patients, 5 to less than 18 years of age, patient weighs at least 15 kg.
Age Restrictions	5 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist or pulmonologist.
Coverage Duration	24 weeks
Other Criteria	None

### 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) cylcobenzaprine (ii) orphenadrine (iii) chlorzoxazone (iv) methocarbamol
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **SKLICE**

#### **Products Affected**

• *ivermectin external lotion* 

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

### **Products Affected**

• SKYRIZI

#### • SKYRIZI PEN

• SKYRIZI (150 MG DOSE)

PA Criteria	Criteria Details
Covered Uses	Moderate to Severe Plaque Psoriasis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Moderate to Severe Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) B. Renewal for all Indications (1) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Skyrizi
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

### SOLARAZE NON FORMULARY

#### **Products Affected**

• diclofenac sodium transdermal gel 3 %

PA Criteria	Criteria Details
Covered Uses	Actinic Keratosis. Medically accepted indications will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	A. ACTINIC KERATOSIS (1) Prescriber attests patient has diagnosis of Actinic Keratosis (2) Failed or not a good candidate to receive liquid nitrogen cryotherapy which is the treatment of choice for single or a few scattered small, thin, or shallow lesions (3) Failed or not a good candidate for surgical curettage (note: usually for isolated, thick Actinic Keratoses particularly on the dorsal arms or hands, and in patients who are immunocompromised) (4) Failed or intolerant to topical 5 fluorouracil (note: for multiple Actinic Keratoses)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### 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 QP 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* 

PA Criteria	Criteria Details
Covered Uses	(Capsules) Invasive Systemic Fungal Infection, Onychomycosis of the Finger Nails, Onychomycosis of the Toe Nails (Oral Solution) Candidiasis of the esophagus with and without HIV infection, Oropharyngeal candidiasis with and without HIV infection
Exclusion Criteria	(1) Congestive heart failure (2) Concomitant administration of itraconazole with drugs metabolized by CYP3A4: oral midazolam, pimozide, quinidine, dofetilide, triazolam, lovastatin, and simvastatin
Required Medical Information	CAPSULES A. INVASIVE SYSTEMIC FUNGAL INFECTION (1) Patient has diagnosis of one of the following Invasive, Systemic Fungal Infections (i) Blastomycosis, pulmonary and extrapulmonary OR (ii) Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-menigeal histoplasmosis OR (iii) Aspergillosis, pulmonary and extra pulmonary in patients who are intolerant of or refractory to amphotericin B therapy B. ONYCHOMYCOSIS OF THE FINGER NAILS, ONYCHOMYCOSIS OF THE TOE NAILS (1) Patient has Clinically Documented Onychomycosis of the Finger Nails or Clinically Documented Onychomycosis of the Toe Nails AND (2) Patient is not immunocompromised AND (3) 6 week trial of, contraindication to, or intolerance to oral terbinafine for fingernails or 12 week trial of, contraindication to, or intolerance to oral terbinafine for toenails. SEE OTHER CRITERIA FOR ORAL SOLUTION
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	T Onchy: 12 weeks F Onchy: 5 weeks Histo/Blastomycosis: 12 months. Asper: 6 months, Cand: 2 months
Other Criteria	ORAL SOLUTION A. ESOPHAGEAL CANDIDIASIS (1) Patient has diagnosis of candidiasis of the esophagus with or without HIV AND (2) Patient has trial and failure to, contraindication to or intolerance to 21-day trial of fluconazole B. OROPHARYNGEAL CANDIDIASIS (1) Patient

PA Criteria	Criteria Details
	has diagnosis of oropharyngeal candidiasis with or without HIV. AND (2). Candidiasis is refractory to a trial and failure of 14-day treatment with fluconazole. AND (3) Patient has trial and failure of, contraindication to, or intolerance to 14-day trial of nystatin suspension or clotrimazole troches

# **SPRIX NON FORMULARY**

#### **Products Affected**

- ketorolac tromethamine injection
   SPRIX
- *ketorolac tromethamine intramuscular*

