

Prior Authorization Detail Colorado July 2023

**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.

- ACITRETIN 10 MG CAPSULE
- ACITRETIN 17.5 MG CAPSULE
- ACITRETIN 25 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: Pregnancy. Patients with severely impaired liver or kidney function and in patients with chronic abnormally elevated blood lipid values. Hypersensitivity to other retinoids. Concurrent use with methotrexate, tetracyclines.
Required Medical Information	N/A
Age Restrictions	18 years of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with, a dermatologist.
Coverage Duration	INITIAL: 3 months. RENEWAL: 1 year.
Other Criteria	INITIAL: Patient has a documented diagnosis of severe psoriasis, AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to a minimum 90 day trial of high dose topical steroid (i.e. betamethasone augmented, halobetasol), AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to, 90 day trial of methotrexate. RENEWAL: Prescriber attests to a positive therapeutic response to therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ACTEMRA (TOCILIZUMAB) SQ

- ACTEMRA 162 MG/0.9 ML SYRINGE P/F, SUV
- ACTEMRA ACTPEN 162 MG/0.9 ML

PA Criteria	Criteria Details
Exclusion Criteria	1. Concurrent use with a Biologic or with a Targeted Synthetic Disease- Modifying Antirheumatic Drug (DMARD). Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Actemra subcutaneous, 2. COVID-19 (Coronavirus Disease 2019) Note: This includes requests for cytokine release syndrome associated with COVID-19. 3. Crohns Disease
Required Medical Information	Initial: Giant Cell Arteritis: Patient has tried one systemic corticosteroid. Interstitial Lung Disease Associated with Systemic Sclerosis: Patient meets ALL of the following (i, ii, and iii): i. Patient has elevated acute phase reactants, defined as at least ONE of the following (a, b, or c): a) CRP greater than or equal to 6 mg/mL, OR b) ESR greater than or equal to 28 mm/h, OR c) Platelet count greater than or equal to 330 x 109/L, AND ii. FVC is greater than 55% of the predicted value, AND iii. Diagnosis is confirmed by high-resolution computed tomography. Polyarticular JIA: ONE of the following (a, b, c, or d): a) Patient has tried one other systemic therapy for this condition OR b) Patient will be starting on Actemra subcutaneous concurrently with methotrexate, sulfasalazine, or leflunomide OR c) Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide OR d) Patient has aggressive disease, as determined by the prescriber AND ONE of the following conditions (a or b): a) Patient has tried Humira OR b) Per the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder. RA: Patient has tried one conventional synthetic DMARD for at least 3 months AND ONE of the following conditions (a or b): a) Patient has tried one other systemic therapy for this condition. Polymyalgia Rheumatica: Patient has tried one systemic corticosteroid. Renewal: Giant Cell Arteritis: Patient has tried one systemic corticosteroid. Renewal: Giant Cell Arteritis: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient had an improvement in at least one symptom, such as decreased headache, scalp, or jaw pain. decreased fatigue, and/or improved vision.

PA Criteria	Criteria Details
Age Restrictions	Initial/Renewal: Interstitial Lung Disease Associated with Systemic Sclerosis: 18 years of age and older
Prescriber Restrictions	Initial: Giant Cell Arteritis, Polyarticular Juvenile Idiopathic Arthritis, Rheumatoid Arthritis, Systemic Juvenile Idiopathic Arthritis, Polymyalgia Rheumatica: Prescribed by or in consultation with a rheumatologist. Initial/Renewal: Interstitial Lung Disease Associated with Systemic Sclerosis: Pulmonologist or a rheumatologist.
Coverage Duration	Initial: Giant Cell Arteritis, JIA, Polymyalgia Rheumatica: 6 mos. SSc- ILD: 12 mos. Renewal: 12 mos
Other Criteria	SSc-ILD: Patient has had a beneficial response to therapy over the previous 1 year while receiving Actemra. Polyarticular JIA: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient had an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living AND patient has tried Humira OR Per the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder OR Per the prescriber, the patient has been established on Actemra subcutaneous for at least 90 days OR Patient has been established on Actemra subcutaneous for at least 90 days and prescription claims indicates at least a 90-day supply of Actemra subcutaneous was dispensed within the past 130 days [verification required] if claims history is not available, according to the prescriber [verification required]. RA: Patient has been on therapy for at least 6 months AND Patient had a beneficial clinical response when assessed by at least one objective measure OR b) Patient had an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue. improved function or activities of daily living. decreased soft tissue swelling in joints or tendon sheaths AND patient has tried Humira OR Per the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder OR Per the prescriber, the patient has been established on Actemra subcutaneous for at least 90 days and prescription claims indicates at least a 90-day supply of Actemra subcutaneous was dispensed within the past 130 days [verification required] if claims history is not available, according to the prescriber the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder OR Per the prescriber, the patient

PA Criteria	Criteria Details
	joint pain/tenderness, stiffness, or swelling. decreased fatigue. improved function or activities of daily living. Polymyalgia Rheumatica: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient had an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness. improved range of motion AND/or decreased fatigue.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Polymyalgia Rheumatica

## **ACYCLOVIR OINTMENT**

#### **Products Affected**

• ACYCLOVIR 5% OINTMENT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months.
Other Criteria	GENITAL HERPES: Patient has diagnosis of Genital Herpes caused by the herpes simplex virus AND Patient has had a trial and failure, intolerance, or contraindication to TWO of the following: oral acyclovir, valacyclovir, or famciclovir. HERPES SIMPLEX VIRUS (HSV): Patient has non-life- threatening mucocutaneous HSV infection AND Patient is immunocompromised.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **ADEFOVIR**

#### **Products Affected**

• ADEFOVIR DIPIVOXIL 10 MG TAB

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
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	Patient has a diagnosis of chronic hepatitis B AND Patient has evidence of active viral replication AND Patient has elevated ALT or AST or histologically active disease AND Patient has had a trial and failure, intolerance, or contraindication to therapy with generic entecavir.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## AMINOCAPROIC ACID

- AMINOCAPROIC ACID 1,000 MG TAB
- AMINOCAPROIC ACID 500 MG TAB

PA Criteria	Criteria Details
Exclusion Criteria	Patients with active intravascular clotting process or disseminated intravascular coagulation (DIC) without concomitant heparin.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Documented diagnosis of hemorrhage caused by hyperfibrinolysis secondary to various disorders including APLASTIC ANEMIA, ABRUPTIO PLACENTAE, HEPATIC CIRRHOSIS, and NEOPLASTIC DISEASES, OR aminocaproic acid is being used to enhance hemostasis when fibrinolysis contributes to bleeding in ONE of the following conditions: a) Bleeding in the urinary tract due to various etiologies b) SICKLE CELL ANEMIA with hematuria (sickling in the vas recta or renal papillary necrosis) c) Hemorrhagic cystitis d) surgery.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **ANABOLIC STEROIDS**

- OXANDROLONE 10 MG TABLET
- OXANDROLONE 2.5 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL: a) Known or suspected carcinoma of the prostate or breast in male patients b) Known or suspected carcinoma of the breast in females with hypercalcemia c) Known or suspected nephrosis (the nephrotic phase of nephritis) d) Known or suspected hypercalcemia e) Severe hepatic dysfunction f) Pregnancy
Required Medical Information	INITIAL: CACHEXIA ASSOCIATED WITH AIDS: Patient is on anti- retroviral therapy ALL OTHER INDICATIONS: None RENEWAL: Prescriber attests to improvement and continued need for treatment
Age Restrictions	N/A
Prescriber Restrictions	CACHEXIA ASSOCIATED WITH AIDS: Prescribed by or in consultation with a gastroenterologist, nutritional Support Specialist (SBS) or Infectious Disease specialist
Coverage Duration	6 months
Other Criteria	N/A
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Cachexia associated with AIDS, Turners syndrome, Adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, Bone pain accompanying osteoporosis, Adjunctive therapy to offset protein catabolism associated with prolonged administration of corticosteroids

## ANTIEPILEPTICS - LACOSAMIDE CARE VALUE POLICY

- LACOSAMIDE 10 MG/ML SOLUTION
- LACOSAMIDE 100 MG TABLET
- LACOSAMIDE 150 MG TABLET
- LACOSAMIDE 200 MG TABLET
- LACOSAMIDE 50 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Treatment of partial-onset seizures: 1 month of age and older. Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures: 4 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Trial of generic lacosamide tablets, generic lacosamide oral solution
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### ARIPIPRAZOLE

- ABILIFY MAINTENA ER 300 MG SYR
- ABILIFY MAINTENA ER 300 MG VL OUTER, SUV
- ABILIFY MAINTENA ER 400 MG SYR SUV
- ABILIFY MAINTENA ER 400 MG VL OUTER, SUV

PA Criteria	Criteria Details
Exclusion Criteria	History of a hypersensitivity reaction to aripiprazole.
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	A. SCHIZOPHRENIA: (1) Patient has a diagnosis of schizophrenia AND (2) There is documentation supporting that patient had a trial and therapeutic failure, intolerance, or contraindication to the formulary alternative: aripiprazole tablet OR B. BIPOLAR I DISORDER: (1) Patient has a diagnosis of bipolar I disorder AND (2) Abilify Maintena will be used as maintenance monotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- ARMODAFINIL 150 MG TABLET
- ARMODAFINIL 200 MG TABLET
- ARMODAFINIL 250 MG TABLET
- ARMODAFINIL 50 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Patients with known hypersensitivity to modafinil
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. Patient has ONE of the following diagnoses: 1. Narcolepsy 2. Shift work sleep disorder 3. Obstructive Sleep Apnea. B. NARCOLEPSY: Patient has a diagnosis of narcolepsy supported by a documented sleep study, AND documentation has been provided to confirm that the diagnosis of narcolepsy is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication, etc.) or another general medical condition. C. SHIFT WORK SLEEP DISORDER: Documentation has been provided to confirm that the patient is experiencing excessive sleepiness and working a minimum of five (or more) overnight shifts per month, AND documentation has been provided to confirm that the diagnosis is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication, etc.). D. OBSTRUCTIVE SLEEP APNEA: Patient has a diagnosis of obstructive sleep apnea supported by a documented sleep study .
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### ASENAPINE

- ASENAPINE 10 MG TABLET SL OUTER
- ASENAPINE 2.5 MG TABLET SL OUTER
- ASENAPINE 5 MG TABLET SL OUTER

PA Criteria	Criteria Details
Exclusion Criteria	Known hypersensitivity to asenapine
Required Medical Information	N/A
Age Restrictions	Bipolar I disorder - ONE of the following: i. Prescribed for acute monotherapy of manic or mixed episodes in a patient 10 years of age or older, OR ii. Prescribed as an adjunctive treatment to lithium or valproate in a patient 18 years of age or older, OR iii. Prescribed as maintenance monotherapy treatment in a patient 18 years of age or older. Schizophrenia - 18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	(1) Patient has a diagnosis of bipolar disorder OR schizophrenia, AND (2) Documentation has been submitted to confirm the patient has had a trial and failure, intolerance, or contraindication to at least TWO formulary alternatives including risperidone ODT, risperidone, quetiapine, olanzapine, ziprasidone (Note: patients chart notes/medical records/electronic claim history required for documentation).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ATOVAQUONE

#### **Products Affected**

• ATOVAQUONE 750 MG/5 ML SUSP

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: 1. Treatment of more severe episodes of PCP 2. Patients who are failing therapy with TMP-SMX for PCP.
Required Medical Information	INITIAL/RENEWAL: PROPHYLAXIS OF PCP: Patients with HIV have one of the following: 1. Documented CD4 count of less than 200 cells/mm3 within the last 3 months OR 2. Documentation to confirm that the patient had an episode of PCP that occurred at a CD4 count greater than 200cells/mm3 while the patient was on antiretroviral therapy.
Age Restrictions	13 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, an Infectious Disease specialist, oncologist, or HIV specialist.
Coverage Duration	INITIAL: Treatment of PCP: 21 days. Prophylaxis of PCP: 12mos. RENEWAL: Prophylaxis of PCP: 12mos
Other Criteria	INITIAL: TREATMENT OF PCP: 1. Patient has a diagnosis of mild-to- moderate PCP, 2. Patient has a documented trial and therapeutic failure, intolerance or contraindication to trimethoprim/sulfamethoxazole (TMP- SMX), 3. Patient has a documented trial and therapeutic failure, intolerance or contraindication to dapsone. PROPHYLAXIS OF PCP: 1. Documentation to confirm that the patient is immunocompromised and requires prevention of Pneumocystis carinii pneumonia (PCP), 2. Patient has a documented trial and therapeutic failure, intolerance or contraindication to trimethoprim/sulfamethoxazole (TMP-SMX), 3. Patient has a documented trial and treatment failure, intolerance or contraindication to dapsone. RENEWAL: PROPHYLAXIS OF PCP: 1. Prescriber attests that patient is responding positively to therapy, 2. Prescriber provides documentation to confirm that the patient has been compliant on the requested medication.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### BENRALIZUMAB

- FASENRA 30 MG/ML SYRINGE P/F,SDV
- FASENRA PEN 30 MG/ML SUV

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Xolair, Dupixent, or another anti-IL5 biologic (such as Nucala, Cinqair, etc.) for the treatment of asthma
Required Medical Information	N/A
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by, or given in consultation with, a physician specializing in pulmonary medicine or allergy medicine
Coverage Duration	Initial: 12 weeks, Renewal: 12 months
Other Criteria	Initial: A. Patient has severe asthma with an eosinophilic phenotype, B. Patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months, C. Documentation has been submitted to confirm that the patient is currently being treated with BOTH of the following: a medium, high-dose, or a maximally tolerated dose of an inhaled corticosteroid AND at least one other maintenance medication which includes a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long acting muscarinic antagonist (such as tiotropium), leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid D. Patient has ONE of the following: 1. Patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months 2. Patient has experienced at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months 3. Patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: a. Daytime asthma symptoms more than twice per week b. Any night waking due to asthma c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week d. Any activity limitation due to asthma. Renewal: A. Patient will continue to use BOTH of the following: an inhaled corticosteroid AND at least one other

PA Criteria	Criteria Details
	maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid, B. Patient has shown a clinical response as evidenced by ONE of the following: 1. Reduction in asthma exacerbation from baseline 2. Decreased use of rescue medications 3. Increase in percent predicted FEV1 from pretreatment baseline 4. Reduction in severity or frequency of asthma.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- REXULTI 0.25 MG TABLET
- REXULTI 0.5 MG TABLET
- REXULTI 1 MG TABLET
- REXULTI 2 MG TABLET
- REXULTI 3 MG TABLET
- REXULTI 4 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	SCHIZOPHRENIA: Patient has diagnosis of Schizophrenia. Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least THREE (3) formulary alternative antipsychotics including, but not limited to, risperidone, olanzapine, aripiprazole, ziprasidone, and quetiapine. MAJOR DEPRESSIVE DISORDER: Patient has diagnosis of Major Depressive Disorder AND Patient will be using Rexulti in combination with other medication(s) used to treat MDD AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO formulary alternative antidepressants including, but not limited to fluoxetine, paroxetine, sertraline, citalopram, venlafaxine, bupropion, escitalopram, desvenlafaxine AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least THREE formulary alternative antipsychotics including, but not limited to olanzapine, aripiprazole, quetiapine ER.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### CALCITONIN GENE-RELATED PEPTIDE INHIBITORS - AIMOVIG PRIOR AUTHORIZATION POLICY

- AIMOVIG 140 MG/ML AUTOINJECTOR
- AIMOVIG 70 MG/ML AUTOINJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	(1) Treatment of acute migraine. (2) Treatment or prevention of cluster headache. (3) Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention [Examples include: Aimovig (erenumab-aooe subcutaneous injection), Ajovy (fremanezumab-vfrm subcutaneous injection), Vyepti (eptinezumab- jjmr intravenous infusion), and Qulipta (atogepant tablets)]. (4) Concurrent use with Nurtec ODT (rimegepant sulfate orally disintegrating tablet) when used as a preventive treatment of migraine. (5) Treatment or prevention of hemiplegic migraine.
Required Medical Information	INITIAL: Patient must meet all of the following (A, B, and C): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class [Note: Examples of standard prophylactic (preventive) pharmacologic therapies for migraine include angiotensin receptor blocker, angiotensin converting enzyme inhibitor, anticonvulsant, beta-blocker, calcium channel blocker, tricyclic antidepressant, other antidepressant], AND C) Patient meets ONE of the following criteria (i, ii, or iii): i. Patient has had inadequate efficacy to both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber, OR ii. Patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber, OR iii. Patient meets BOTH of the following (a and b): a) Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapies, according to the prescriber, OR iii. Patient meets BOTH of the following (a and b): a) Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy, AND b) Patient has experienced adverse event(s) severe enough to warrant discontinuation to another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber.
Age Restrictions	18 years of age and older

PA Criteria	Criteria Details
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	CONTINUATION: Patient is currently taking Aimovig and has had a significant clinical benefit from the medication as determined by the prescriber. (Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Aimovig was initiated.)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## CALCIUM ACETATE

#### **Products Affected**

• PHOSLYRA 667 MG/5 ML SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Patients with hypercalcemia
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a nephrologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of hyperphosphatemia associated with chronic kidney disease, dialysis, end stage renal disease (ESRD), or renal failure AND Patient is on a phosphate-restricted diet AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to calcium acetate AND sevelamer carbonate AND Documentation of laboratory test results for 2 to 3 consecutive months been submitted to confirm that the patient's phosphorus level is GREATER THAN 4.5mg/dl OR calcium levels are above 9.6
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## CHLORAMBUCIL

#### **Products Affected**

• LEUKERAN 2 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Patients whose disease has demonstrated a prior resistance to the Leukeran. Patients who have demonstrated hypersensitivity to chlorambucil and other alkylating agents.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of chronic lymphatic (lymphocytic) leukemia, malignant lymphomas including lymphosarcoma, giant follicular lymphoma, or Hodgkins disease AND Leukeran is being used as palliative treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **CHORIONIC GONADOTROPIN**