PA Criteria	Criteria Details
Covered Uses	Acute Pain. Medically accepted indications will also be considered for approval.
Exclusion Criteria	<ul><li>(1) Patient is less than 18 years of age (2) Patient has high risk of GI bleed</li><li>(3) Patient has any risk of bleed potential, including CVA and TIA (4)</li><li>Patient needs medication for a longer period than 5 days</li></ul>
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

PA Criteria	Criteria Details
Age Restrictions	See Required Medical Info
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	Moderate to Severe Plaque Psoriasis, Psoriatic Arthritis, Moderate to Severely Active Crohns Disease, Moderate to Severely Active Ulcerative Colitis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Moderate to Severe Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) B. Psoriatic Arthritis (1) Patient has diagnosis of psoriatic arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) C. Crohns Disease (1) Patient has diagnosis of moderately to severely active Crohns Disease AND (2) Patient has documented trial and failure of or intolerance to or contraindication to at least one form of conventional therapy including aminosalicylates (mesalamine and sulfasalazine), immunomodulators (azathioprine), or corticosteroids AND (3) Patient has completed IV induction dose before starting subcutaneous therapy D. Ulcerative Colitis (1) Patient has diagnosis of moderately to severely active Ulcerative Colitis AND (2) Patient has documented trial and failure of or intolerance to or contraindication to at least one form of conventional therapy including aminosalicylates (mesalamine and sulfasalazine), immunomodulators (azathioprine), or corticosteroids AND (3) Patient has completed IV induction dose before starting subcutaneous therapy D. Ulcerative Colitis AND (2) Patient has documented trial and failure of or intolerance to or contraindication to at least one form of conventional therapy including aminosalicylates (mesalamine and sulfasalazine), immunomodulators (azathioprine), or corticosteroids AND (3) Patient has completed IV induction dose before starting subcutaneous therapy E. Renewal for all Indications (1) Patient achieves or maintains a positive clinical response after at l
Age Restrictions	Plaque Psoriasis: 6 years of age and older; all other indications 18 years of age or older

PA Criteria	Criteria Details
Prescriber Restrictions	Crohns Disease/Ulcerative Colitis= prescribed by or in consultation with gastroenterologist, Plaque psoriasis: prescribed by or in consultation with dermatologist, Psoriatic arthritis= prescribed by or in consultation with dermatologist or rheumatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

# **STIMATE NON FORMULARY**

#### **Products Affected**

• STIMATE

PA Criteria	Criteria Details
I A CIIteria	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 Colorectal 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 colorectal cancer (CRC) who has been previously treated with the following: (I) Flouropyrimidine-, 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 soafenib (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

PA Criteria	Criteria Details
	significant adverse drug effects (i.e. Liver toxicity, Hemorrhage, GI perforation or fistula, Skin toxicity, Reversible posterior leukoencephalopathy syndrome (RPLS)
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 auto-injector 6 mg/0.5ml
- *sumatriptan succinate subcutaneous solution*

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) (5) Tried 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**

• *sunitinib malate* 

	1
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. GASTROITESTINAL 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

PA Criteria	Criteria Details
Age Restrictions	None
Prescriber Restrictions	Prescribed by an Oncologist
Coverage Duration	12 months
Other Criteria	None

# SYLATRON NON FORMULARY

#### **Products Affected**

• SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG

PA Criteria	Criteria Details
Covered Uses	Malignant Melanoma, 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. MALIGNANT MELANOMA (1) Prescriber attests patient has diagnosis of Malignant Melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including lymphadenectomy (2) Patient is at least 18 years of age (3) Patient has not received the requested medication for longer than 5 years B. CONTINUATION OF THERAPY (1) Initial criteria continues to be met (2) Prescriber attests to patient demonstrating a clinical response to therapy with Sylatron (e.g. disease progression has slowed or halted)
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **SYMDEKO**

#### **Products Affected**

• SYMDEKO

PA Criteria	Criteria Details
Covered Uses	Cystic Fibrosis
Exclusion Criteria	Not to be used in conjunction with another cystic fibrosis transmembrane regulator (Kalydeco, Orkambi, or Trikafta)
Required Medical Information	A. CYSTIC FIBROSIS, INITIAL : (1) Documentation 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). 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).
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, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849+10kbC-T

### **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

PA Criteria	Criteria Details
	chest radiography or chest CT that persist when stable) or weight for length less than the 10th percentile
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 procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extra-coporeal 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.