- CHORIONIC GONAD 10,000 UNIT VL MDV
- NOVAREL 10,000 UNIT VIAL
- PREGNYL 10,000 UNIT VIAL 10ML, W/DILUENT, MDV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	HYPOGONADOTROPIC HYPOGONADISM: 1. Patient has low testosterone (based on normal reference level) AND 2. Patient has low LH OR low FSH (based on normal reference level).
Age Restrictions	Infertility: 18 years of age and older. Prepubertal Cryptorchidism: less than 13 years of age.
Prescriber Restrictions	INFERTILITY: Reproductive endocrinologist or infertility specialist. HYPOGONADOTROPIC HYPOGONADISM: Urologist. PREPUBERTAL CRYPTORCHIDISM: Pediatric specialist.
Coverage Duration	INFERTILITY:1mo renewable twice (3 cycles total) for CO/NC HH:1yr PREPUBERTAL CRYPTORCHIDISM:6wks
Other Criteria	A. FEMALE INFERTILITY: (1) Patient has a diagnosis of female infertility AND (2) Patient has or will be pre-treated with a follicular stimulating agent (e.g., clomiphene). B. HYPOGONADOTROPIC HYPOGONADISM: (1) Patient has a diagnosis of hypogonadotropic hypogonadism. C. PREPUBERTAL CRYPTORCHIDISM: (1) Patient has a diagnosis of prepubertal cryptorchidism not due to anatomical obstruction
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# CIMZIA (CERTOLIZUMAB)

#### **Products Affected**

• CIMZIA 200 MG VIAL KIT

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease- Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	Initial: CD: Patient meets 1 of the following: Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient, OR Patient has tried other conventional systemic therapy for CD OR Patient has enterocutaneous or rectovaginal fistulas, OR Patient had ileocolonic resection, AND Documentation that the patient has tried Humira. nr-axSpA: Patient has objective signs of inflammation, defined as at least one of the following: CRP elevated beyond the ULN for the reporting laboratory, OR Sacroiliitis reported on MRI. PsO: Patient meets ONE of the following conditions: Patient has tried at least 1 traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR Patient has a contraindication to MTX, per the prescriber, AND Documentation that the patient has tried 2 of Enbrel, Humira, Otezla, Skyrizi SC, Stelara SC, Taltz, and Tremfya. RA: Documentation that the patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, Xeljanz/XR, AND Patient has tried 1 conventional synthetic DMARD for at least 3 months OR patient already had a 3-month trial of at least one biologic other than the requested drug (Please Note: A biosimilar of the requested biologic does not count.) Spondyloarthritis, Other Subtypes: Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet, AND Documentation that the patient has tried at least 1 conventional synthetic DMARD. AS: Patient has tried at least 1 conventional synthetic DMARD. AS: Patient has tried at least 1 convention that the patient has tried 2 of Enbrel, Humira, Rinvoq, Taltz, and Xeljanz/XR. PsA: Patient has tried at least 1 convention that the patient has tried 2 of Enbrel, Humira, Rinvoq, Skyrizi SC, Stelara SC, Taltz, Tremfya, and Xeljanz/XR. SpA, Other Subtypes: Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND Patient has tried at least ONE conventional DMARD.
Age Restrictions	Crohns Disease, Plaque Psoriasis: 18 years of age or older.
Prescriber Restrictions	Ankylosing Spondylitis, Non-Radiographic Axial Spondyloarthritis, Rheumatoid Arthritis, Spondyloarthritis, Other Subtypes: prescribed by, or in consultation with, a rheumatologist. Crohns Disease: prescribed by, or in

PA Criteria	Criteria Details
	consultation with, a gastroenterologist. Plaque Psoriasis: prescribed by, or in consultation with, a dermatologist. Psoriatic Arthritis: prescribed by, or in consultation with, a rheumatologist or a dermatologist.
Coverage Duration	Initial: Plaque Psoriasis: 3 months, all other indications: 6 months Renewal: 1 year
Other Criteria	Renew: AS: Patient has been on therapy for at least 6 mos, AND Patient meets at least 1 of the following: When assessed by at least 1 objective measure, patient had a beneficial clinical response from baseline, OR Compared to baseline, patient had an improvement in at least 1 symptom or improvement in function or activities of daily living, AND Patient has tried 2 of Enbrel, Humira, Rinvoq, Taltz, and Xeljanz/XR. CD: Patient has been on therapy for at least 6 mos, AND Patient meets at least 1 of the following: When assessed by at least 1 objective measure, patient had a beneficial clinical response from baseline, OR Compared to baseline, patient had an improvement in at least 1 symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool, AND Patient has tried Humira. nr-axSpA: Patient has been on therapy for at least 6 mos, AND Patient meets at least 1 objective measure, patient had a beneficial clinical response from baseline, OR Compared with baseline, patient had an improvement in at least 1 objective measure, patient had a beneficial clinical response from baseline, OR Compared with baseline, patient had an improvement from baseline in at least 1 of the following: When assessed by at least 1 symptom, or improvement in function/activities of daily living. PsO: Patient has been on therapy for at least 90 days, AND Patient had a beneficial clinical response, defined as improvement from baseline, patient had an improvement in at least 1 symptom, such as decreased pain, itching, and/or burning, AND Patient has tried 2 of Enbrel, Humira, Otezla, Skyrizi SC, Stelara SC, Taltz, and Tremfya. PsA: Patient has been on therapy for at least 6 mos, AND Patient has tried 2 of Enbrel, Humira, Otezla, Rinvoq, Skyrizi SC, Stelara SC, Taltz, Tremfya, and Xeljanz/XR. RA: Documentation has been provided to confirm that the patient has tried TWO of Actemra SC, Enbrel, Humira, Rinvoq, Xeljanz/XR, AND Patient has been on therapy for at least 1 objective measure, patient had an improvement in at least 1 symptom

PA Criteria	Criteria Details
	beneficial clinical response from baseline, OR Compared with baseline, patient had an improvement in at least one symptom.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Spondyloarthritis, Other Subtypes

# **CYCLOSPORINE SOLUTION**

#### **Products Affected**

• SANDIMMUNE 100 MG/ML SOLN

PA Criteria	Criteria Details
Exclusion Criteria	Patients with a hypersensitivity to Sandimmune (cyclosporine) and/or Cremophor EL (polyoxyethylated castor oil).
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to BOTH of the following: cyclosporine capsule (generic Sandimmune capsule) AND Gengraf Solution 100mg/mL.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### DALFAMPRIDINE

#### **Products Affected**

• DALFAMPRIDINE ER 10 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: (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 has a history of hypersensitivity to AMPYRA or 4-aminopyridine.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with a neurologist.
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: (1) Patient has a diagnosis of Indication of multiple sclerosis (MS), AND (2) Ampyra is being used to improve walking, (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. RENEWAL: (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.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- DANAZOL 100 MG CAPSULE
- DANAZOL 200 MG CAPSULE
- DANAZOL 50 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	Undiagnosed abnormal genital bleeding, Markedly impaired hepatic, renal, or cardiac function, Pregnancy, Breast feeding, Porphyria-Danazol can induce ALA synthetase activity and hence porphyrin metabolism, Androgen-dependent tumor, Active thrombosis or thromboembolic disease and history of such events.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	ENDOMETRIOSIS: Prescribed by, or in consultation with, a gynecologist. HEREDITARY ANGIOEDEMA: Prescribed by or in consultation with an allergist/immunologist.
Coverage Duration	12 months
Other Criteria	A. Patient has ONE of the following diagnoses: 1. Endometriosis amenable to hormonal management 2. Hereditary angioedema, B. For ENDOMETRIOSIS AMENABLE TO HORMONE MANAGEMENT: 1. Patient has a diagnosis of endometriosis confirmed by laparoscopy, OR If the diagnosis is not confirmed by surgery, then documentation of an adequate work-up and the clinical rationale for the diagnosis must be provided, AND 2. Patient has 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, C. For HEREDITARY ANGIOEDEMA: 1. Danazol will be used as prophylactic therapy for the prevention of hereditary angioedema attacks.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### DEFERIPRONE

#### **Products Affected**

• FERRIPROX 100 MG/ML SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	RENEWAL: Documentation of 2 lab values in the previous 3 months showing serum ferritin levels consistently greater than 500mcg/L.
Age Restrictions	INITIAL/RENEWAL: Tablets: 8 years of age or older. Solution: Greater than or equal to 3 years of age and Less than or equal to 17 years of age.
Prescriber Restrictions	Prescribed by or given in consultation with a hematologist or hematologist/oncologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months
Other Criteria	Solution INITIAL: (1) Patient has a diagnosis of Iron overload, chronic- transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias, (2) Patient meets one of the following: (2a) Patient has an intolerance (intolerable toxicities or clinically significant adverse effects) or contradiction to AT LEAST ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine), OR (2b) Patient has had a trial and therapeutic failure (inadequate response) to AT LEAST ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine) AND Patient meets one of the following: (i) Documentation of 2 lab values in the previous 3 months showing serum ferritin levels are consistently above 1000mcg/L, OR (ii) Documentation of evidence of cardiac iron accumulation (i.e., cardiac T2star MRI less than 10 milliseconds, iron induced cardiomyopathy, fall in LVEF, arrhythmia indicating inadequate chelation). Tablets Initial: Patient has a diagnosis of Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias, (2) Patient meets one of the following: (2a) Patient has an intolerance (intolerable toxicities or clinically significant adverse effects) or contradiction to AT LEAST ONE of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine), OR (2b) Patient has had a trial and therapeutic failure (inadequate response) to AT LEAST ONE of

PA Criteria	Criteria Details
	the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine). RENEWAL: (1) Patient has a diagnosis of Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### DENOSUMAB

#### **Products Affected**

• PROLIA 60 MG/ML SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia. Pregnancy.
Required Medical Information	OSTEOPOROSIS IN MEN AND WOMEN: Patient has a diagnosis of osteoporosis and have ONE of the following: (1) Documentation of Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius, (2) Documentation of T-score less than or equal to -1 or low bone mass and a history of fragility fracture to the hip or spine, (3) Documentation of T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture greater than or equal to 3%. TREATMENT OF BONE LOSS IN MEN WITH PROSTATE CANCER: Patient has a documentation of Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -1, OR Patient has ONE of the following: (1) Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius, (2) T-score less than or equal to -1 or low bone mass and a history of fragility fracture to the hip or spine, (3) T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture greater than or equal to -2.5 and/or forearm DXA 33% (one-third) radius, (2) T-score less than or equal to -1 or low bone mass and a history of fragility fracture to the hip or spine, (3) T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture greater than or equal to 20% or hip fracture greater than or equal to 3%.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	ALL INDICATIONS: Patient must be at high risk for fracture defined as one or more of the following: (1) History of an osteoporotic fracture as an adult, (2) Parental history of hip fracture, (3) Low BMI, (4) Rheumatoid arthritis, (5) Alcohol intake (3 or more drinks per day), (5) Current smoking, (6) History of oral glucocorticoids ≥5 mg/d of prednisone (or equivalent) for greater than 3 months (ever). OSTEOPOROSIS IN MEN AND WOMEN: Patient is post-menopausal (Women ONLY), AND Patient has had a documented trial and therapeutic failure to a minimum

PA Criteria	Criteria Details
	(12) month trial with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid (NOTE: Therapeutic failure to previous therapy is defined as: (1) Decrease in T-score in comparison with baseline T-score from DXA scan AND/OR (2) Patient has a new fracture while on bisphosphonate therapy), OR Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid (Examples of contraindications to oral bisphosphonate therapy: (1) Documented inability to sit or stand upright for at least 30 minutes, (2) Documented pre-existing gastrointestinal disorder such as inability to swallow, Barretts esophagus, esophageal stricture, dysmotility, or achalasia). GLUCOCORTICOID-INDUCED OSTEOPOROSIS: Patient will be initiating or is continuing systemic glucocortic di therapy at a daily dosage equivalent to $\geq 7.5$ mg of prednisone and is expected to remain on glucocortic oid therapy for at least 6 months, AND Patient has had a documented trial and therapeutic failure to a minimum (12) month trial with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid (NOTE: Therapeutic failure to previous therapy is defined as: (1) Decrease in T-score in comparison with baseline T-score from DXA scan AND/OR (2) Patient has a new fracture while on bisphosphonate therapy), OR Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonate such as alendronate, risedronate, ibandronate, or zoledronic acid (Examples of contraindications to oral bisphosphonate therapy: (1) Documented inability to sit or stand upright for at least 30 minutes, (2) Documented pre-existing gastrointestinal disorder such as inability to swallow, Barretts esophagus, esophageal stricture, dysmotility, or achalasia). TREATMENT OF BONE LOSS IN WOMEN WITH BREAST CANCER: Patient is receiving androgen deprivation therapy for no
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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## **DESMOPRESSIN SOLUTION**

#### **Products Affected**

• DESMOPRESSIN AC 4 MCG/ML VIAL INNER

PA Criteria	Criteria Details
Exclusion Criteria	Known hypersensitivity to desmopressin acetate. Patients with moderate to severe renal impairment (defined as a creatinine clearance below 50 mL/min). Patients with hyponatremia or a history of hyponatremia. Treatment of nephrogenic diabetes insipidus. Treatment of severe classic von Willebrands disease (Type I) and when there is evidence of an abnormal molecular form of factor VIII antigen. Treatment of hemophilia A with factor VIII coagulant activity levels equal to or less than 5%, or treatment of hemophilia B, or patients who have factor VIII antibodies.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. Patient has ONE of the following diagnoses: 1. Central cranial diabetes insipidus 2. Mild to moderate Von Willebrands disease 3. Hemophilia A. B. For central cranial diabetes insipidus: 1. Desmopressin is being used as antidiuretic replacement therapy OR desmopressin is being used to treat temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. C. For mild to moderate Von Willebrands disease: 1. Patient has a diagnosis of mild to moderate classic von Willebrands disease (Type I) AND 2. Patient has factor VIII levels greater than 5% AND 3. Patient is undergoing a surgical procedure OR Patient is experiencing an episode of bleeding due to spontaneous or trauma-induced injury such as hemarthroses, intramuscular hematomas or mucosal bleeding. D. For hemophilia A: 1. Patient has factor VIII coagulant activity levels greater than 5% AND 2. Patient is undergoing a surgical procedure OR Patient is experiencing an episode of bleeding due to spontaneous or trauma-induced injury such as hemarthroses, intramuscular hematomas or mucosal bleeding. D. For hemophilia A: 1. Patient has factor VIII coagulant activity levels greater than 5% AND 2. Patient is undergoing a surgical procedure OR Patient is experiencing an episode of bleeding due to spontaneous or trauma-induced injury such as hemarthroses, intramuscular hematomas or mucosal bleeding.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **DIHYDROERGOTAMINE MESYLATE**

#### **Products Affected**

• DIHYDROERGOTAMINE MESYLATE 4 MG/ML NASAL SPRAY OUTER

PA Criteria	Criteria Details
Exclusion Criteria	Prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine. Coadministration with potent CYP3A4 inhibitors (ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin, troleandomycin, ketoconazole, itraconazole). Coadministration with peripheral or central vasoconstrictors. Concomitant use or use within 24 hours of 5-HT1 receptor agonists (e.g., sumatriptan), ergotamine containing or ergot type medications, or methysergide. Following vascular surgery. Ischemic heart disease (e.g., angina pectoris, history of myocardial infarction, or recorded silent ischemia). Patients having symptoms consistent with coronary artery vasospasm, including Prinzmetals variant angina. Nursing mothers. Peripheral arterial disease. Pregnancy. Sepsis. Severe hepatic impairment. Severe renal impairment. Uncontrolled hypertension.
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of moderate to severe migraine headaches with or without aura AND Patient has had a documented trial and therapeutic failure, intolerance or contraindication to TWO of the following oral triptans: almotriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, AND Patient has had a documented trial and therapeutic failure, intolerance or contraindication to sumatriptan nasal spray or sumatriptan injection (generic Imitrex).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **DORNASE ALFA**

#### **Products Affected**

• PULMOZYME 1 MG/ML AMPUL INNER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of cystic fibrosis (CF).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **DOXEPIN CREAM**

### **Products Affected**

• DOXEPIN 5% CREAM

PA Criteria	Criteria Details
Exclusion Criteria	Patients with untreated narrow angle glaucoma. Patient with a tendency to urinary retention.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Patient has a diagnosis of moderate pruritis associated with atopic dermatitis OR lichen simplex chronicus AND Patient has tried and failed previous treatment with at least TWO (2) topical steroid creams AND The request is for short term (up to 8 days) use.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### DUPILUMAB

- DUPIXENT 100 MG/0.67 ML SYRING INNER, SUV, P/F
- DUPIXENT 200 MG/1.14 ML PEN INNER, SUV, P/F
- DUPIXENT 200 MG/1.14 ML SYRING OUTER, SUV, P/F
- DUPIXENT 300 MG/2 ML PEN OUTER, SUV
- DUPIXENT 300 MG/2 ML SYRINGE OUTER, SUV, P/F

PA Criteria	Criteria Details
Exclusion Criteria	Atopic dermatitis: concurrent use with other systemic biologics or JAK inhibitors (e.g., Adbry, Rinvoq, Cibinqo). Asthma: Concurrent use with Xolair or an anti-IL5 biologic (e.g., Nucala, Cinqair, Fasenra).
Required Medical Information	ATOPIC DERMATITIS: INITIAL: Prescriber attests that patient has dermatitis involving 10% body surface area (BSA) involvement OR dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas. ASTHMA with an eosinophilic phenotype: INITIAL: (1) Documentation that the patient's peripheral blood eosinophil (EOS) count is greater than or equal to 150 cells per microliter within the past 12 months AND (2) Documentation confirming the patient's asthma is oral corticosteroid-dependent
Age Restrictions	ASTHMA: 6 years of age or older. ATOPIC DERMATITIS: 6 months of age or older. RHINOSINUSITIS WITH NASAL POLYPS: 18 years of age or older. Eosinophilic esophagitis: Patient is 18 years of age or older, OR 12 to 17 years of age AND weighs at least 40kg.
Prescriber Restrictions	Atopic dermatitis: Prescribed by, or in consultation with an allergist, immunologist, or dermatologist. Asthma: Prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine. Rhinosinusitis: Prescribed by, or in consultation with an allergist, immunologist, or otolaryngologist.
Coverage Duration	INITIAL: Chronic Rhinosinusitis/Atopic Dermatitis: 6 months, Asthma: 12 months. RENEWAL: 12 months.
Other Criteria	ATOPIC DERMATITIS: INITIAL: (1) Patient has documented diagnosis of moderate to severe atopic dermatitis AND (2) Must have tried (for at least 6 months) and failed ONE of the following, unless contraindicated: a. Topical corticosteroid b. Topical calcineurin inhibitor c. Topical PDE-4 inhibitor d. Topical JAK inhibitor e. Phototherapy, AND (3) The patient has TWO of the following: intractable pruritus, cracking and

PA Criteria	Criteria Details
	oozing/bleeding of affected skin, impaired activities of daily living. RENEWAL: (1) The patient has shown improvement while on therapy. MODERATE TO SEVERE ASTHMA: INITIAL: (1) Patient has moderate to severe asthma with an eosinophilic phenotype (supported by documentation from the patients chart notes/medical records) or moderate to severe oral corticosteroid-dependent asthma (2) The patient is concurrently treated with medium, high-dose, or maximally tolerated ICS AND at least one other maintenance medication (e.g., LABA, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline), (3) Dupixent will NOT be used concurrently with Xolair or an anti-IL5 biologic when these are used for the treatment of asthma (4) Patient meets ONE of the following: i. Patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months, OR ii. Patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: a. Daytime asthma symptoms more than twice per week b. Any night waking due to asthma c. SABA reliever for symptoms more than twice per week d. Any activity limitation due to asthma. RENEWAL: 1. The patient will continue to use an ICS AND at least one other maintenance medication (e.g., LABA, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline), 2. The patient has shown a clinical response as evidenced by ONE of the following: a. Reduction in asthma exacerbation from baseline b. Decreased utilization of rescue medications c. Increase in percent predicted FEV1 from pretreatment baseline, OR d. Reduction in severity or frequency of asthma-related symptoms CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSwNP) iNITIAL: (1) Patient has a documented diagnosis (supported by documentation from the patients chart notes/medical records)
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A

# ELBASVIR/GRAZOPREVIR

### **Products Affected**

• ZEPATIER 50-100 MG TABLET OUTER

PA Criteria	Criteria Details
Exclusion Criteria	Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions. Patient has moderate or severe hepatitis impairment (Child-Pugh B or C). Patient is currently taking any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily, sofosbuvir (Sovaldi) (as a single agent), velpatasvir/sofosbuvir (Epclusa), ledipasvir/sofosbuvir (Harvoni), pibrentasvir/glecaprevir (Mavyret), or velpatasvir/sofosbuvir/voxilaprevir (Vosevi).
Required Medical Information	Patient has a recent HCV infection documented by one detectable HCV RNA level within the last 6 months (Note: Chart notes or lab reports required for documentation).
Age Restrictions	12 years of age or older OR weighs at least 30kg
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model.
Coverage Duration	12- 16 weeks
Other Criteria	A. Patient has chronic hepatitis C OR has genotype 1 or genotype 4 hepatitis C, B. The patient meets ONE of the following criteria: has a contraindication to Epclusa AND Harvoni, OR has previously failed a short trial with Epclusa or Harvoni (e.g., inability to tolerate, adverse effect early in therapy) [NOTE: An individual who has completed a full course of therapy with Harvoni or Epclusa that did not achieve SVR will not be approved], C. Patients with genotype 1a infection require testing for baseline NS5A (nonstructural protein 5A) polymorphisms, D. Ribavirin use is required if the patient meets ANY of the following: 1) Patient has

PA Criteria	Criteria Details
	genotype 1a or 1b infection and was previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (such as Victrelis, Incivek, Olysio) plus peginterferon/ribavirin, 2) Patient has genotype 1a infection, is treatment naive, and has baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein), 3) Patient has genotype 1a infection, was previously treated, and has baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein), 4) Patient has genotype 4 infection and was previously treated, E. Treatment experienced patients will be approved per product labeling (previous failure of peginterferon/ribavirin for genotype 1a, 1b or 4 and previous failure of HCV protease inhibitor triple therapy regimen for genotype 1a or 1b infection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **ENDOTHELIN RECEPTOR ANTAGONISTS**

- AMBRISENTAN 10 MG TABLET
- AMBRISENTAN 5 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Idiopathic pulmonary fibrosis
Required Medical Information	INITIAL: PAH (WHO Group 1) (1) NYHA-WHO Functional Class II to IV symptoms AND (2) Documented confirmatory PAH diagnosis based on right heart catheterization
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	12 months
Other Criteria	1. Patient has a diagnosis of pulmonary arterial hypertension (WHO Group 1). 2. RENEWAL: REQUIRES EITHER (3a) improvement from baseline in the 6-minute walk distance test, OR (3b) patient is stable from baseline in the 6-minute walk distance test AND WHO functional class has remained stable or has improved.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **EPOETIN ALFA-EPBX**

#### **Products Affected**

• RETACRIT 2,000 UNIT/ML VIAL P/F, INNER, SDV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: A. ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD): (1) Hemoglobin level of less than 12.9g/dL. B. ANEMIA DUE TO ZIDOVUDINE THERAPY, OR ANEMIA DUE TO CONCURRENT HEPATITIS C TREATMENT: (1) Hemoglobin level of less than 10g/dL. C. ANEMIA DUE TO CANCER CHEMOTHERAPY: (1) Hemoglobin level of less than 11g/dL, OR (2) Hemoglobin level has decreased at least 2g/dL below baseline level. D. ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY: (1) Hemoglobin level of less than 13g/dL. RENEWAL: A. ANEMIA DUE TO CKD: One of the following: (1) hemoglobin level of less than 12.9g/dL if not on dialysis, OR (2) hemoglobin level of less than 11g/dL if on dialysis, OR (3) hemoglobin level has reached 12.9g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions OR (4) hemoglobin level has reached 11g/dL (if on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions. B. ANEMIA DUE TO CANCER CHEMOTHERAPY, DUE TO ZIDOVUDINE THERAPY, OR DUE TO CONCURRENT HEPATITIS C TREATMENT: (1) Hemoglobin level between 10g/dL and 12g/dL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL:SURGERY:1mo,INITIAL/RENEW:ANEMIA:CKD, CHEMO, ZIDOVUDINE:12mo, ANEMIA: WITH HEP-C TX:6mo
Other Criteria	INITIAL/RENEWAL: A. ANEMIA DUE TO CONCURRENT HEPATITIS C TREATMENT: (1) Patient has a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, AND (2) Trial of or contraindication to ribavirin dose reduction. (INITIAL ONLY) B. ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD) (1) Patient has a diagnosis of anemia associated with chronic kidney disease (CKD). C. ANEMIA DUE

PA Criteria	Criteria Details
	TO CANCER CHEMOTHERAPY: (1) Patient has a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy. D. ANEMIA DUE TO ZIDOVUDINE THERAPY: (1) Patient has a diagnosis of anemia related to zidovudine therapy. INITIAL: A. ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY: (1) Patient is undergoing elective, noncardiac, nonvascular surgery.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anemia due to concurrent hepatitis C treatment with ribavirin plus an interferon alfa or peginterferon alfa.

# **ERGOLOID MESYLATES ORAL**

### **Products Affected**

• ERGOLOID MESYLATES 1 MG TAB

PA Criteria	Criteria Details
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Exclusion Criteria	INITIAL/RENEWAL: Known hypersensitivity to ergoloid mesylates or in patients with known ergot alkaloid hypersensitivity, Ergoloid mesylate used in patients acute or chronic psychosis regardless of etiology.
Required Medical Information	None
Age Restrictions	INITIAL/RENEWAL: 18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	A. INITIAL: 1. Documented diagnosis of Alzheimers disease, vascular dementia, or primary progressive dementia. 2. Patient intolerance to, or adequate trial of TWO of the following: galantamine, donepezil or rivastigmine. B. RENEWAL: 1. Documented diagnosis of Alzheimers disease, vascular dementia, or primary progressive dementia. 2. Documented positive clinical response to ergoloid therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **ESTRAMUSTINE PHOSPHATE SODIUM**

### **Products Affected**

• EMCYT 140 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	Patients with known hypersensitivity to either estradiol or to nitrogen mustard. Active thrombophlebitis or thromboembolic disorders, except in those cases where the actual tumor mass is the cause of the thromboembolic phenomenon.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of metastatic and/or progressive prostate cancer AND Emcyt (extramustine phosphate sodium) is being used for palliative treatment.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ETHACRYNIC ACID

### **Products Affected**

• ETHACRYNIC ACID 25 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: Patients with anuria. Patients that have experienced severe, watery diarrhea with previous treatment with ethacrynic acid.
Required Medical Information	None
Age Restrictions	1 year of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	INITIAL: Patient has a documented diagnosis of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome, ascites due to malignancy, idiopathic edema, or lymphedema AND Patient has a documented sulfa allergy OR Patient had a trial and therapeutic failure of a 30-day trial of furosemide, bumetanide, AND torsemide. RENEWAL: Prescriber attests that patient is responding positively to therapy AND Patient has not experienced an increasing electrolyte imbalance, azotemia, and/or oliguria occur during treatment of severe, progressive renal disease AND Patient has not experienced severe, watery diarrhea.
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A

### FIDAXOMICIN

#### **Products Affected**

• DIFICID 200 MG TABLET

• DIFICID 40 MG/ML SUSPENSION OUTER

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Patient has diagnosis of C. difficile-associated diarrhea (CDAD) confirmed by a positive stool assay
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist.
Coverage Duration	3 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to oral vancomycin after a trial of at least 10 days. QTY LIMIT 20 per 10-day supply
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### FILGRASTIM

- NIVESTYM 300 MCG/0.5 ML SYRING P/F, SUV, OUTER
- NIVESTYM 300 MCG/ML VIAL P/F, SUV, INNER
- NIVESTYM 480 MCG/0.8 ML SYRING P/F, SUV, OUTER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### FINGOLIMOD

#### **Products Affected**

• FINGOLIMOD 0.5 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	(1) Recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure OR (2) History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker OR (3) Baseline QTC interval 500 msec or above OR (4) Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti- arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol).
Required Medical Information	N/A
Age Restrictions	10 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## FOLLITROPIN ALFA

- GONAL-F RFF REDI-JECT 300 UNITS PEN
- GONAL-F RFF REDI-JECT 450 UNIT PEN
- GONAL-F RFF REDI-JECT 900 UNIT PEN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a reproductive endocrinologist or infertility specialist
Coverage Duration	1 month
Other Criteria	FEMALE INFERTILITY 1. Patient has diagnosis of infertility AND 2. Cause of infertility is not due to primary ovarian failure AND 3. Must have tried and failed, have an intolerance to, or contraindication to clomiphene and provide number of treatment cycles the patient has had
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### FONDAPARINUX

- FONDAPARINUX 10 MG/0.8 ML SYR SDV,OUTER
- FONDAPARINUX 2.5 MG/0.5 ML SYR SDV, OUTER
- FONDAPARINUX 5 MG/0.4 ML SYR SDV, OUTER
- FONDAPARINUX 7.5 MG/0.6 ML SYR SDV, OUTER

PA Criteria	Criteria Details
Exclusion Criteria	ALL: Severe renal impairment (creatinine clearance [CrCl] less than 30 mL/min). Active major bleeding. Bacterial endocarditis. Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months.
Other Criteria	Prophylaxis of Deep Vein Thrombosis: Fondaparinux will be used as prophylaxis of deep vein thrombosis (DVT) AND Patients body weight is 50 kg or more AND patient is undergoing hip fracture surgery, including extended prophylaxis OR patient is undergoing hip replacement surgery OR patient is undergoing knee replacement surgery OR patient is undergoing abdominal surgery who are at risk for thromboembolic complications. Treatment of Acute Deep Vein Thrombosis: Patient has a diagnosis of acute deep vein thrombosis AND fondaparinux will be administered in conjunction with warfarin sodium. Treatment of Acute Pulmonary Embolism: Patient has a diagnosis of acute pulmonary embolism AND fondaparinux will be administered in conjunction with warfarin sodium AND initial therapy will be administered in the hospital.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# FORMOTEROL FUMARATE

#### **Products Affected**

• FORMOTEROL 20 MCG/2 ML NEB VL OUTER

PA Criteria	Criteria Details
Exclusion Criteria	Treatment of asthma
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to ALL of the following: Serevent, Spiriva, Stiolto Respimat, and Anoro Ellipta.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# GANIRELIX

- FYREMADEL 250 MCG/0.5 ML SYR
- GANIRELIX ACET 250 MCG/0.5 ML SUV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a reproductive endocrinologist or infertility specialist
Coverage Duration	1 month
Other Criteria	FEMALE INFERTILITY 1. Patient has diagnosis of infertility AND 2. Will be used in conjunction with assisted reproductive technology
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

#### **Products Affected**

• LEUPROLIDE 2WK 14 MG/2.8 ML KT MDV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): (1) The patient has high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) AND luteinizing hormone (LH) (level greater 0.2 to 0.3 mIU/mL) at diagnosis.
Age Restrictions	CENTRAL PRECOCIOUS PUBERTY: 2 years of age or older.
Prescriber Restrictions	CPP: Prescribed by or in consultation with a pediatric endocrinologist (hormone doctor).
Coverage Duration	12 months
Other Criteria	INITIAL: A. CENTRAL PRECOCIOUS PUBERTY (CPP, early sexual development in girls and boys): (1) Patient has a diagnosis of CPP AND (2) Documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast (in females) or genital (in males) development (stage 2 or above) AND pubic hair growth (stage 2 or above) AND (3) For female patients: a. The patient is/was younger than 8 years of age when the condition started (4) For male patients: a. the patient is/was younger than 9 years of age when the condition started. (5) ONE of the following: a. the request is for Leuprolide (generic), OR b. the patient tried and failed or have intolerance or contraindication to Lupron Depot or Leuprolide 1mg/0.2mL. RENEWAL: CPP (1) Patient has a diagnosis of CPP AND (2) Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year (3) Patient has not reached actual age which corresponds to current pubertal age.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	gender dysphoria

# GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

- LUPRON DEPOT 11.25 MG 3MO KIT 3 MONTH, SUV
- LUPRON DEPOT 22.5 MG 3MO KIT SINGLE DOSE
- LUPRON DEPOT 3.75 MG KIT P/F, SUV
- LUPRON DEPOT 45 MG 6MO KIT
- LUPRON DEPOT 7.5 MG KIT SINGLE DOSE
- LUPRON DEPOT-4 MONTH KIT SINGLE DOSE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	ENDOMETRIOSIS: Prescribed by or in consultation with an obstetrician/gynecologist.
Coverage Duration	UL:3mos(3.75 mg) 1 fill(11.25 mg). GENDER DYSPHORIA/PROSTATE CANCER:12mos. ENDOMETRIOSIS:6mos
Other Criteria	INITIAL: A. ENDOMETRIOSIS: (1) Patient has a diagnosis of moderate to severe pain associated with endometriosis, AND(2) Patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID), AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation), AND (3) Request is for Lupron Depot (3.75mg or 11.25mg). B. UTERINE LEIOMYOMATA: (1) Patient with anemia caused by uterine leiomyomata (fibroids), AND (2) Requested medication will be used concomitantly with iron therapy for the preoperative hematologic improvement, AND (3) Request is for Lupron Depot (3.75mg or 11.25mg). RENEWAL: A. ENDOMETRIOSIS: (1) Patient has a diagnosis of moderate to severe pain associated with endometriosis, AND (2) Patient has Improvement of pain related to endometriosis while on therapy, AND (3) Patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation), AND (4) Patient has NOT received a total course of therapy

PA Criteria	Criteria Details
	exceeding 12 months, AND (5) Request is for Lupron Depot (3.75mg or 11.25mg). INITIAL/RENEWAL: A. PROSTATE CANCER: (1) Patient has a diagnosis of advanced prostate cancer, AND (2) Request is for one of the following: (2a) Lupron Depot (7.5mg, 22.5mg, 30mg, 45mg), OR (2b) Camcevi. B. GENDER DYSPHORIA: (1) Request is for patient who is being treated for gender dysphoria, AND (2) Request is for one of the following: (2a) Lupron Depot 3.75mg (1 month kit), OR (2b) Lupron Depot 7.5mg (1 month kit), OR (2c) Lupron Depot 11.25mg (3 month kit).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	gender dysphoria

# HEREDITARY ANGIOEDEMA (PA)

### **Products Affected**

• ICATIBANT 30 MG/3 ML SYRINGE SUV, P/F,OUTER

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: ICATIBANT, SAJAZIR: History of anaphylactic or life-threatening hypersensitivity reactions to icatibant or any component of the formulation. TAKHZYRO: History of anaphylactic or life-threatening hypersensitivity reactions to lanadelumab or any component of the formulation. Renewal (ICATIBANT, SAJAZIR): Concurrent use with alternative acute treatment for HAE attacks (e.g., Berinert, Kalbitor, Ruconest, icatibant). Renewal (TAKHZYRO): Concurrent use with alternative prophylactic treatment for HAE (e.g., Cinryze, Takhzyro, Haegarda, Orladeyo, danazol).
Required Medical Information	INITIAL: HAE ACUTE (ICATIBANT, Sajazir), HAE PROPHYLAXIS (TAKHZYRO): (1) The patient has a diagnosis of Type I or Type II hereditary angioedema (HAE) evidenced by ONE of the following: (a) Documentation of BOTH of the following (there must be TWO separate low measurements for each test defined as below the testing laboratorys 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 (b) Documentation that the patient has a mutation in the C1-INH gene altering protein synthesis and/or function.
Age Restrictions	Takhzyro: 2 years and older Icatibant, Sajazir: 18 years and 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	INITIAL: HAE ACUTE (ICATIBANT, Sajazir): (1) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, estrogens) AND (2) 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 (3) 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 INITIAL: HAE PROPHYLAXIS (TAKHZYRO): (1) The requested agent will be used for