PA Criteria	Criteria Details
	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 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 ORAL CAPSULE 250 MG trientine hcl
- SYPRINE

PA Criteria	Criteria Details
Covered Uses	Wilson's 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 MEALNOMA, 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

# **TAGRISSO NON FORMULARY**

#### **Products Affected**

• TAGRISSO

PA Criteria	Criteria Details
Covered Uses	Non-small cell lung cancer (NSCLC)
Exclusion Criteria	None
Required Medical Information	A. Non-Small Cell Lung Cancer (NSCLC): Tagrisso will be used as adjuvant therapy after tumor resection in patients whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. B. Metastatic NSCLC: Tagrisso will be used as first-line treatment in patients whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. C. Metastatic NSCLC: Patients disease is EGFR T790M mutation-positive, as detected by an FDA-approved test, and have had disease progression on or after EGFR tyrosine kinase inhibitor (TKI) therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate]).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in conjunction with, an oncologist.
Coverage Duration	12 months
Other Criteria	None

# TALTZ NON FORMULARY

### **Products Affected**

• TALTZ

PA Criteria	Criteria Details
Covered Uses	Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Non- radiographic Axial Spondylarthritis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) AND (4) Patient has documented trial and failure of Enbrel, Humira, Otezla, Skyrizi, Stelara, AND Cosentyx B. Psoriatic Arthritis (1) Patient has diagnosis of psoriatic arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Otezla, Stelara, AND Cosentyx C. Ankylosing Spondylitis and Non-radiographic Axial Spondylarthritis (1) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (2) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Otezla, Stelara, AND Cosentyx C. Ankylosing Spondylitis and Non-radiographic Axial Spondylarthritis (1) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (2) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel AND Cosentyx D. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Taltz
Age Restrictions	18 years of age or older
Prescriber Restrictions	Ankylosing spondylitis, Non-radiographic Axial Spondylarthritis - prescribed by or in consultation with rheumatologist; Psoriatic arthritis- prescribed by or in consultation with rheumatologist or dermatologist; Plaque Psoriasis-Prescribed by or in consultation with dermatologist Ulcerative colitis-prescribed by or in consultation with gastroenterologist

PA Criteria	Criteria Details
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

## TARCEVA

#### **Products Affected**

• erlotinib hcl

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 cream

• 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
   TECFIDERA
- *dimethyl fumarate starter pack*

PA Criteria	Criteria Details
Covered Uses	Relapsing-Remitting Multiple Sclerosis. FDA approved 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) Patient has diagnosis of relapsing-remitting multiple sclerosis supported by documentation from the patient's 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 IF REQUESTING BRAND, MUST HAVE 3 MONTH TRIAL AND FAILURE OF GENERIC (CHART NOTES REQUIRED)
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**

- ANDROGEL TRANSDERMAL GEL 25 MG/2.5GM (1%), 50 MG/5GM (1%)
- FORTESTA
- *methyltestosterone oral*
- NATESTO
- TESTIM

- TESTOPEL
- testosterone implant
- testosterone transdermal gel
- VOGELXO
- VOGELXO PUMP