PA Criteria	Criteria Details
	prophylaxis against HAE attacks AND (a) The patient is receiving only ONE agent indicated for prophylaxis against HAE attacks, OR other agent being used for prophylaxis will be discontinued before starting the requested agent AND (b) The patient has had at least 2 acute severe attacks per month (i.e. swelling of the throat, cutaneous or incapacitating abdominal swelling) AND (2) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, and estrogens) AND (3) Member has tried and failed, intolerant to, or has a contraindication to danazol AND (4) Prescribed dosage follows Food and Drug Administration (FDA) label unless there is a documented clinical reasoning for higher dosage (Takhzyro: 300mg every 2 weeks). RENEWAL: HAE ACUTE (ICATIBANT, SAJAZIR): (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). RENEWAL: HAE PROPHYLAXIS (TAKHZYRO): (1) Documentation of a decrease in HAE attack frequency AND (2) Decrease in severity and duration of attacks (Note to prescriber: consider increasing dosing interval to every 4 weeks if the patient is attack free for 6 months).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **ILOPROST**

### **Products Affected**

• VENTAVIS 10 MCG/1 ML SOLUTION SINGLE-USE,P/F

• VENTAVIS 20 MCG/1 ML SOLUTION SNGLE-USE,P/F,INNER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: Documentation confirming patient's pulmonary arterial hypertension diagnosis based on right heart catheterization.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	INITIAL: Patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms, For WHO (World Health Organization) Functional Class III symptoms: ONE of the following: 1. The patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO of the following agents from different drug classes: a. Oral endothelin receptor antagonist (such as, ambrisentan, bosentan, or macitentan) b. Oral phosphodiesterase-5 inhibitor (such as, sildenafil or tadalafil) c. Oral cGMP inhibitor (such as, riociguat) 2. There is evidence of rapid progression or poor prognosis, For WHO Functional Class IV symptoms: Patient has had a trial and therapeutic failure, intolerance, or contraindication (harmful for) to at least ONE intravenous or subcutaneous prostacyclin (such as, epoprostenol or treprostinil). RENEWAL: ONE of the following: 1. Patient had improvement from baseline in the 6-minute walk distance test, OR 2. Patient has remained stable in the 6-minute walk distance test AND has a stable or improved World Health Organization (WHO) functional class.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **IMMUNE GLOBULIN**

- HYQVIA 10 GM-800 UNIT PACK
- HYQVIA 2.5 GM-200 UNIT PACK
- HYQVIA 20 GM-1,600 UNIT PACK
- HYQVIA 30 GM-2,400 UNIT PACK
- HYQVIA 5 GM-400 UNIT PACK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Subcutaneous Use Only. Primary immunodeficiency disease only.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# INFLAMMATORY CONDITIONS - ADALIMUMAB PRODUCTS PRIOR AUTHORIZATION POLICY

- AMJEVITA(CF) 10 MG/0.2 ML SYRINGE 10 mg/0.2 mL
- HUMIRA 40 MG/0.8 ML SYRINGE P/F, SUV
- HUMIRA PEN 40 MG/0.8 ML P/F, SUV
- HUMIRA PEN CROHN'S-UC-HS STARTER 40 MG/0.8 ML
- HUMIRA PEN PSORIASIS-UVEITIS-ADOL HS STARTER 40 MG/0.8 ML
- HUMIRA(CF) 10 MG/0.1 ML SYRINGE
- HUMIRA(CF) 20 MG/0.2 ML SYRINGE
- HUMIRA(CF) 40 MG/0.4 ML SYRINGE
- HUMIRA(CF) PEDIATRIC CROHN'S START 80 MG/0.8 ML-40 MG/0.4 ML
- HUMIRA(CF) PEDIATRIC CROHN'S STARTER 80 MG/0.8 ML SYRINGE
- HUMIRA(CF) PEN 40 MG/0.4 ML SUV, P/F
- HUMIRA(CF) PEN CROHN'S-UC-HS STARTER 80 MG/0.8 ML
- HUMIRA(CF) PEN PEDIATRIC ULCER COLITIS STARTER 80 MG/0.8 ML
- HUMIRA(CF) PEN PS-UV-ADOL HS START 80 MG/0.8 ML-40 MG/0.4 ML

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease- Modifying Antirheumatic Drug (Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with an adalimumab product), Polymyalgia Rheumatica (PMR)
Required Medical Information	Initial: CD: ONE of the following: 1. Patient tried or is taking corticosteroids, or it is contraindicated OR 2. Patient has tried one other conventional systemic therapy for Crohns disease such as azathioprine or methotrexate (exception: has already tried one biologic other than the requested medication) OR 3. Patient has enterocutaneous or rectovaginal fistulas OR 4. Patient had ileocolonic resection. JIA: ONE of the following: 1. Patient tried one other systemic therapy for this condition (Previous trial of one biologic other than the requested medication also counts) OR 2. Patient will start on adalimumab with methotrexate, sulfasalazine, or leflunomide OR 3. Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide OR 4. Patient has aggressive disease, as determined by the prescriber. HS: Patient tried at least ONE other therapy such as oral corticosteroids or systemic antibiotics. PsO: Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant (exception: patient had a 3-month trial or intolerance to one biologic other than the requested medication) OR has a

PA Criteria	Criteria Details
I A CITUEITa	contraindication to methotrexate, as determined by the prescriber. RA: Patient tried ONE conventional synthetic DMARD (some examples include methotrexate, leflunomide) for at least 3 months (exception: patient had a 3-month trial of one biologic other than the requested medication). UC: Patient has tried one systemic therapy (Previous trial of one biologic other than the requested medication also counts), OR Patient has pouchitis AND Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Uveitis (including other posterior uveitides and panuveitis syndromes): Patient tried ONE of the following therapies: periocular, intraocular, or systemic corticosteroids, immunosuppressives (Previous trial of one biologic other than the requested medication also counts).
Age Restrictions	Plaque Psoriasis: 18 years of age or older. Crohn's disease: 6 years of age or older. Ulcerative colitis: 5 years of age or older.
Prescriber Restrictions	RA, JIA, AS, Spondyloarthritis, Other Subtypes: Prescribed by or in consultation w/rheumatologist. PsA: Prescribed by or in consult w/rheumatologist or derm. PsO, HS, PG: Prescribed or in consult w/derm. CD, UC: Prescribed or in consult w/GE. Uveitis, Scleritis or Sterile Corneal Ulceration: Prescribed or in consult w/ophthalmologist BD: Prescribed or in consult w/rheumatologist,derm,ophthalmologist,GE, or neurologist Sarcoidosis: Prescribed or in consult w/pulmonologist,ophthalmologist,or derm
Coverage Duration	INIT:HS,PlaquePsoriasis,BehcetsDisease,Sarcoidosis:3moPyodermaGangr enosum:4mo,Others:6mo.RENEW:12mo
Other Criteria	Behcets Disease: Patient tried at least ONE conventional therapy (A trial of one biologic other than the requested medication also counts) OR has ophthalmic manifestations of Behcets disease. Pyoderma Gangrenosum: Patient tried one systemic corticosteroid OR tried one other immunosuppressant for at least 2 months or was intolerant. Sarcoidosis: Patient tried at least one corticosteroid AND tried at least one immunosuppressive medication. Scleritis or Sterile Corneal Ulceration: Patient tried at least one other therapy condition. Spondyloarthritis, Other Subtypes (Note: Includes undifferentiated arthritis, non-radiographic axial spondyloarthritis, reactive arthritis (Reiters disease), or arthritis associated with inflammatory bowel disease): ONE of the following (a or b): a. Patient has arthritis in the knees, ankles, elbows, wrists, hands, and/or feet AND tried at least one conventional synthetic DMARD, OR b. Patient has axial spondyloarthritis AND has objective signs of inflammation, defined as C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on magnetic resonance

PA Criteria	Criteria Details
	imaging. Renewal: AS, JIA, PsA, RA: Patient on therapy for at least 6 months, AND experienced a beneficial clinical response from baseline via an objective measure prior to initiating an adalimumab product OR compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain, or improvement in function or activities of daily living. CD, UC: Patient on therapy for at least 6 months, AND experienced a beneficial clinical response from baseline via an objective measure (some examples include fecal markers, serum markers) OR compared with baseline patient experienced an improvement in at least one symptom, such as decreased pain, stool frequency. HS, PsO, Behcets Disease, Sarcoidosis: Patient on therapy for at least 90 days, AND experienced a beneficial clinical response from baseline via an objective measure AND compared with baseline patient experienced an improvement in at least one symptom. Uveitis (including other posterior uveitides and panuveitis syndromes): Patient on therapy for at least 6 months, AND experienced a beneficial clinical response from baseline via an objective measure OR compared with baseline (prior to initiating an adalimumab product) experienced an improvement in at least one symptom. Pyoderma Gangrenosum: Patient on therapy for at least 4 months, AND experienced a beneficial clinical response from baseline via an objective measure OR compared with baseline (prior to initiating an adalimumab product) experienced an improvement in at least one symptom. Pyoderma Gangrenosum: Patient on therapy for at least 4 months, AND experienced a beneficial clinical response from baseline in at least one of the following: size, depth, or number of lesions AND compared with baseline experienced an improvement in at least one symptom. Scleritis or Sterile Corneal Ulceration, Spondyloarthritis, Other Subtypes: Patient on therapy for at least 6 months, AND experienced a beneficial clinical response from baseline OR compared w
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Behcet's Disease, Pyoderma Gangrenosum, Sarcoidosis, Scleritis or Sterile Corneal Ulceration, Spondyloarthritis, Other Subtypes

# INFLAMMATORY CONDITIONS - OTEZLA PRIOR AUTHORIZATION POLICY

- OTEZLA 28 DAY STARTER PACK
- OTEZLA 30 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Ankylosing Spondylitis, Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD), Rheumatoid Arthritis
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	Behcets disease: The medication is prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis: The medication is prescribed by or in consultation with a dermatologist. Psoriatic Arthritis: The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	Initial: 6 months. Renewal: 1 year
Other Criteria	Behcets Disease: A. Initial: Patient has oral ulcers or other mucocutaneous involvement AND Patient has tried at least ONE other systemic therapy, B. Renewal: Patient has been established on therapy for at least 4 months AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Otezla) AND Compared with baseline (prior to initiating Otezla), patient experienced an improvement in at least one symptom, such as decreased pain, or improved visual acuity (if ophthalmic manifestations). Plaque Psoriasis: A. Initial: Patient meets ONE of the following conditions (a or b): a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR b) Patient has a contraindication to methotrexate, as determined by the prescriber, B. Renewal: Patient has been established on therapy for at least 4 months AND Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by

PA Criteria	Criteria Details
	psoriasis AND Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning. Psoriatic Arthritis: A. Renewal: Patient has been established on the requested drug for at least 6 months AND Patient meets at least one of the following (a or b): a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Otezla) OR b) Compared with baseline (prior to initiating Otezla), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue, improved function or activities of daily living, decreased soft tissue swelling in joints or tendon sheaths.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# INFLAMMATORY CONDITIONS - SKYRIZI INTRAVENOUS PRIOR AUTHORIZATION POLICY

#### **Products Affected**

• SKYRIZI 600 MG/10 ML VIAL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or with Targeted Synthetic Disease- Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation, with a gastroenterologist.
Coverage Duration	Three doses for induction
Other Criteria	The medication will be used as induction therapy, AND Patient meets one of the following (i, ii, iii, or iv): i. Patient has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this patient, OR ii. Patient has tried one other conventional systemic therapy for Crohns disease (Note: Examples of conventional systemic therapy for Crohns disease include azathioprine, 6-mercaptopurine, or methotrexate. A previous trial of a biologic also counts as a trial of one other agent for Crohns disease.), OR iii. Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, OR iv. Patient had ileocolonic resection (to reduce the chance of Crohns disease recurrence).
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A

# INFLAMMATORY CONDITIONS - SKYRIZI SUBCUTANEOUS PRIOR AUTHORIZATION POLICY

- SKYRIZI 150 MG/ML PEN
- SKYRIZI 150 MG/ML SYRINGE
- SKYRIZI 180 MG/1.2 ML ON-BODY OUTER, SUV, P/F
- SKYRIZI 360 MG/2.4 ML ON-BODY INNER, SUV, P/F

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or with Targeted Synthetic Disease- Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	N/A
Age Restrictions	Plaque Psoriasis: 18 years of age or older.
Prescriber Restrictions	Crohns Disease: prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: prescribed by or in consultation with a dermatologist. Psoriatic Arthritis: prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	Crohns Disease, Psoriatic Arthritis: 6 mos/1yr Plaque Psoriasis: 3mos/1yr
Other Criteria	Initial: Crohns Disease. Patient meets ONE of the following conditions (a, b, c, or d): a) Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient, OR b) Patient has tried one other conventional systemic therapy for Crohns disease, OR c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, OR d) Patient had ileocolonic resection (to reduce the chance of Crohns disease recurrence), AND According to the prescriber, the patient will receive induction dosing with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous. Plaque Psoriasis. Patient meets ONE of the following conditions (a or b): a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant, OR Patient has a contraindication to methotrexate, as determined by the prescriber. Renewal: Crohns Disease: Patient has been established on therapy for at least 6 months, AND Patient meets at least one of the

PA Criteria	Criteria Details
	following (a or b): a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Skyrizi), OR Compared with baseline (prior to initiating Skyrizi), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool. Plaque Psoriasis: Patient has been established on the requested drug for at least 90 days, AND Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis, AND Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning. Psoriatic Arthritis: Patient has been established on therapy for at least 6 months, AND ii. Patient meets at least one of the following (a or b): a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Skyrizi), OR Compared with baseline (prior to initiating skyrizi), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue, improved function or activities of daily living, or decreased soft tissue swelling in joints or tendon sheaths.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

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# INFLAMMATORY CONDITIONS PRIOR AUTHORIZATION POLICY - ACTEMRA INTRAVENOUS

### **Products Affected**

• ACTEMRA 80 MG/4 ML VIAL

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease- Modifying Antirheumatic Drug (DMARD). 2. Crohns Disease 3. COVID- 19 (Coronavirus Disease 2019)- Non-Hospitalized Patient.
Required Medical Information	Initial: CRS with CAR T-Cell Therapy: a patient who has been or will be treated with a chimeric antigen receptor (CAR) T-cell therapy. GCA: Patient has tried one systemic corticosteroid. PJIA: Patient has tried 1 other systemic therapy for this condition OR Patient will be starting on Actemra intravenous concurrently with methotrexate, sulfasalazine, or leflunomide OR Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide OR Patient has tried 1 conventional synthetic DMARD for at least 3 months. SJIA: Patient has tried 1 other systemic therapy for this condition. COVID-19: hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO), Note: includes requests for cytokine release syndrome in a patient hospitalized with COVID-19. Inflammatory Arthritis Associated with Checkpoint Inhibitor Therapy: Patient is symptomatic despite a trial of at least 1 systemic corticosteroid. Stills Disease: Patient has tried 1 corventional synthetic DMARD such as methotrexate given for at least 2 months or was intolerant to a conventional synthetic DMARD. Renewal: Inflammatory Arthritis Associated with Checkpoint Inhibitor Therapy: Patient is requested 1 objective measure, patient has a tried 1 conventional synthetic DMARD such as methotrexate given for at least 2 months or was intolerant to a conventional synthetic DMARD. Renewal: Inflammatory Arthritis Associated with Checkpoint Inhibitor Therapy: Patient has been on therapy for at least 6 months AND When assessed by at least 1 objective measure, patient had a beneficial clinical response from baseline (prior to initiating the requested drug) OR Compared with baseline (prior to initiating the requested drug), patient had an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling. decreased fatigue.
Age Restrictions	None

PA Criteria	Criteria Details
Prescriber Restrictions	GCA, PJIA, RA, SJIA, Polymyalgia Rheumatica, Stills Disease: prescribed by or in consultation with a rheumatologist. Castlemans Disease: prescribed by or in consultation with an oncologist or hematologist. Inflammatory Arthritis Associated with Checkpoint Inhibitor Therapy: prescribed by or in consultation with a rheumatologist or an oncologist.
Coverage Duration	CRS with CAR T-Cell Therapy, COVID19: 1 wk. All others: initial:6mos renewal:1yr
Other Criteria	GCA: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline , patient had an improvement in at least one symptom, such as decreased headache, scalp, or jaw pain. decreased fatigue, and/or improved vision. PJIA: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient had an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living. RA: Patient has been on therapy for at least 6 months AND Patient had a beneficial clinical response when assessed by at least one objective measure OR Patient had an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue. improved function or activities of daily living. decreased soft tissue swelling in joints or tendon sheaths. SJIA: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling. decreased fatigue. improved function or activities of daily living. Castlemans Disease: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient had an improvement in at least one symptom, such as improvement or resolution of constitutional symptoms (e.g., fatigue, physical function). Polymyalgia Rheumatica: Patient has been on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from ba

PA Criteria	Criteria Details
	stiffness, or swelling. decreased fatigue. improved function or activities of daily living.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

# **INFLAMMATORY CONDITIONS PRIOR AUTHORIZATION POLICY - ETANERCEPT**

- ENBREL 25 MG/0.5 ML SYRINGE INNER, P/F, SUV
- ENBREL 25 MG/0.5 ML VIAL OUTER, P/F, SUV
- ENBREL 50 MG/ML MINI CARTRIDGE INNER, P/F, SUV
- ENBREL 50 MG/ML SURECLICK INNER, P/F, SUV
- ENBREL 50 MG/ML SYRINGE INNER, P/F, SUV

PA Criteria	Criteria Details
Exclusion Criteria	<ol> <li>Concurrent Use with a Biologic or with a Targeted Synthetic Disease- Modifying Antirheumatic Drug (DMARD), 2. Crohns Disease, 3.</li> <li>Inflammatory Myopathies (Polymyositis, Dermatomyositis, Inclusion Body Myositis), 4. Hidradenitis Suppurativa, 5. Polymyalgia Rheumatica (PMR), 6. Sarcoidosis, 7. Large Vessel Vasculitis (e.g., Giant Cell Arteritis, Takayasus Arteritis, 8. Wegeners Granulomatosis</li> </ol>
Required Medical Information	AS. Patient has been established on therapy for at least 6 months, Patient meets at least 1 of the following: When assessed by at least 1 objective measure, patient had a beneficial clinical response from baseline, OR Compared with baseline, patient had an improvement in at least 1 symptom. JIA: Initial: Patient has tried 1 other systemic medication, OR Patient will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide, OR Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide, OR Patient has been established on therapy for at least 6 months, AND Patient meets at least 1 of the following: When assessed by at least 1 objective measure, patient had a beneficial clinical response from baseline, OR Compared with baseline, patient has tried an improvement in at least 1 symptom. PoS: Initial Therapy: Patient has tried at least 1 traditional systemic agent for psoriasis for at least 3 months, unless intolerant, OR Patient has a contraindication to methotrexate, as determined by the prescriber OR Patient has been on therapy for at least 90 days, AND Patient had a beneficial clinical response, defined as improvement from baseline in at least 1 of the following: estimated BSA, erythema, induration/thickness, and/or scale of areas affected by psoriasis, AND Compared with baseline, patient had an improvement in at least 1 symptom. PsA: Patient has been on therapy for at least 1 symptom. PsA: Patient has been on therapy for at least 6 months, AND When assessed by at least 1 objective measure, patient had a beneficial clinical response from baseline, patient has been on therapy for at least 1 symptom. PsA: Patient has been on therapy for at least 6 months, AND

PA Criteria	Criteria Details
	tried 1 conventional synthetic DMARD for at least 3 months OR Patient has been on therapy for at least 6 months, AND Patient had a beneficial clinical response when assessed by at least 1 objective measure, OR Patient had an improvement in at least 1 symptom.
Age Restrictions	Initial: Plaque psoriasis: 4 years of age and older
Prescriber Restrictions	Initial: AS, JIA, RA, Spondyloarthritis, other subtypes, Stills Disease: Prescribed by or in consultation with a rheumatologist. PsO, Pyoderma Gangrenosum: Dermatologist. Psoriatic Arthritis: Rheumatologist or dermatologist. Behcets Disease: Rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. Graft-Versus-Host Disease: Oncologist, hematologist, or a physician affiliated with a transplant center.
Coverage Duration	Initial:AS,JIA,PsA,RA,SpA,StillsDis:6mo PsO,Bechets:3mo GVHD:1mo PG:4mo. Renew:GVHD:3mo. Others:12mo
Other Criteria	Behcets Disease: Initia: Patient has tried at least 1 conventional therapy OR Patient has been on therapy for at least 90 days, AND When assessed by at least 1 objective measure, patient had a beneficial clinical response from baseline, AND Compared with baseline, patient had an improvement in at least 1 symptom. Graft-Vs-Host Disease: Initial: Patient has tried at least 1 conventional systemic treatment for graft-versus-host disease, Patient has been established on an etanercept product for at least 1 month, AND Patient meets at least 1 of the following: When assessed by at least one objective measure, patient had a beneficial clinical response from baseline, OR patient had an improvement in at least 1 symptom. Pyoderma Gangrenosum: Initial: Patient has tried one systemic corticosteroid OR one other immunosuppressant for at least 2 months or was intolerant to one of these medications, OR Patient has been on therapy for at least 4 months, AND Patient had a beneficial clinical response, Compared with baseline, patient had an improvement in at least 1 symptom. Spondyloarthritis, Other Subtypes: Initial: Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least 1 conventional synthetic DMARD has been tried, OR Patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least 1 of the following: CRP elevated beyond the ULN for the reporting laboratory, OR (2) Sacroiliitis reported on MR) OR Patient has been on therapy for at least 6 months, AND When assessed by at least 1 objective measure, patient had a beneficial clinical response from, OR Compared with baseline, patient had an improvement in at least 2 months or was intolerant, OR

PA Criteria	Criteria Details
	Patient has been on an this medication for at least 6 months, AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline, OR Compared with baseline, patient experienced an improvement in at least one symptom.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	1. Behcets Disease 2. Graft-Versus-Host Disease 3. Pyoderma Gangrenosum 4. Spondyloarthritis, Other Subtype 5. Stills Disease

# INFLAMMATORY CONDITIONS PRIOR AUTHORIZATION POLICY - TREMFYA

- TREMFYA 100 MG/ML INJECTOR
- TREMFYA 100 MG/ML SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with other Biologics or with Targeted Synthetic Disease- Modifying Antirheumatic Drugs (DMARDs). Note: This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with Tremfya.
Required Medical Information	Patient has ONE of the following diagnoses: 1. Plaque psoriasis OR 2. Psoriatic arthritis. 1. Plaque Psoriasis. Patient meets ONE of the following (A or B): A) Initial Therapy. Patient meets ALL of the following (i, and ii): i. Patient meets ONE of the following conditions (a or b): a) Patient has tried at least ONE traditional systemic agent for psoriasis for at least 3 months, unless intolerant Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (such as, Humira, Orencia, Actemra, etc.) other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to step back and try a traditional systemic agent for psoriasis OR b) Patient has a contraindication to methotrexate, as determined by the prescriber OR B) Patient is Currently Receiving Tremfya. Patient meets ALL of the following (i, ii, and iii): i. Patient has been established on the requested drug for at least 90 days, Note: A patient who has received less than 90 days of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy) AND ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis AND iii. Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.
Age Restrictions	Initial: Plaque psoriasis: 18 years of age and older

PA Criteria	Criteria Details
Prescriber Restrictions	Initial: Plaque psoriasis: Requested agent is prescribed by or in consultation with a dermatologist. Psoriatic arthritis: Requested agent is prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	Initial: Plaque psoriasis: 3 months Psoriatic arthritis: 6 months Renewal: 12 months
Other Criteria	2. Psoriatic Arthritis. Patient meets ONE of the following (A or B): A) Initial Therapy requirements OR B) Patient is Currently Receiving Tremfya. Patient meets BOTH of the following (i and ii): i. Patient has been established on the requested drug for at least 6 months, Note: A patient who has received less than 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy) AND ii. Patient meets at least one of the following (a or b): a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug), Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C- reactive protein, erythrocyte sedimentation rate) OR b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue, improved function or activities of daily living, decreased soft tissue swelling in joints or tendon sheaths.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# INFLAMMATORY CONDITIONS PRIOR AUTHORIZATION POLICY - STELARA SUBCUTANEOUS

- STELARA 45 MG/0.5 ML SYRINGE
- STELARA 45 MG/0.5 ML VIAL SDV, P/F
- STELARA 90 MG/ML SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Ankylosing Spondylitis, 2. Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD)
Required Medical Information	Initial: CD: Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient OR Patient has tried one conventional systemic therapy for Crohns disease OR c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR d) Patient had ileocolonic resection (to reduce the chance of Crohns disease recurrence) AND Per the prescriber, the patient will receive a single induction dose with Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous. PsO: 45mg syringe/vial: Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant, OR Patient has a contraindication to methotrexate as determined by the prescriber. Note: If the 90 mg syringe is requested, patient meets one of the following: patient weighs greater than 100 kg OR patient is currently receiving the 90 mg syringe OR patient has received standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy. PsA: Note: If the 90 mg syringe is requested, patient meets one of the following: patient is currently receiving the 90 mg syringe is requested, patient meets one of the following: patient has moderate to severe plaque psoriasis AND weighs greater than 100 kg OR patient is currently neceived standard dosing with the 45 mg syringe/vial for at least 3 months with inadequate efficacy. UC: Patient has had a trial of one systemic agent for ulcerative colitis, OR BOTH of the following [(1) and (2)]: (1) Patient has pourchitis AND (2) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema AND Per the prescriber, the patient will receive a single induction dose with Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous
Age Restrictions	Plaque Psoriasis and Psoriatic Arthritis: 6 years of age or older

PA Criteria	Criteria Details
Prescriber Restrictions	CD: prescribed by or in consultation with a gastroenterologist, PsO: prescribed by or in consultation with a dermatologist, PsA: prescribed by or in consultation with a rheumatologist or a dermatologist, UC: prescribed by or in consultation with a gastroenterologist.
Coverage Duration	CD, PsA, UC: 6 months/1 year PsO: 3 mos/1 year
Other Criteria	Renewal: CD: Patient has been on the requested drug for at least 6 months AND Patient meets at least one of the following: When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug) OR Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool. PsO: Patient has been on the requested drug for at least 90 days AND Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis AND Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning. PsA: Patient has been on the requested drug for at least 6 months AND Patient meets at least one of the following: When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug) OR Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue. improved function or activities of daily living. decreased soft tissue swelling in joints or tendon sheaths. UC: Patient has been on the requested drug for at least 6 months AND Patient meets at least one of the following: a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug) OR Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# INFLAMMATORY CONDITIONS PRIOR AUTHORIZATION POLICY -TALTZ

- TALTZ 80 MG/ML AUTOINJECTOR (2-PACK)
- TALTZ 80 MG/ML AUTOINJECTOR (3-PACK)
- TALTZ 80 MG/ML AUTOINJECTOR P/F,SDV,OUTER
- TALTZ 80 MG/ML SYRINGE P/F,SUV,OUTER

PA Criteria	Criteria Details
Exclusion Criteria	1. Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) 2. Inflammatory Bowel Disease (i.e., Crohns disease, ulcerative colitis)
Required Medical Information	Initial: nr-axSpA: Patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory, OR Sacroiliitis reported on magnetic resonance imaging, PoS: Patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant, OR Patient has a contraindication to methotrexate, as determined by the prescribing physician
Age Restrictions	PsO: Greater than or equal to 6 years of age
Prescriber Restrictions	AS: prescribed by or in consultation with a rheumatologist nr-axSpa: prescribed by or in consultation with a rheumatologist. PsO: prescribed by or in consultation with a dermatologist. PsA: prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	Initial: AS, nr-axSpa, PsA: 6months PsO: 3 months. Renewal: 1 year
Other Criteria	Renewal: AS: Patient has been established on therapy for at least 6 months, AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Taltz), OR Compared with baseline (prior to initiating Taltz), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living. nr-axSpA: Patient has been established on therapy for at least 6 months, AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Taltz), OR Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness,

PA Criteria	Criteria Details
	or improvement in function or activities of daily living. PsO: Patient has been established on therapy for at least 90 days, AND Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Taltz) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis, AND Compared with baseline (prior to initiating Taltz), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning. PsA: Patient has been established on therapy for at least 6 months, AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Taltz), Compared with baseline (prior to initiating Taltz), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue, improved function or activities of daily living, decreased soft tissue swelling in joints or tendon sheaths.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **ISOTRETINOIN**

- AMNESTEEM 10 MG CAPSULE OUTER
- AMNESTEEM 20 MG CAPSULE OUTER
- AMNESTEEM 40 MG CAPSULE OUTER
- CLARAVIS 10 MG CAPSULE OUTER
- CLARAVIS 20 MG CAPSULE OUTER
- CLARAVIS 30 MG CAPSULE OUTER
- CLARAVIS 40 MG CAPSULE OUTER
- ISOTRETINOIN 10 MG CAPSULE OUTER
- ISOTRETINOIN 20 MG CAPSULE OUTER
- ISOTRETINOIN 30 MG CAPSULE OUTER
- ISOTRETINOIN 40 MG CAPSULE OUTER
- ZENATANE 10 MG CAPSULE INNER
- ZENATANE 20 MG CAPSULE INNER
- ZENATANE 30 MG CAPSULE OUTER, 3X10
- ZENATANE 40 MG CAPSULE INNER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	INITIAL/RENEWAL: 12 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	INITIAL/RENEWAL: 12 months.
Other Criteria	INITIAL: Patient has a diagnosis of severe recalcitrant nodular acne, treatment-resistant or scarring acne AND Patient has had a trial and therapeutic failure with at least TWO (2) topical acne medications AND a trial of an oral tetracycline or tetracycline derivative. RENEWAL: Patient has had 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. QUANTITY RESTRICTION, Maximum 60 capsules / 30 days.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **ITRACONAZOLE ORAL**

- ITRACONAZOLE 10 MG/ML SOLUTION
- ITRACONAZOLE 100 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	1. Concomitant administration of itraconazole with drugs metabolized by CYP3A4: oral midazolam, pimozide, quinidine, dofetilide, triazolam, lovastatin, and simvastatin 2. Treatment of onychomycosis to pregnant patients or to women contemplating pregnancy 3. Patients who have shown hypersensitivity to itraconazole, 4. Itraconazole capsules should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF.
Required Medical Information	ONYCHOMYCOSIS OF THE FINGERNAILS/TOENAILS: Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be obtained to confirm the diagnosis of onychomycosis. Patient has a documented diagnosis of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	Toe/Finger Onychomycosis: 12/5 weeks Histo/Blasto: 12 months Asper: 6 months Candidiasis: 2 months
Other Criteria	ORAL CAPSULES ONLY: Blastomycosis or histoplasmosis Onychomycosis of the fingernails/toenails: Patient is not immunocompromised, AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to 6 weeks of oral terbinafine for the fingernails OR 12 weeks of oral terbinafine for toenails. Aspergillosis: That patient is intolerant of or refractory (disease did not respond to treatment) to amphotericin B therapy ORAL SOLUTION ONLY: Esophageal Candidiasis: Patient has diagnosis of candidiasis of the esophagus with or without HIV, AND Patient has trial and failure, contraindication, or intolerance to 21-day trial of fluconazole. Oropharyngeal Candidiasis: Patient has diagnosis of oropharyngeal candidiasis with or without HIV. AND Patient has had a trial and therapeutic failure, contraindication, or

PA Criteria	Criteria Details
	intolerance to a 14-day treatment with fluconazole, AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to a 14-day trial of nystatin suspension or clotrimazole troches.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **IVABRADINE**

- CORLANOR 5 MG TABLET
- CORLANOR 7.5 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: Acute decompensated heart failure. Clinically significant hypotension (e.g., 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). Clinically significant bradycardia (e.g., 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	INITIAL: A. STABLE, SYMPTOMATIC HEART FAILURE (NYHA II- IV): 1. Left ventricular ejection fraction less than or equal to 35% AND 2. Resting heart rate greater than or equal to 70 beats per minute. B. SYMPTOMATIC NYHA CLASS II-IV HEART FAILURE DUE TO DILATED CARDIOMYOPATHY: 1. Patient has a resting heart rate of greater than or equal to 70 beats per minute.
Age Restrictions	Stable, symptomatic heart failure (NYHA II-IV): 18 years of age or older. Symptomatic NYHA class II-IV heart failure due to dilated cardiomyopathy: 6 months of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: A. STABLE, SYMPTOMATIC HEART FAILURE (NYHA II- IV): 1. Patient has a diagnosis of stable, symptomatic heart failure (NYHA II-IV) AND 2. Patient is in sinus rhythm AND 3. Patient has symptoms despite maximal beta-blocker therapy OR has a documented contraindication to beta-blocker use. AND 4. Trial, failure, or contraindication to ACE-inhibitor or ARB therapy. B. SYMPTOMATIC NYHA CLASS II-IV HEART FAILURE DUE TO DILATED CARDIOMYOPATHY: 1. Patient has a diagnosis of symptomatic NYHA class II-IV heart failure due to dilated cardiomyopathy AND 2. Patient is in sinus rhythm. RENEWAL CRITERIA: 1. Patient continues to meet initial

PA Criteria	Criteria Details
	criteria AND 2. Patient has experienced disease stabilization or improvement with medication as determined by the prescriber.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### LANREOTIDE

- LANREOTIDE 120 MG/0.5 ML SYRNG
- SOMATULINE DEPOT 120 MG/0.5 ML SUV
- SOMATULINE DEPOT 60 MG/0.2 ML SUV
- SOMATULINE DEPOT 90 MG/0.3 ML

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	INITIAL: ACROMEGALY: Prescriber must provide documentation of the following baseline laboratory results from the patient's medical record: 1) Elevated serum IGF-1 level for patient's age range and gender, and 2) Elevated growth hormone level defined by a GH level greater than or equal to 1 ng/mL during oral glucose tolerance test (OGTT). RENEWAL: ACROMEGALY: Patient has documented disease response confirmed by reduction of growth hormone (GH) and/or IGF-I blood levels from baseline, AND serum insulin-like growth factor-I (IGF-I) levels remain outside normal limits.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	INITIAL: ACROMEGALY Patient has a documented diagnosis of acromegaly AND patient has had an inadequate response to surgery and/or radiation therapy, OR documentation has been provided to confirm surgery and radiation therapy are not appropriate.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# LEDIPASVIR/SOFOSBUVIR