PA Criteria	Criteria Details
Covered Uses	Primary or Secondary Hypogonadism, Gender Dysphoria. 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) Documentation confirming low testosterone levels: morning serum testosterone level less than 300ng/dl (10.4 nmol/L) or free serum testosterone level of less than 5 pg/ml (0.17nmol/L) copy of labs must be submitted with request. (3) Must be prescribed by or in consultation with an endocrinologist (4) Must have tried and failure or intolerance to TESTOSTERONE ENANTHATE. B. Delayed puberty (1) documented diagnosis of delayed puberty (2) Prescribed by or in consultation with an endocrinologist (3) Must have tried and failed TESTOSTERONE ENANTHATE C. Gender Dysphoria (1) Patient has diagnosis of gender dysphoria as defined by DSM-5 criteria AND (3) Provider has documentation that the patient has the capacity to make fully informed decisions and consents to treatment D. Renewal for all Indications (1) Patient previously met all initial authorization criteria AND (2)Patient achieves or maintains a positive clinical response
Age Restrictions	Hypogonadism-18 years of age or older (testosterone pellet implant ONLY- 14 years of age or older); Breast cancer-18 years of age or older
Prescriber Restrictions	See Criteria

PA Criteria	Criteria Details
Coverage Duration	Initial: 6 months, Renewal: 1 year (indication of delayed puberty may NOT be renewed)
Other Criteria	None

# **TESTOSTERONE ENANTHATE**

#### **Products Affected**

• *testosterone enanthate intramuscular* 

PA Criteria	Criteria Details
Covered Uses	Treatment of Primary hypogonadism (congenital or acquired) in males, Treatment of Hypogonadotropic hypogonadism (congenital or acquired) in males, Delayed puberty in males, Metastatic mammary cancer in females, Gender Dysphoria, and FDA approved indications will be considered for approval.
Exclusion Criteria	Men with carcinoma of the breast or known or suspected carcinoma of the prostate, Patients with known hypersensitivity to any of the products ingredients, including testosterone USP that is chemically synthesized from soy, Females who are pregnant or breastfeeding
Required Medical Information	A. Primary hypogonadism and Hypogonadotropic hypogonadism (1) Patient is male with diagnosis of primary of hypogonadotropic hypogonadism AND (2) Documentation confirming low testosterone levels: morning serum testosterone level less than 300ng/dl (10.4 nmol/L) or free serum testosterone level of less than 5 pg/ml (0.17 nmol/L) (copy of labs must be submitted with request) B.: Delayed Puberty (1) Patient is male with diagnosis of delayed puberty AND (2) Prescribed by or in consultation with an endocrinologist C. Breast cancer (1) Patient is female with diagnosis of inoperable, metastatic breast cancer AND (2) Patient is 1-5 years postmenopausal AND (3) Prescribed by or in consultation with an oncologist D. Gender Dysphoria (1) Patient has diagnosis of gender dysphoria as defined by DSM-5 criteria AND (2) Provider has documentation that the patient has the capacity to make fully informed decisions and consents to treatment
Age Restrictions	Breast cancer-18 years of age or older
Prescriber Restrictions	See Criteria
Coverage Duration	Initial: 6 months, Renewal: 1 year (indication of delayed puberty may NOT be renewed)

PA Criteria	Criteria Details
Other Criteria	E. Renewal for all Indications (1) Patient previously met all initial authorization criteria AND (2)Patient achieves or maintains a positive clinical response

# 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

PA Criteria	Criteria Details
	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 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

PA Criteria	Criteria Details
	combination with standard chemotherapeutic agents including dexamethasone. Dosing/Regimen: (1) Erytherma 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 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 Thryoglobulin (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	All FDA approved indications.
Exclusion Criteria	Patients with a known hypersensitivity to any aminoglycoside. Patients with an FEV1 less than 25% or greater than 75% predicted. Patients colonized with Burkholderia cepacia
Required Medical Information	Patient has a documented diagnosis of lung infection due to Pseudomonas aeruginosa; AND Patients does not have a known hypersensitivity to any aminoglycoside; AND Patients FEV1 is greater than 25% or less than 75% predicted; AND Patient is not colonized with Burkholderia cepacian.
Age Restrictions	6 years of age or older
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