#### **Products Affected**

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- HARVONI 33.75-150 MG PELLET PK OUTER
- HARVONI 45-200 MG PELLET PACKT OUTER
- HARVONI 45-200 MG TABLET
- HARVONI 90-400 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	(1) Currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, (Sovaldi), elvitegravir/cobicistat/emtricitabine/tenofovir (Stribild), tipranavir/ritonavir, pibrentasvir/glecaprevir (Mavyret), velpatasvir/sofosbuvir (Epclusa), elbasvir/grazoprevir (Zepatier), or velpatasvir/sofosbuvir/voxilaprevir (Vosevi). (2) Limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation).
Required Medical Information	Patient has a recent HCV infection documented by one detectable HCV RNA level within the last 6 months (Note: Chart notes or lab reports required for documentation).
Age Restrictions	3 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
Coverage Duration	ledipasvir/sofosbuvir
Other Criteria	Patient has a diagnosis of chronic hepatitis C with genotype 1, genotype 4, genotype 5, OR genotype 6 and meets any of the following: (1) Treatment-experienced patients with no cirrhosis and genotype 1, previous treatment should include ONE of the following: a) peginterferon and ribavirin, b) triple therapy with HCV protease inhibitor, peginterferon and ribavirin, OR c) a prior non-NS5A inhibitor, sofosbuvir-containing regimen (2) For patients who are treatment-experienced with compensated cirrhosis and genotype 1, previous treatment should include either a) peginterferon and ribavirin, OR b) triple therapy with HCV protease inhibitor, peginterferon and ribavirin, and ribavirin, OR b) triple therapy with HCV protease inhibitor, peginterferon and ribavirin, OR b) triple therapy with HCV protease inhibitor, peginterferon and ribavirin, OR b) triple therapy with HCV protease inhibitor, peginterferon and ribavirin. (3) Patients who have decompensated cirrhosis or are post-

PA Criteria	Criteria Details
	liver transplant (without cirrhosis or with compensated cirrhosis), approval also requires that the requested medication will be used with ribavirin. (4) Requests for Harvoni 45mg/200mg pellets require that the patient is unable to swallow tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **LIDOCAINE PATCH 5%**

### **Products Affected**

• LIDOCAINE 5% PATCH

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	12 months.
Other Criteria	POSTHERPETIC NEURALGIA Patient has a diagnosis of post-herpetic neuralgia (shingles or herpes zoster) AND Patient has documentation of trial and therapeutic failure, 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 AND Patient has documentation of trial and therapeutic failure, intolerance, or contraindication to gabapentin. DIABETIC PERIPHERAL NEUROPATHY Patient has had a diagnosis of diabetic peripheral neuropathy AND Patient has documentation of trial and therapeutic failure, 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 AND Patient has documentation of trial and therapeutic failure, intolerance, or contraindication to a one month trial of ALL of the following: At least TWO (2) tricyclic antidepressants (amitriptyline, desipramine, imipramine, and nortriptyline) AND a traditional anticonvulsant (e.g., carbamazepine, sodium valproate) AND duloxetine. (Note: Chart notes or medical records required for documentation).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Diabetic peripheral neuropathy

### LOMUSTINE

- GLEOSTINE 10 MG CAPSULE
- GLEOSTINE 100 MG CAPSULE
- GLEOSTINE 40 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	The requested medication will be used in combination with other chemotherapies
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# LUMACAFTOR-IVACAFTOR

- ORKAMBI 100 MG-125 MG TABLET
- ORKAMBI 100-125 MG GRANULE PKT
- ORKAMBI 150-188 MG GRANULE PKT
- ORKAMBI 200 MG-125 MG TABLET
- ORKAMBI 75-94 MG GRANULE PKT

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: Documentation that the patient is homozygous for the F508del- CFTR gene mutation
Age Restrictions	1 year of age or older
Prescriber Restrictions	Initial: Prescribed by or in consultation with a pulmonologist or CF expert
Coverage Duration	INITIAL: 24 weeks. RENEWAL: Lifetime
Other Criteria	RENEWAL: Improvement in clinical status as shown by ONE of the following: (a) Patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume), OR (b) Patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index), OR (c) Reduction in rate of pulmonary exacerbations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- LURASIDONE HCL 120 MG TABLET
- LURASIDONE HCL 20 MG TABLET
- LURASIDONE HCL 40 MG TABLET
- LURASIDONE HCL 60 MG TABLET
- LURASIDONE HCL 80 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.). Strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. Johns wort, phenytoin, carbamazepine, etc.).
Required Medical Information	N/A
Age Restrictions	Bipolar depression: 10 years of age and older. Schizophrenia: 13 years of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with, a psychiatrist.
Coverage Duration	12 months.
Other Criteria	Patient has a diagnosis of major depressive episode associated with bipolar I disorder (bipolar depression) or schizophrenia AND Documentation of trial and therapeutic failure, intolerance, or contraindication to at least THREE (3) of the following: risperidone, quetiapine, olanzapine, ziprasidone, aripiprazole. (Note: Chart notes, medical records, or electronic claim history required for documentation).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# MARPLAN (ISOCARBOXAZID)

### **Products Affected**

• MARPLAN 10 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of MAO inhibitors or dibenzazepine derivatives, sympathomimetics (including amphetamines), some central nervous system depressants (including narcotics and alcohol), antihypertensive, diuretic, antihistaminic, sedative or anesthetic drugs, buproprion HCL, buspirone HCL, dextromethorphan, cheese or other foods with a high tyramine content OR excessive quantities of caffeine. Patients with confirmed or suspected cerebrovascular defect. Patient with cardiovascular disease or hypertension. Patients with pheochromocytoma, as such tumors secrete pressor substances. Patients with a history of liver disease, or in those with abnormal liver function tests. Patients with severe impairment of renal function.
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has had a therapeutic trial and failure, contraindication, or intolerance to THREE antidepressants with at least 2 different mechanisms of action
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **MELPHALAN**

### **Products Affected**

• MELPHALAN 2 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Patients whose disease has demonstrated a prior resistance to this agent. Patients who have demonstrated hypersensitivity to melphalan.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	ORAL TABLET: Documentation of patients diagnosis of multiple myeloma OR non-resectable epithelial carcinoma of the ovary AND melphalan is being used for palliative treatment. INTRAVENOUS INJECTION: Documentation of patients diagnosis of multiple myeloma AND melphalan is being used for palliative treatment AND oral melphalan therapy is not appropriate (dysphagia, difficulty swallowing, etc.).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **MEMANTINE ORAL SOLUTION**

### **Products Affected**

• MEMANTINE HCL 2 MG/ML SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Known hypersensitivity to memantine hydrochloride
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. Patient has a diagnosis of moderate to severe dementia of the Alzheimers type. B. Patient has had a trial and therapeutic failure, intolerance, or contraindication to generic memantine tablets AND C. Patient is unable to ingest solid oral dosage forms due to one of the following: (1) Oral/motor difficulties OR (2) Dysphagia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **MENOTROPINS**

### **Products Affected**

• MENOPUR 75 UNIT VIAL OUTER, SUV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a reproductive endocrinologist or infertility specialist
Coverage Duration	1 month
Other Criteria	FEMALE INFERTILITY 1. Patient has diagnosis of infertility AND 2. Will be used in conjunction with assisted reproductive technology or intrauterine insemination
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **Products Affected**

• MESNEX 400 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a Hematologist or Oncologist
Coverage Duration	12 months
Other Criteria	The request is for the prophylaxis of ifosfamide-induced hemorrhagic cystitis.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **METHOXSALEN**

### **Products Affected**

• METHOXSALEN 10 MG SOFTGEL

PA Criteria	Criteria Details
Exclusion Criteria	Patients exhibiting idiosyncratic reactions to psoralen compounds. Patients possessing a specific history of light-sensitive disease states (e.g., lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism). Patients with melanoma or with a history of melanoma. Patients with invasive squamous cell carcinomas. Patients with aphakia because of the significantly increased risk of retinal damage due to the absence of lenses.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a dermatologist
Coverage Duration	12 months
Other Criteria	A. Patient has a diagnosis of severe, recalcitrant, disabling psoriasis AND B. Patients diagnosis is documented by biopsy AND C. Patients disease is not adequately responsive to other forms of therapy AND D. Methoxsalen will be used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation. (Note: Chart notes required for documentation.)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# MIGRAINE - CALCITONIN GENE-RELATED PEPTIDE INHIBITORS - EMGALITY PRIOR AUTHORIZATION POLICY

- EMGALITY 120 MG/ML PEN P/F, SUV, OUTER
- EMGALITY 120 MG/ML SYRINGE P/F, SUV, OUTER
- EMGALITY 300 MG DOSE (100 MG/ML X 3 SYRINGES) P/F, SUV, OUTER

PA Criteria	Criteria Details
Exclusion Criteria	(1) Treatment of acute migraine. (2) Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention [Examples include: Aimovig (erenumab-aooe subcutaneous injection), Ajovy (fremanezumab-vfrm subcutaneous injection), Vyepti (eptinezumab-jjmr intravenous infusion), and Qulipta (atogepant tablets)]. (3) Concurrent use with Nurtec ODT (rimegepant sulfate orally disintegrating tablet) when used as a preventive treatment of migraine.
Required Medical Information	Treatment of episodic cluster headache: INITIAL: Patient must meet ALL of the following: Patient has between one headache every other day and eight headaches per day, AND Patient has tried at least one standard prophylactic pharmacologic therapy for cluster headache, AND Patient has had inadequate efficacy or has experienced adverse event(s) severe enough to warrant discontinuation of the standard prophylactic pharmacologic therapy, according to the prescriber. Migraine headache prevention: INITIAL: Patient must meet all of the following: Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND Patient has tried at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class [Note: Examples of standard prophylactic (preventive) pharmacologic therapies for migraine include angiotensin receptor blocker, angiotensin converting enzyme inhibitor, anticonvulsant, beta-blocker, calcium channel blocker, tricyclic antidepressant, other antidepressant. Of note, standard prophylactic (preventive) pharmacologic therapies do not include oral or injectable CGRP inhibitors], AND Patient meets ONE of the following criteria: Patient has had inadequate efficacy to both of those standard prophylactic pharmacologic therapies, according to the prescriber, OR Patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic pharmacologic therapies, according to the prescriber, OR Patient meets BOTH of the

PA Criteria	Criteria Details
	following: Patient has had inadequate efficacy to one standard prophylactic pharmacologic therapy, AND Patient has experienced adverse event(s) severe enough to warrant discontinuation to another standard prophylactic pharmacologic therapy, according to the prescriber.
Age Restrictions	18 years of age and older
Prescriber Restrictions	NA
Coverage Duration	Treatment of episodic cluster headache treatment: 6 months. Migraine headache prevention: 12 months
Other Criteria	Migraine headache prevention: CONTINUATION - Patient is currently taking Emgality and has had a significant clinical benefit from the medication as determined by the prescriber. (Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated.)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **MIGRAINE - NURTEC ODT CARE VALUE POLICY**

### **Products Affected**

#### • NURTEC ODT 75 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taken for the preventive treatment of episodic migraine.
Required Medical Information	N/A
Age Restrictions	18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Migraine, Acute Treatment: Patient meets ONE of the following: Patient has tried at least one triptan therapy OR Patient has a contraindication to triptan(s) according to the prescriber. (Note: Examples of contraindications to triptans include a history of coronary artery disease. cardiac accessory conduction pathway disorders. history of stroke, transient ischemic attack, or hemiplegic or basilar migraine. peripheral vascular disease. ischemic bowel disease. uncontrolled hypertension OR severe hepatic impairment.) Preventive Treatment of Episodic Migraine: Patient meets the following criteria (A, B, C, and D): (A) Patient has $\geq$ 4 and less than 15 migraine headache days per month (prior to initiating a migraine-preventive medication) AND (B) Patient has tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class (Note: Examples of standard prophylactic (preventive) pharmacologic therapies include angiotensin receptor blocker, anticonvulsant, beta- blocker, tricyclic antidepressant, other antidepressant) AND (C) Patient meets ONE of the following criteria (i, ii, or iii): (i) Patient has had inadequate efficacy to both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber OR (ii) Patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic (preventive) pharmacologic therapies,

PA Criteria	Criteria Details
	according to the prescriber OR (iii) Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy and has experienced adverse event(s) severe enough to warrant discontinuation of another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber AND (D) If the patient is currently taking Nurtec ODT, patient has had a significant clinical benefit from the medication as determined by the prescriber. (Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Nurtec ODT was initiated).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# MIGRAINE - REYVOW/UBRELVY CARE VALUE POLICY

- REYVOW 100 MG TABLET
- REYVOW 50 MG TABLET
- UBRELVY 100 MG TABLET OUTER
- UBRELVY 50 MG TABLET OUTER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	MIGRAINE, ACUTE TREATMENT: Patient meets ONE of the following: (1) Patient has tried at least one triptan therapy OR (2) Patient has a contraindication to triptan(s) according to the prescriber (Note: Examples of contraindications to triptans include a history of coronary artery disease. cardiac accessory conduction pathway disorders. history of stroke, transient ischemic attack, or hemiplegic or basilar migraine. peripheral vascular disease. ischemic bowel disease. uncontrolled hypertension OR severe hepatic impairment).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### MITOTANE

### **Products Affected**

• LYSODREN 500 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of inoperable, functional or nonfunctional adrenal cortical carcinoma
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### **Products Affected**

• MODAFINIL 100 MG TABLET

• MODAFINIL 200 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Hypersensitivity to modafinil or armodafinil.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist, pulmonologist, or sleep specialist.
Coverage Duration	12 months
Other Criteria	NARCOLEPSY: Patient has a documented diagnosis of narcolepsy supported by a sleep study AND Documentation has been provided to confirm diagnosis of narcolepsy is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least one formulary/preferred treatment, such as methylphenidate or dextroamphetamine. SHIFT WORK SLEEP DISORDER: Patient is experiencing excessive sleepiness and documentation of current work schedule is provided showing that patient is working a minimum of five (or more) overnight shifts per month AND Documentation has been provided to confirm 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. OBSTRUCTIVE SLEEP APNEA: Patient has a documented diagnosis of obstructive sleep apnea is supported by a sleep study AND Patient is experiencing residual excessive sleepiness defined as an Epworth Sleepiness Scale (ESS) score of greater than or equal to 10 AND Patient has been on CPAP for at least 2 months and is using it on average greater than or equal to 4 hours per night.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# MS AGENTS (AVONEX, PLEGRIDY, COPAXONE, GLATOPA) - PRIOR AUTHORIZATION POLICY

- AVONEX PEN 30 MCG/0.5 ML KIT OUTER, SUV, P/F
- AVONEX PREFILLED SYR 30 MCG KIT OUTER, SUV, P/F
- GLATIRAMER 20 MG/ML SYRINGE OUTER, SUV
- GLATIRAMER 40 MG/ML SYRINGE INNER, SDV
- GLATOPA 20 MG/ML SYRINGE OUTER, SUV
- GLATOPA 40 MG/ML SYRINGE OUTER, SUV

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis. Non-Relapsing Forms of Multiple Sclerosis.
Required Medical Information	Renewal: Patient is Currently Receiving this medication for greater than or equal to 1 Year AND Patient meets one of the following: (1) Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions]. stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score. achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4. improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale. reduction or absence of relapses. improvement or maintenance on the six-minute walk test or 12-Item MS Walking Scale. improvement on the Multiple Sclerosis Functional Composite (MSFC) score AND/or attenuation of brain volume loss OR (2) Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Avonex, Plegridy, Copaxone & Glatopa: Patient has a relapsing form of multiple sclerosis (for example: clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# MULTIPLE SCLEROSIS PRIOR AUTHORIZATION POLICY - AUBAGIO

- AUBAGIO 14 MG TABLET
- AUBAGIO 7 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	(1) Concurrent use with other Disease-Modifying Agents Used for Multiple Sclerosis. (2) Non-relapsing forms of Multiple Sclerosis.
Required Medical Information	RENEWAL: A. Patient is currently receiving Aubagio for greater than or equal to 1 year AND B. Patient has a relapsing form of multiple sclerosis (Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease) AND C. Patient meets one of the following: (1) Patient experienced a beneficial clinical response when assessed by at least one objective measure (Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions], stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score, achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4, improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale, reduction or absence of relapses, improvement or maintenance on the six-minute walk test or 12-Item MS Walking Scale, improvement on the Multiple Sclerosis Functional Composite (MSFC) score AND/or attenuation of brain volume loss) OR (2) Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year
Other Criteria	Initial: Patient has a relapsing form of multiple sclerosis (Note: Examples of relapsing forms of multiple sclerosis include clinically isolated

PA Criteria	Criteria Details
	syndrome, relapsing remitting disease, and active secondary progressive disease).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

### MULTIPLE SCLEROSIS PRIOR AUTHORIZATION POLICY - DIMETHYL FUMARATE

- DIMETHYL FUMARATE 30D START PK
- DIMETHYL FUMARATE DR 120 MG CP
- DIMETHYL FUMARATE DR 240 MG CP

PA Criteria	Criteria Details
Exclusion Criteria	(1) Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis. (2) Non-relapsing forms of Multiple Sclerosis.
Required Medical Information	RENEWAL: Patient Has Been Receiving Dimethyl Fumarate for 1 Year, AND Patient has a relapsing form of multiple sclerosis, AND Patient experienced a beneficial clinical response when assessed by at least one objective measure. Note: Examples include stabilization or reduced worsening in disease activity as evaluated by magnetic resonance imaging (MRI) [absence or a decrease in gadolinium enhancing lesions, decrease in the number of new or enlarging T2 lesions], stabilization or reduced worsening on the Expanded Disability State Scale (EDSS) score, achievement in criteria for No Evidence of Disease Activity-3 (NEDA-3) or NEDA-4, improvement on the fatigue symptom and impact questionnaire-relapsing multiple sclerosis (FSIQ-RMS) scale, reduction or absence of relapses, improvement or maintenance on the six-minute walk test or 12-Item Multiple Sclerosis Walking Scale, improvement on the Multiple Sclerosis Functional Composite (MSFC) score, and/or attenuation of brain volume loss, OR Patient experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Initial: Patient has a relapsing form of multiple sclerosis (Examples of relapsing forms of multiple sclerosis include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **ONCOLOGY (INJECTABLE) - FULVESTRANT PRIOR AUTHORIZATION POLICY**

#### **Products Affected**

• FULVESTRANT 250 MG/5 ML SYRINGE SUV, INNER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	2. Breast Cancer - Fulvestrant Combination Therapy: A) Patient has recurrent or metastatic hormone receptor (HR)-positive (i.e., estrogen receptor- [ER] or progesterone receptor [PR]-positive) disease AND B) Patient meets ONE of the following criteria (i or ii): i. Patient is a postmenopausal female or a male OR ii. Patient is pre/perimenopausal female and meets one of the following (a or b): a) Patient is receiving ovarian suppression/ovarian ablation with a gonadotropin-releasing hormone (GnRH) agonist, examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), or Zoladex (goserelin acetate subcutaneous implant), OR b) Patient has had surgical bilateral oophorectomy or ovarian irradiation, AND C) Patient meets one of the following criteria (i or ii): i. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer and meets one of the following criteria (a or b): a) Patient has progressed on or after at least one prior endocrine-based therapy and patient meets one of the following criteria (1 or 2) [Note: Examples of endocrine therapy are tamoxifen, anastrozole, letrozole, exemestane]: (1) Patient has a phosphatidylinositol 4,5- bisphosphate 3-kinase catalytic subunit alpha (PIK3CA)-mutated tumor and the medication is used in combination with Piqray (alpelisib tablets) OR (2) The medication will be used in combination with everolimus OR b)

PA Criteria	Criteria Details
	The medication will be used in combination with a cyclin dependent kinase 4/6 (CDK 4/6) inhibitor or a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole) [Note: Examples of CDK4/6 inhibitors are Kisqali (ribociclib tablets), Ibrance (palbociclib capsules), Verzenio (abemaciclib tablets).] OR ii. Patient has human epidermal growth factor receptor 2 (HER2)-positive breast cancer and the medication is used in combination with a trastuzumab product. 3. Endometrial Carcinoma. 4. Ovarian/Fallopian Tube/Primary Peritoneal Cancer: A) Patient has recurrent low-grade serous carcinoma. 5. Uterine Sarcoma: A) Patient meets one of the following criteria (i, ii, or ii): i. Patient has low-grade endometrial stromal sarcoma OR ii. Patient has hormone receptor positive uterinesarcoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Endometrial Carcinoma. Ovarian/Fallopian Tube/Primary Peritoneal Cancer. Uterine Sarcoma

# **ONCOLOGY (INJECTABLE) - TRASTUZUMAB PRODUCTS PRIOR AUTHORIZATION POLICY**

#### **Products Affected**

• KANJINTI 420 MG VIAL

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	1. Breast Cancer: A) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND B) Patient meets ONE of the following criteria (i or ii): i. trastuzumab is used for neoadjuvant (preoperative)/adjuvant therapy, OR ii. trastuzumab is used for recurrent or metastatic disease. 2. Gastric, Esophageal, or Gastroesophageal Junction Cancer: A) Patient has locally advanced or metastatic disease, AND B) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND C) Patient meets the following criteria (i and ii): i. Trastuzumab will be used as first-line therapy, AND ii. Trastuzumab will be used in combination with chemotherapy. Note: Examples of chemotherapy are cisplatin, oxaliplatin, capecitabine, 5-fluorouracil (5-FU). 3. Biliary Tract Cancer: A) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND C) The medication will be used in combination with common epidermal growth factor receptor 2 (HER2)-positive disease, AND B) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND C) The medication will be used in combination with chemotherapy. Note: Examples of chemotherapy are cisplatin, oxaliplatin, capecitabine of a systemic regimen include: gemcitabine and cisplatin, 5-fluorouracil and oxaliplatin, capecitabine and oxaliplatin, or gemcitabine and oxaliplatin. 4. Colon or Rectal Cancer: A) Patient has advanced or metastatic disease, AND B) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND B)

PA Criteria	Criteria Details
	(pertuzumab intravenous infusion) or lapatinib. 5. Endometrial Carcinoma: A) Patient has advanced or recurrent uterine serous carcinoma, AND B) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND C) Trastuzumab will be used in combination with chemotherapy, Note: Examples of chemotherapy are carboplatin, paclitaxel. 6. Salivary Gland Tumor: A) Patient has recurrent, unresectable, or metastatic disease, AND B) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Biliary Tract Cancer, Colon or Rectal Cancer, Endometrial Carcinoma, Salivary Gland Tumor

### ONCOLOGY (INJECTABLE)- GONADOTROPIN-RELEASING HORMONE ANALOGS PRIOR AUTHORIZATION POLICY

- ELIGARD 22.5 MG SYRINGE KIT OUTER, SUV
- ELIGARD 30 MG SYRINGE KIT OUTER, SUV
- ELIGARD 45 MG SYRINGE KIT OUTER, SUV
- ELIGARD 7.5 MG SYRINGE KIT OUTER, SUV

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	None
Prescriber Restrictions	Prostate Cancer: prescribed by or in consultation with an oncologist or urologist. Head and Neck Cancer - Salivary Gland Tumors: prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	For Camcevi, Eligard, Leuprolide Depot, Firmagon, or Trelstar: diagnosis of Prostate Cancer. For Camcevi or Eligard: A) Diagnosis of Head and Neck Cancer - Salivary Gland Tumors, AND B) Patient has recurrent, unresectable or metastatic disease AND C) Patient has androgen receptor- positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Head and Neck Cancer - Salivary Gland Tumors.

## **ONCOLOGY- ABIRATERONE ACETATE** (GENERIC) PRIOR AUTHORIZATION POLICY

- ABIRATERONE ACETATE 250 MG TAB
- ABIRATERONE ACETATE 500 MG TAB

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Prostate Cancer (Very-High-Risk Group): 2 years. All others: 1 year
Other Criteria	A. Patient has ONE of the following: 1. Prostate Cancer - Metastatic, Castration-Resistant (mCRPC) 2. Prostate Cancer - Metastatic, Castration- Sensitive (mCSPC) 3. Prostate Cancer (Regional Risk Group) 4. Prostate Cancer (Very-High-Risk Group). B. mCRPC: 1. The medication is used in combination with prednisone or dexamethasone, AND 2. Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist. Note: Examples of GnRH agonists include: Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Vantas (histrelin acetate subcutaneous implant), OR ii. The medication is concurrently used with Firmagon (degarelix for injection), OR iii. Patient has had a bilateral orchiectomy. C. mCSPC: 1. The medication is used in combination with prednisone, AND 2. Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, OR ii. The medication is used in combination with prednisone, AND 2. Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, OR ii. The medication is concurrently used with Firmagon (degarelix for injection), OR iii. Patient has had a bilateral orchiectomy. D. Prostate Cancer (Regional Risk Group): 1. The medication is used in combination with prednisone, AND 2. Patient has regional lymph node metastases and no

PA Criteria	Criteria Details
	distant metastases, AND 3. Patient meets one of the following criteria (i, ii, or iii): i. The medication is concurrently used with a gonadotropin- releasing hormone (GnRH) agonist, OR ii. The medication is concurrently used with Firmagon (degarelix for injection), OR iii. Patient has had a bilateral orchiectomy. E. Prostate Cancer (Very-High-Risk Group): 1. According the prescriber, the patient is in the very-high-risk group. Note: Very-high-risk group includes patients that have one of the following: primary Gleason pattern 5, 2 or 3 high-risk features, greater than 4 cores with Grade Group 4 or 5, tumor that invades seminal vesicles, tumor that is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall, AND 2. The medication is used in combination with external beam radiation therapy, AND 3. Patient meets one of the following criteria (i, ii, or iii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, OR ii. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, OR ii. The medication is concurrently used with a gonadotropin-
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Prostate Cancer (Regional Risk Group), Prostate Cancer (Very-High-Risk Group)

# ONCOLOGY- ALECENSA PRIOR AUTHORIZATION POLICY

#### **Products Affected**

• ALECENSA 150 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Non-Small Cell Lung Cancer: A) Patient has advanced or metastatic disease AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease AND C) The mutation was detected by an approved test. 2. Anaplastic Large Cell Lymphoma: A) Patient has anaplastic lymphoma kinase (ALK)-positive disease, AND B) Patient meets one of the following criteria (i or ii): i. Patient has relapsed disease OR ii. Patient has refractory disease. 3. Erdheim-Chester Disease: A) Patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. 4. Inflammatory Myofibroblastic Tumor: A) Patient has anaplastic lymphoma kinase (ALK)-positive disease AND B) Patient meets one of the following criteria (i or ii): i. Patient has advanced, recurrent, or metastatic disease OR ii. The tumor is inoperable.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Anaplastic Large Cell Lymphoma. Erdheim-Chester Disease. Inflammatory Myofibroblastic Tumor.

# **ONCOLOGY- BEXAROTENE (ORAL) PRIOR AUTHORIZATION**

#### **Products Affected**

• BEXAROTENE 75 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or a dermatologist.
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma: A) Patient has cutaneous manifestations/lesions.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **ONCOLOGY- BOSULIF PRIOR AUTHORIZATION POLICY**

- BOSULIF 100 MG TABLET
- BOSULIF 400 MG TABLET
- BOSULIF 500 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Chronic Myeloid Leukemia: Patient has Philadelphia chromosome- positive chronic myeloid leukemia. 2. Acute Lymphoblastic Leukemia: Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia, AND Patient has tried at least one other tyrosine kinase inhibitor for Philadelphia chromosome-positive acute lymphoblastic leukemia. Note: Examples include imatinib and Sprycel (dasatinib tablets). 3. Myeloid/Lymphoid Neoplasms with Eosinophilia: The tumor has an ABL1 rearrangement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute Lymphoblastic Leukemia. Myeloid/Lymphoid Neoplasms with Eosinophilia.

# **ONCOLOGY- CABOMETYX PRIOR AUTHORIZATION POLICY**

- CABOMETYX 20 MG TABLET
- CABOMETYX 40 MG TABLET
- CABOMETYX 60 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Metastatic Castration-Resistant Prostate Cancer (mCRPC).
Required Medical Information	N/A
Age Restrictions	Thyroid Carcinoma (Differentiated): 12 years of age or older. All others, except Bone Cancer: 18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Hepatocellular Carcinoma: Patient has been previously treated with at least one systemic regimen. Note: Examples of a systemic regimen include one of the following drugs: Tecentriq (atezolizumab intravenous infusion), bevacizumab, Nexavar (sorafenib tablets), Lenvima (lenvatinib capsules), or Opdivo (nivolumab intravenous infusion). 2. Renal Cell Carcinoma: Patient has relapsed or stage IV disease. 3. Thyroid Carcinoma, Differentiated: Patient has differentiated thyroid carcinoma. Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hurthle cell thyroid carcinoma, AND Patient is refractory to radioactive iodine therapy, AND Patient has tried Lenvima (lenvatinib capsules) or Nexavar (sorafenib tablets). 4. Bone Cancer: Patient has tried at least one previous systemic regimen [Note: Examples of a systemic regimen include one of the following: vincristine, doxorubicin, cyclophosphamide, topotecan, irinotecan, cisplatin, ifosfamide, Stivarga (regorafenib tablets), sorafenib], AND Patient meets ONE of the following (i or ii): i. Patient has Ewing sarcoma, OR ii. Patient has osteosarcoma. 5. Endometrial Carcinoma: Patient has tried one systemic regimen. Note: Examples of a systemic regimen include one of the following: carboplatin,

PA Criteria	Criteria Details
	paclitaxel, trastuzumab, docetaxel, doxorubicin, cisplatin, and topotecan. 6. Gastrointestinal Stromal Tumors: Patient has tried each of the following (i, ii, iii, and iv): i. One of imatinib or Ayvakit (avapritinib tablets), AND ii. One of Sutent (sunitinib capsules) or Sprycel (dasatinib tablets), AND iii. Stivarga (regorafenib tablets), AND iv. Qinlock (ripretinib tablets). 7. Non- Small Cell Lung Cancer: Patient has a RET rearrangement positive tumor.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone Cancer. Endometrial Carcinoma. Gastrointestinal Stromal Tumors. Non-Small Cell Lung Cancer.

# **ONCOLOGY- CAPECITABINE PRIOR AUTHORIZATION**

- CAPECITABINE 150 MG TABLET
- CAPECITABINE 500 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Breast Cancer 2. Colon Cancer 3. Esophageal and Esophagogastric Junction Cancers 4. Gastric Cancer 5. Pancreatic Adenocarcinoma
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ampullary Adenocarcinoma, Anal Carcinoma, Central Nervous System Cancers, Gestational Trophoblastic Neoplasia, Head and Neck Cancers, Hepatobiliary Cancers, Neuroendocrine and Adrenal Tumors, Occult Primary, Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer, Penile Cancer, Rectal Cancer, Small Bowel Adenocarcinoma, Squamous Cell Skin Cancer, Thymomas and Thymic Carcinomas

# ONCOLOGY- CAPRELSA PRIOR AUTHORIZATION POLICY

- CAPRELSA 100 MG TABLET
- CAPRELSA 300 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Thyroid Carcinoma, Medullary. 2. Thyroid Carcinoma, Differentiated: A) Patient has differentiated thyroid carcinoma [Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hurthle cell carcinoma)] AND B) The disease is refractory to radioactive iodine therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thyroid Carcinoma, Differentiated

# ONCOLOGY- COMETRIQ PRIOR AUTHORIZATION POLICY

- COMETRIQ 100 MG DAILY-DOSE PK
- COMETRIQ 140 MG DAILY-DOSE PK
- COMETRIQ 60 MG DAILY-DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	Metastatic Castration-Resistant Prostate Cancer (mCRPC).
Required Medical Information	N/A
Age Restrictions	Thyroid Carcinoma (Medullary) AND Non-Small Cell Lung Cancer: 18 years of age or older. Thyroid Carcinoma (Differentiated): 12 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Thyroid Carcinoma, Medullary. 2. Non-Small Cell Lung Cancer: Patient has RET gene rearrangements. 3. Thyroid Carcinoma, Differentiated: Patient has differentiated thyroid carcinoma. Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hurthle cell carcinoma), AND The disease is refractory to radioactive iodine therapy, AND Patient has tried Lenvima (lenvatinib capsules) or Nexavar (sorafenib tablets).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Non-Small Cell Lung Caner. Thyroid Carcinoma, Differentiated.

# ONCOLOGY- ERIVEDGE PRIOR AUTHORIZATION POLICY

#### **Products Affected**

• ERIVEDGE 150 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	1. Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Odomzo (sonidegib capsules). Note: This does not apply to a patient already started on Erivedge. 2. Metastatic Colorectal Cancer. 3. Ovarian Cancer.
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Basal Cell Carcinoma, Locally Advanced. Initial Therapy: Patient meets one of the following (a or b): a) Patient has recurrent basal cell carcinoma following surgery or radiation therapy, OR b) Patient meets BOTH of the following [(1) and (2)]: (1) Patient is not a candidate for surgery, AND (2) According to the prescriber, the patient is not a candidate for radiation therapy. Renewal: Patient is Currently Receiving Erivedge. 2. Basal Cell Carcinoma, Metastatic (Note: This includes primary or recurrent nodal metastases and distant metastastatic disease). 3. Central Nervous System Cancer (Note: This includes brain and spinal cord tumors.): Patient has medulloblastoma AND Patient has tried at least one chemotherapy agent. Note: Examples of chemotherapy include etoposide, carboplatin, cisplatin, AND According to the prescriber, the patient has a mutation of the sonic hedgehog pathway.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Cancer

# ONCOLOGY- ERLEADA PRIOR AUTHORIZATION POLICY

#### **Products Affected**

• ERLEADA 60 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Prostate Cancer - Non-Metastatic, Castration-Resistant: A) Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist [Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).] OR ii. The medication is concurrently used with Firmagon (degarelix subcutaneous injection) OR iii. Patient has had a bilateral orchiectomy. 2. Prostate Cancer - Metastatic, Castration-Sensitive: A) Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist [Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant)] OR ii. The medication is concurrently used with Firmagon (degarelix subcutaneous injection) OR iii. Patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

# ONCOLOGY- ERLOTINIB PRIOR AUTHORIZATION POLICY

- ERLOTINIB HCL 100 MG TABLET
- ERLOTINIB HCL 150 MG TABLET
- ERLOTINIB HCL 25 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Breast Cancer. Colon cancer, Advanced. Glioblastoma Multiforme (GBM). Head and Neck Cancer, Squamous Cell, Recurrent and/or Metastatic. Hepatocellular Carcinoma, Advanced. Renal Cell Carcinoma, Advanced - Clear Cell Histology
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Non-Small Cell Lung Cancer: A) Patient has advanced or metastatic disease, AND B) Patient has sensitizing EGFR mutation-positive non-small cell lung cancer as detected by an approved test, Note: Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I. 2. Pancreatic Cancer: A) Patient has locally advanced, metastatic, or recurrent disease, AND B) The medication is used in combination with gemcitabine. Bone Cancer: A) Patient has chordoma AND B) Patient has tried at least one previous therapy. 4. Renal Cell Carcinoma: A) Patient meets one of the following criteria (i or ii): i. Patient has recurrent or advanced renal cell carcinoma of non-clear cell histology OR ii. Patient meets both of the following criteria (a and b): a. Patient has hereditary leiomyomatosis and renal cell carcinoma AND b. The medication is used in combination with bevacizumab. 5. Vulvar Cancer: A) Patient has advanced, recurrent, or metastatic disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Bone Cancer. Renal Cell Carcinoma. Vulvar Cancer.