# **TOLVAPTAN NON FORMULARY**

#### **Products Affected**

• JYNARQUE

• tolvaptan

• SAMSCA

PA Criteria	Criteria Details
Covered Uses	Clinically significant hypervolemic and euvolemic hyponatremia (SAMSCA), to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (JYNARQUE). FDA approved indications will also be considered for approval.
Exclusion Criteria	[SAMSCA AND JYNARQUE]: Urgent need to raise serum sodium acutely, patient inability to sense or respond to thirst, hypovolemic hyponatremia, concomitant use of a strong CYP 3A inhibitor. [SAMSCA ONLY]: Autosomal dominant polycystic kidney disease (ADPKD) [JYNARQUE ONLY]: Those with a history, signs or symptoms of significant liver impairment or injury (NOT including uncomplicated polycystic liver disease), uncorrected urinary outflow obstruction, anuria, uncorrected abnormal blood sodium concentrations
Required Medical Information	A. SAMSCA or generic tolvaptan- CLINICALLY SIGNIFICANT HYPERVOLEMIC AND EUVOLEMIC HYPONATREMIA: INITIAL: (1) Patient has clinically significant hypervolemic or euvolemic hyponatremia, defined as serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and resisted correction with fluid restrictions. AND (2) Initial sodium correction has taken place in a hospital setting AND (3) Patient has not yet received 30 days of SAMSCA. B. JYNARQUE- AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD): INITIAL: (1) Patient has diagnosis of rapidly progressing ADPKD. RENEWAL [JYNARQUE ONLY]: (1) Documentation of positive clinical response to Jynarque.
Age Restrictions	18 years of age or older
Prescriber Restrictions	JYNARQUE: Prescribed by or in consultation with a nephrologist. SAMSCA: No prescriber restriction
Coverage Duration	SAMSCA initial: 30 days. Renewal not allowed. JYNARQUE initial: 3 months, renewal: 12 months

PA Criteria	Criteria Details
Other Criteria	

# TRACLEER

## **Products Affected**

• bosentan

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) Patient has diagnosis of Pulmonary Arterial Hypertension WHO Group 1 WHO Functional Class II to IV symptoms (documented by chart notes/patient medical records with diagnosis based on right heart catheterization with the following parameters: mean pulmonary artery pressure (PAP) greater than or equal to 25mmHg, pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg or pulmonary vascular resistance (PVR) > 3 Wood units) AND (2) Patient does not have idiopathic pulmonary fibrosis (IPF) AND (3) Not utilizing Flolan or Remodulin RENEWAL CRITERIA: (1) Patient has diagnosis of pulmonary arterial hypertension AND (2) Patient has remained stable or improved in exercise ability (e.g. 6-minute walk test) OR patients WHO functional class remained stable or improved.
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, Psoriatic Arthritis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Plaque Psoriasis (1) Patient has chronic (greater than or equal to 1 year) moderate to severe plaque psoriasis AND (2) Patient has minimum body surface area involvement of plaque psoriasis of greater than or equal to 10% AND (3) Patient has documented trial and failure of or intolerance to or contraindication of at least a 3-month trial of systemic agent (MTX, cyclosporine, acitretin, PUVA) AND (4) Patient has documented trial and failure of Enbrel, Humira, Otezla, Skyrizi, Stelara, AND Cosentyx B. Psoriatic Arthritis (1) Patient has diagnosis of psoriatic arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3-month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindications to Humira, Enbrel, Otezla, Stelara, AND Cosentyx C. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Tremfya
Age Restrictions	18 years of age or older
Prescriber Restrictions	Plaque Psoriasis-Prescribed by or in consultation with dermatologist; Psoriatic Arthritis-Prescribed by or in consultation with dermatologist or rheumatologist
Coverage Duration	Initial= 3 months, Renewal = 3 years
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 LYMPOHOMA (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	Cystic Fibrosis
Exclusion Criteria	Not to be used in conjunction with another cystic fibrosis transmembrane regulator (Kalydeco, Orkambi, or Symdeko)
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 OR a mutation in the CFTR gene that is responsive to elexacaftor;tezacaftor;ivacaftor based on in vitro data or clinical evidence (refer to other criteria section) (2) 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)
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]:

# 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 patient's 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, setraline) (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 agonism. The

PA Criteria	Criteria Details
	contribution of these activities to vortioxetines antidepressant effect has 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. FDA approved 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) AND (4) Trial and failure or contraindication to Linzess OR lubiprostone (CO members excluded from this requirement)
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **TUDORZA NON FORMULARY**

### **Products Affected**

• TUDORZA PRESSAIR

PA Criteria	Criteria Details
Covered Uses	Chronic Obstructive Pulmonary Disease (COPD)
Exclusion Criteria	Treatment of asthma or acute bronchospasms, Severe hypersensitivity to milk proteins
Required Medical Information	1. Patient has a diagnosis of COPD AND 2. Patient has had a documented adequate trial and therapeutic failure or intolerance to BOTH Spiriva/Spiriva Respimat AND Incruse Ellipta.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## **TYKERB**

### **Products Affected**

• *lapatinib ditosylate* 

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 STARTER

• TYVASO REFILL

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 patient's 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 HYPERTENSION WHO GROUP I (1) Patient has a diagnosis of Pulmonary hypertension WHO group I NYHA Functional Class II-III (documented by chart notes/patient medical records with diagnosis based on right heart catheterization with the following parameters: mean pulmonary artery pressure (PAP) of ? 25mmHg, pulmonary capillary wedge pressure (PCWP) ? 15 mmHg or pulmonary vascular resistance (PVR) > 3 Wood units) AND (2) Patient does not have idiopathic pulmonary fibrosis (IPF) AND (3) Must have trial and failure or intolerance to Sildenafil (Revatio) or Adcirca (tadalafil) AND Letairis (ambrisentan) RENEWAL CRITERIA (1) Patient diagnosed with pulmonary arterial hypertension AND (2) Patient has shown improvement or remained stable from baseline in the 6-minute walk distance test OR (3) Patients WHO functional class remained stable or has improved
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

PA Criteria	Criteria Details
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# VANTAS NON FORMULARY

#### **Products Affected**

• VANTAS SUBCUTANEOUS KIT 50 MG

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 HYPERPHOSHATEMIA (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 patient's 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

DA Caritoria	Critaria Dataila
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

PA Criteria	Criteria Details
Prescriber Restrictions	None
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

## **Products Affected**

• sildenafil citrate oral tablet

PA Criteria	Criteria Details
Covered Uses	Erectile Dysfunction. FDA approved indications will also be considered for approval.
Exclusion Criteria	<ul> <li>(1) Patient receiving organic nitrates in any form, either regularly or intermittently due to potentiation of the hypotensive effects of nitrates (2) Concomitant use with riociguat or any other guanylate cyclase stimulator</li> <li>(3) Hypersensitivity reaction or contraindication to sildenafil</li> </ul>
Required Medical Information	A. ERECTILE DYSFUNCTION (1) 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
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	All FDA approved indications.
Exclusion Criteria	Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue. The indicated diagnosis (including any applicable labs and /or tests) and medication usage is not supported by documentation from the patient's medical records and/or electronic claim history
Required Medical Information	Patient has had an adequate trial and failure, intolerance, or contraindication with at least ONE (1) generic SSRI AND Patient has had had an adequate trial and failure, intolerance, or contraindication with at least ONE (1) generic SNRI. [Documentation Required]
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# VIMOVO NON FORMULARY

### **Products Affected**

• naproxen-esomeprazole

• VIMOVO

PA Criteria	Criteria Details
Covered Uses	The relief of signs and symptoms of ankylosing spondylitis, osteoarthritis, juvenile idiopathic arthritis and/or rheumatoid arthritis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.
Exclusion Criteria	1. Initial treatment of acute pain 2. Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to naproxen, esomeprazole magnesium, substituted benzimidazoles, or omeprazole 3. The treatment peri-operative pain iIn the setting of a coronary artery bypass graft (CABG) surgery.2. Initial treatment of acute pain 4. History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs 5. Concomitant use with rilpivirine-containing products
Required Medical Information	1. Diagnosis of osteoarthritis, juvenile idiopathic arthritis, rheumatoid arthritis and/or ankylosing spondylitis, AND 2. Patient has a history or current diagnosis of peptic ulcer (gastric or duodenal), gastrointestinal (GI) bleed, GI obstruction, or GI perforation, AND 3. Patient has had a documented adequate trial and therapeutic failure, intolerance, or contraindication of at least TWO (2) generic NSAIDs AND 4. Patient has had a documented adequate trial and therapeutic failure, intolerance, or contraindication to at least TWO (2) generic PPIs, AND 4. Patient has had a documented adequate trial and therapeutic failure of an NSAID taken WITH a PPI.
Age Restrictions	Juvenile idiopathic arthritis: 12 years of age and older. All other indications: 18 years of age and older.
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None

## VIMPAT

### **Products Affected**

• VIMPAT ORAL

PA Criteria	Criteria Details
Covered Uses	Partial-Onset Seizures Requiring Adjunct Therapy, Tonic-Clonic Seizure Requiring Adjunct Therapy, and FDA approved 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) An inadequate response, intolerance to, or contraindication to a trial of at least two alternative anticonvulsants B. PRIMARY GENERALIZED TONIC-CLONIC SEIZURES REQUIRING ADJUNCT THERAPY (1) Prescriber attests patient has diagnosis of Primary Generalized Tonic-Clonic Seizures and requires adjunct therapy AND (2) An inadequate response, intolerance to, or contraindication to a trial of at least two alternative anticonvulsants
Age Restrictions	Partial Seizure= 1 month or older. Tonic-clonic= 4 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.
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	<ul> <li>A. CHRONIC HEPATITIS C INFECTION GENOTYPE 1B, 2, 4, 5, OR</li> <li>6 (1) 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) Patient has diagnosis of Chronic Hepatitis C (HCV) infection genotype (GT) 1a or 3 (2) Patient has previously been treated with a HCV regimen documentation of dates of treatment required 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 AND</li> <li>(3) History of previous HCV therapies, AND (4) Presence/Absence of Cirrhosis. For patients with cirrhosis, cirrhosis must be documented by FibroScan, Fibrotest Actitest, liver biopsy, or radiological imaging.</li> </ul>
Age Restrictions	18 years of age or older
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

# 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 NON FORMULARY**

#### **Products Affected**

• XELJANZ

#### • XELJANZ XR

PA Criteria	Criteria Details
Covered Uses	Psoriatic Arthritis, Rheumatoid Arthritis, Ulcerative Colitis
Exclusion Criteria	Concurrent use with a biologic DMARD
Required Medical Information	A. Psoriatic Arthritis (1)Patient has diagnosis of psoriatic arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to at least 3- month trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Otezla, Stelara, AND Cosentyx B. Rheumatoid Arthritis (1) Patient has diagnosis of moderate to severe Rheumatoid Arthritis AND (2) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of NSAID/COX-2 or steroid therapy AND (3) Patient has documented failure or intolerance to or contraindication to trial of DMARD (MTX, leflunomide, sulfasalazine) AND (4) Patient has documented failure or intolerance to or contraindication to Humira, Enbrel, Rinvoq, AND Kevzara C. Ulcerative Colitis (1) Patient has diagnosis of Ulcerative Colitis AND (2) Patient has documented failure or intolerance to or contraindication to trial of at least one form of conventional therapy including aminosalicylates (mesalamine and sulfasalazine), 6-mercaptopurine immunomodulators (azathioprine) or corticosteroids AND (3) Patient has documented failure or intolerance to or contraindication to Humira AND Stelara D. Renewal for all Indications (1) Patient meets all initial authorization criteria AND (2) Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Xeljanz/Xeljanz XR
Age Restrictions	18 years of age or older
Prescriber Restrictions	Rheumatoid Arthritis-Prescribed by or in consultation with a rheumatologist; Psoriatic Arthritis-Prescribed by or in consultation with a rheumatologist or dermatologist; Ulcerative Colitis-Prescribed by or in consultation with a gastroenterologist

PA Criteria	Criteria Details
Coverage Duration	Initial= 3 months, Renewal = 3 years
Other Criteria	None

## 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, METASTASES, PANCREATIC ADENOCARCINOMA, 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

PA Criteria	Criteria Details
	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 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's 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

PA Criteria	Criteria Details
	completed required training for use of Xiaflex in the treatment of Peyronies disease
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	<ul> <li>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) AND (3)</li> </ul>

## 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

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, and all FDA approved indications.
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) documented diagnosis of moderate to severe persistent asthma AND (2) medication is not being used for acute bronchospasm or status asthmaticus. AND (3a) For patients 12 years of age or older: documented (labs/chart notes required) serum IgE level between 30-700 IU/mL AND Body weight between 66 and 330 lbs OR (3b) For patients 6 to less than 12 years of age: documented serum IgE level between 30-1300 IU/mL AND Body weight between 44 and 330 lbs. AND (4) Patient has a positive skin test or in vitro testing (i.e., blood test for allergen-specific IgE antibodies such as the radioallergosorbent test (RAST) for one or more perennial aeroallergen, AND/OR for one or more season aeroallergen. AND (5) Patients asthma symptoms have not been adequately controlled by inhaled corticosteroids after at least 3 months of therapy. AND (6) Patient is currently using a long acting beta-agonist in combination with a high dose inhaled corticosteroids at maximum doses for a minimum of 3 months. There is evidence of reversible airway disease (12% or greater improvement in FEV1 with at least a 200ml increase of 20% or greater improvement in PEF). Spirometry chart notes required. AND (6) Xolair will not be used in conjunction with benralizumab (Cinqair) B. CHRONIC IDIOPATHIC URTICARIA (CIU): INITIAL: (1) documented diagnosis of moderate to severe chronic idiopathic urticaria AND (2) 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	12 months
Other Criteria	(3) Documentation that the member is symptomatic despite being compliant with: THREE (3) or more H1 antihistamines AND one (1) or more of the following: H2 receptor antagonist antihistamine, oral corticosteroids, and leukotriene modifiers. AND (4) 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) 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: patient has continued to use inhaled corticosteroid OR (3b) FOR CIU: patient continues to used H1 antihistamine AND (4) 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

# **ZEGERID NON FORMULARY**

#### **Products Affected**

• ZEGERID

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

## ZERVIATE

### **Products Affected**

• ZERVIATE

PA Criteria	Criteria Details
Covered Uses	Allergic conjunctivitis
Exclusion Criteria	Hypersensitivity to cetirizine hydrochloride or any of its ingredients, levocetirizine, or hydroxyzine
Required Medical Information	A. ALLERGIC CONJUNCTIVITIS (1) Documented diagnosis of allergic conjunctivitis AND (2) Patient has had a clinical trial and failure, intolerance, or contraindication to two of the following: Azelastine ophthalmic solution, Cromolyn sodium ophthalmic solution, Epinastine ophthalmic solution
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## ZOHYDRO

### **Products Affected**

• hydrocodone bitartrate er oral capsule extended release 12 hour

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	<ul> <li>(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</li> </ul>
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	Not indicated as an as-needed (PRN) analgesic

# **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 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. 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 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, 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

PA Criteria	Criteria Details
	and fluid and electrolyte replacement to prevent dehydration. Monitoring: Blood cell counts and chemistry tests, including electrolytes, glucose and serum creatinine, every 2 weeks during the first 2 months of therapy and monthly thereafter.

# ZORTRESS

### **Products Affected**

• everolimus oral tablet

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. FDA approved 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, valacyclovir, or famciclovir.
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* 

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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