## **ONCOLOGY- EVEROLIMUS (GENERIC) PRODUCTS PRIOR AUTHORIZATION POLICY**

- EVEROLIMUS 10 MG TABLET OUTER
- EVEROLIMUS 2 MG TAB FOR SUSP INNER
- EVEROLIMUS 2.5 MG TABLET OUTER
- EVEROLIMUS 3 MG TAB FOR SUSP INNER
- EVEROLIMUS 5 MG TAB FOR SUSP INNER
- EVEROLIMUS 5 MG TABLET OUTER
- EVEROLIMUS 7.5 MG TABLET OUTER

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	A. Patient has ONE of the following: 1. Breast cancer 2. Neuroendocrine Tumors of the Pancreas, Gastrointestinal Tract, Lung, and Thymus (Carcinoid Tumors) 3. Renal Cell Carcinoma 4. Tuberous Sclerosis Complex-Associated Renal Angiomyolipoma 5. Tuberous Sclerosis Complex-Associated Subependymal Giant Cell Astrocytoma (SEGA) 6. Tuberous Sclerosis Complex-Associated Partial Onset Seizures 7. Endometrial Carcinoma 8. Gastrointestinal Stromal Tumors 9. Histiocytic Neoplasm 10. Classic Hodgkin Lymphoma 11. Uterine Sarcoma 12. Soft Tissue Sarcoma 13. Thymomas and Thymic Carcinomas 14. Thyroid Carcinoma, Differentiated 15. Waldenstroms Macroglobulinemia/Lymphoplasmacytic Lymphoma. B. Breast Cancer: 1. Recurrent or metastatic, hormone receptor positive (HR+) [such as, estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease, AND 2. Has human epidermal growth factor receptor 2 (HER2)- negative breast cancer, AND 3. Has tried at least one prior endocrine therapy (for example, anastrozole, letrozole, or tamoxifen), AND 4. ONE of the following conditions: i. Postmenopausal woman or a man, OR ii. Pre/perimenopausal woman and one of the following: a. Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist such as leuprolide acetate, Lupron Depot, Trelstar etc. OR b) Past surgical bilateral oophorectomy or ovarian irradiation, AND 5. ONE of the following conditions: i. Medication will be used in combination with exemestane and patient meets one of the following (a or b): a. Patient is a man and is receiving a GnRH analog such as leuprolide acetate, Lupron Depot, Trelstar etc. OR b. Patient is a woman OR ii. Medication will be used in combination with fulvestrant or

PA Criteria	Criteria Details
	tamoxifen, AND 6. Patient has not had disease progression while on everolimus.
Age Restrictions	18 years of age and older for all EXCEPT Tuberous Sclerosis Complex- Associated SEGA, Tuberous Sclerosis Complex-Associated Partial Onset Seizures, Tuberous Sclerosis Complex-Associated Renal Angiomyolipoma
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	C. Renal Cell Carcinoma: 1. Patient has relapsed or Stage IV disease, AND 2. ONE of the following criteria (i or ii): i. Patient has non-clear cell disease, OR ii. Both of the following: a. Patient has clear cell disease, AND b. Patient has tried at least one prior systemic therapy such as Inlyta, Lenvima, Keytruda etc. D. Tuberous Sclerosis Complex-Associated SEGA: 1. Therapeutic intervention is required but SEGA cannot be curatively resected. E. Endometrial Carcinoma: 1. Medication will be used in combination with letrozole. F. Gastrointestinal Stromal Tumors: 1. Patient tried each of following (i, ii, iii, and iv): i. One of imatinib or Ayvakit (avapritinib tablets), AND iii. One of Sutent (sunitinib capsules) or Sprycel (dasatinib tablets), AND iii. Stivarga (regorafenib tablets), AND iv. Qinlock (ripretinib tablets), AND 2. Medication will be used in combination with imatinib, Sutent (sunitinib capsules), or Stivarga (regorafenib tablets). G. Histiocytic Neoplasm: 1. One of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following: a) Bone disease, OR b) Central nervous system lesions, OR c) Multisystem disease, OR d) Pulmonary disease, OR ii. Patient has Erdheim-Chester disease, OR iii. Patient has Rosai-Dorfman disease, AND 3. Patient has a PIK3CA mutation. H. Classic Hodgkin Lymphoma: 1. Patient has relapsed or refractory disease. I. Uterine Sarcoma: 1. Patient has a perivascular epithelioid cell tumor (PEComa), AND 3. Patient has tried at least one systemic regimen. Note: Examples of systemic regimen include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine. J. Soft Tissue Sarcoma: 1. ONE of the following (i or ii): i. Perivascular epitheloid cell tumor (PEComa), OR ii. Recurrent angiomyolipoma/lymphangioleiomyomatosis. K. Thymomas and Thymic Carcinomas: 1. One of the following (i or ii): i. Patient has tried chemotherapy. Note: Examples are cisplatin, doxorubicin, and cyclophosphamide, cisplatin plus etoposide, carboplatin plus paclitaxel, OR ii. P

PA Criteria	Criteria Details
	Differentiated: Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hurthle cell thyroid carcinoma, 1. Disease is refractory to radioactive iodine therapy. M. Waldenstroms Macroglobulinemia/Lymphoplasmacytic Lymphoma: 1. One of the following (i or ii): i. Patient has not responded to primary therapy. Note: Examples of primary therapy are bortezomib, dexamethasone, and rituximab, bendamustine and rituximab, cyclophosphamide, rituximab and dexamethasone, Imbruvica (ibrutinib capsules), and Brukinsa (zanubrutinib capsules), OR ii. Patient has progressive or relapsed disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Endometrial Carcinoma, Gastrointestinal Stromal Tumors, Histiocytic Neoplasm, Soft Tissue Sarcoma, Thymomas and Thymic Carcinomas, Thyroid Carcinoma, Differentiated, Classic Hodkin Lymphona. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma.

# ONCOLOGY- IBRANCE PRIOR AUTHORIZATION POLICY

- IBRANCE 100 MG CAPSULE
- IBRANCE 100 MG TABLET INNER
- IBRANCE 125 MG CAPSULE
- IBRANCE 125 MG TABLET INNER
- IBRANCE 75 MG CAPSULE
- IBRANCE 75 MG TABLET INNER

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Breast Cancer in Women: A) Patient has recurrent or metastatic disease, AND B) Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer, AND D) Patient meets ONE of the following criteria (i or ii): i. Patient is postmenopausal OR ii. Patient is pre/perimenopausal and meets one of the following (a or b): a) Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection), OR b) Patient has had surgical bilateral oophorectomy or ovarian irradiation, AND E) Patient meets ONE of the following criteria (i or ii): i. Ibrance will be used in combination with anastrozole, exemestane, or letrozole, OR ii. Ibrance will be used in combination with fulvestrant. 2. Breast Cancer in Men: A) Patient has

PA Criteria	Criteria Details
	recurrent or metastatic disease, AND B) Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer, AND D) Patient meets ONE of the following criteria (i or ii): i. Patient meets BOTH of the following criteria (a and b): a) Patient is receiving a gonadotropin-releasing hormone (GnRH) analog, Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet), AND b) Ibrance will be used in combination with anastrozole, exemestane, or letrozole, OR ii. Ibrance will be used in combination with fulvestrant. 3. Liposarcoma: A) Patient has well-differentiated/dedifferentiated liposarcoma.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Liposarcoma

# **ONCOLOGY- IMATINIB (GENERIC) PRIOR AUTHORIZATION POLICY**

- IMATINIB MESYLATE 100 MG TAB F/C
- IMATINIB MESYLATE 400 MG TAB F/C

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	Melanoma (Cutaneous), Kaposi Sarcoma, Aggressive Systemic Mastocytosis, Dermatofibrosarcoma Protuberans, Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia, Myelodysplastic/Myeloproliferative Disease, Myeloid/Lymphoid Neoplasms with Eosinophilia: 18 years of age and older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	A. Patient has ONE of the following: 1. Acute Lymphoblastic Leukemia. 2. Aggressive Systemic Mastocytosis 3. Chronic Myeloid Leukemia 4. Dermatofibrosarcoma Protuberans 5. Gastrointestinal Stromal Tumors 6. Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia 7. Myelodysplastic/Myeloproliferative Disease 8. Chordoma 9. 9. Desmoid Tumors (Aggressive Fibromatosis) 10. Graft-Versus-Host Disease, Chronic 11. Kaposi Sarcoma 12. 12. Melanoma, Cutaneous 13. Myeloid/Lymphoid Neoplasms with Eosinophilia 14. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. B. Acute Lymphoblastic Leukemia: 1. Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia. C. Chronic Myeloid Leukemia: Patient has Philadelphia chromosome-positive chronic myeloid leukemia. D. Myelodysplastic/Myeloproliferative Disease: 1. Condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements. E. Graft-Versus-Host Disease, Chronic: 1. Patient has tried at least one conventional systemic treatment for graft-versus-host disease.

PA Criteria	Criteria Details
	Note: Examples include corticosteroids (methylprednisolone, prednisone), cyclosporine, tacrolimus, mycophenolate mofetil, Imbruvica (ibrutinib capsules and tablets), low-dose methotrexate, sirolimus, Rezurock (belumosudil tablets), and Jakafi (ruxolitinib tablets). F. Kaposi Sarcoma: 1. Patient has tried at least one medication. Note: Examples include liposomal doxorubicin, paclitaxel, Pomalyst (pomalidomide capsules), lenalidomide, etoposide, and Thalomid (thalidomide capsules), AND 2. Patient has relapsed or refractory disease. G. 12. Melanoma, Cutaneous: 1) Patient has metastatic or unresectable disease, AND 2) Patient has an activating KIT mutation, AND 3) Patient has tried at least one systemic regimen. Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets). H. Myeloid/Lymphoid Neoplasms with Eosinophilia: 1. Patient meets one of the following: i. The tumor has an ABL1 rearrangement OR ii. The tumor has an FIP1L1-PDGFRA or PDGFRB rearrangement. I. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor: 1. Patient has tried Turalio (pexidartinib capsules), OR 2. Patient cannot take Turalio, according to the prescriber. Note: Examples of reasons for not being able to take Turalio include patients with elevated liver enzymes or concomitant use of medications that are associated with hepatotoxicity.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chordoma, Desmoid Tumors (Aggressive Fibromatosis), Graft-Versus- Host Disease, Chronic, Kaposi Sarcoma, Melanoma (Cutaneous), Myeloid/Lymphoid Neoplasms with Eosinophilia, Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor

# ONCOLOGY- IMBRUVICA 140 AND 280 MG TABLETS CARE VALUE POLICY

- IMBRUVICA 140 MG TABLET
- IMBRUVICA 280 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	<ul> <li>A. Patient has tried Imbruvica 140 mg capsules, AND b. Patient has ONE of the following: 1. Chronic Lymphocytic Leukemia 2. Graft-Versus-Host Disease, Chronic 3. Mantle Cell Lymphoma 4. Marginal Zone Lymphoma 5. Small Lymphocytic Lymphoma 6. Waldenstrom Macroglobulinemia 7. B-Cell Lymphoma 8. Central Nervous System Lymphoma (Primary) 9. Hairy Cell Leukemia.</li> </ul>
Age Restrictions	Graft-Versus-Host Disease, Chronic: 1 year of age and older, ALL others: 18 years of age and older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	B. Graft-Versus-Host Disease, Chronic: 1. Patient tried at least one conventional systemic treatment for graft-versus-host disease. Note: Examples of conventional systemic treatments include: corticosteroids (methylprednisolone, prednisone), imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, and Jakafi (ruxolitinib tablets). C. Mantle Cell Lymphoma: 1) Patient is continuing therapy with Imbruvica, AND 2) Patient meets one of the following criteria: (i or ii): i. Patient meets one of the following criteria (a or b): a) Patient has tried at least one systemic regimen (Examples of a systemic regimen include one or more of the following products: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, cytarabine, carboplatin, cisplatin, oxaliplatin, or lenalidomide.), OR b) According to the prescriber, patient is not a candidate for a systemic regimen (i.e., an elderly person who is frail), OR ii. Imbruvica is used in combination with rituximab prior to induction therapy. Examples of induction therapy include: rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone. D)

PA Criteria	Criteria Details
	Marginal Zone Lymphoma: Note: Marginal zone lymphoma includes gastric mucosa-associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma. 1) Patient is continuing therapy with Imbruvica, AND 2) Patient has tried at least one systemic regimen. Examples of a systemic regimen include one or more of the following products: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, or lenalidomide. E. B-Cell Lymphoma: Note: Examples of B-cell lymphomas include: diffuse large B-cell lymphomas, Acquired Immune Deficiency Syndrome (AIDS)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, double/triple hit lymphoma, and high-grade B-cell lymphoma, AND 1. Patient tried at least one systemic regimen. Note: Examples of a systemic regimen includes one or more of the following products: cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab. F. Central Nervous System Lymphoma (Primary): 1. Patient meets one of the following criteria (i or ii): i. According to the prescriber, the patient is not a candidate for or is intolerant to high-dose methotrexate, OR ii. Patient tried at least one therapy. Note: Examples of therapies include methotrexate, rituximab, vincristine, procarbazine, or rituximab. G. Hairy Cell Leukemia: 1. Patient tried at least two systemic regimens. Note: Examples of a systemic regimen include one or more of the following products: cladribine, Nipent (pentostatin injection), rituximab, or Pegasys (peginterferon alfa-2a subcutaneous injection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma, Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, Mantle Cell Lymphoma, Marginal Zone Lymphoma

# ONCOLOGY- IMBRUVICA PRIOR AUTHORIZATION POLICY

- IMBRUVICA 140 MG CAPSULE
- IMBRUVICA 420 MG TABLET
- IMBRUVICA 70 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	A. Patient has ONE of the following: 1. Chronic Lymphocytic Leukemia 2. Graft-Versus-Host Disease, Chronic 3. Mantle Cell Lymphoma 4. Marginal Zone Lymphoma 5. Small Lymphocytic Lymphoma 6. Waldenstrom Macroglobulinemia 7. B-Cell Lymphoma 8. Central Nervous System Lymphoma (Primary) 9. Hairy Cell Leukemia.
Age Restrictions	Graft-Versus-Host Disease, Chronic: 1 year of age and older, ALL others: 18 years of age and older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	B. Graft-Versus-Host Disease, Chronic: 1. Patient tried at least one conventional systemic treatment for graft-versus-host disease. Note: Examples of conventional systemic treatments include: corticosteroids (methylprednisolone, prednisone), imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, and Jakafi (ruxolitinib tablets). C. Mantle Cell Lymphoma: 1) Patient is continuing therapy with Imbruvica, AND 2) Patient meets one of the following criteria: (i or ii): i. Patient meets one of the following criteria (a or b): a) Patient has tried at least one systemic regimen (Examples of a systemic regimen include one or more of the following products: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, cytarabine, carboplatin, cisplatin, oxaliplatin, or lenalidomide.), OR b) According to the prescriber, patient is not a candidate for a systemic regimen (i.e., an elderly person who is frail), OR ii. Imbruvica is used in combination with rituximab prior to induction therapy. Examples of induction therapy include: rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone. D)

PA Criteria	Criteria Details
	Marginal Zone Lymphoma: Note: Marginal zone lymphoma includes gastric mucosa-associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma. 1) Patient is continuing therapy with Imbruvica, AND 2) Patient has tried at least one systemic regimen. Examples of a systemic regimen include one or more of the following products: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, or lenalidomide. E. B-Cell Lymphoma: Note: Examples of B-cell lymphomas include: diffuse large B-cell lymphomas, Acquired Immune Deficiency Syndrome (AIDS)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, double/triple hit lymphoma, and high-grade B-cell lymphoma, AND 1. Patient tried at least one systemic regimen. Note: Examples of a systemic regimen includes one or more of the following products: cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab. F. Central Nervous System Lymphoma (Primary): 1. Patient meets one of the following criteria (i or ii): i. According to the prescriber, the patient is not a candidate for or is intolerant to high-dose methotrexate, OR ii. Patient tried at least one therapy. Note: Examples of therapies include methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab. G. Hairy Cell Leukemia: 1. Patient tried at least two systemic regimens. Note: Examples of a systemic regimen include one or more of the following products: cladribine, Nipent (pentostatin injection), rituximab, or Pegasys (peginterferon alfa-2a subcutaneous injection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell Lymphoma, Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, Mantle Cell Lymphoma, Marginal Zone Lymphoma

# ONCOLOGY- INLYTA PRIOR AUTHORIZATION POLICY

- INLYTA 1 MG TABLET
- INLYTA 5 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Renal Cell Cancer: Patient has relapsed or advanced disease. 2. Thyroid Carcinoma, Differentiated: Patient has differentiated thyroid carcinoma, examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hurthle cell carcinoma) AND The disease is refractory to radioactive iodine therapy. 3. Soft Tissue Sarcoma: Patient has alveolar soft part sarcoma AND B) The medication will be used in combination with Keytruda (pembrolizumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Thyroid Carcinoma, Differentiated. Soft Tissue Sarcoma.

# **ONCOLOGY- KISQALI CARE VALUE POLICY**

### **Products Affected**

• KISQALI 200 MG DAILY DOSE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	A. Patient meets ONE of the following criteria: i. Patient has been taking Kisqali and is continuing therapy [documentation required], OR ii. Patient will be using Kisqali in combination with an aromatase inhibitor as initial endocrine-based therapy, OR iii. Kisqali will be used in combination with fulvestrant in postmenopausal female or male patients as initial endocrine- based therapy, OR iv. Patient has tried one of Ibrance or Verzenio, AND B. Patient meets ONE of the following: 1. Breast Cancer in Women: Patient has recurrent or metastatic disease, AND Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, AND Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer, AND Patient meets ONE of the following criteria (i or ii): i. Patient is postmenopausal, OR ii. Patient is pre/perimenopausal and meets one of the following (a or b): a) Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist. Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), OR b) Patient has had surgical bilateral oophorectomy or ovarian irradiation, AND Patient meets ONE of the following criteria (i or ii): i. Kisqali will be used in combination with anastrozole, exemestane, or letrozole, OR ii. Kisqali will be used in combination with fulvestrant.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	2. Breast Cancer in Men: Patient has recurrent or metastatic disease, AND Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, AND

PA Criteria	Criteria Details
	Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer, AND Patient meets ONE of the following criteria (i or ii): i. Patient meets BOTH of the following criteria (a and b): a) Patient is receiving a gonadotropin-releasing hormone (GnRH) analog. Note: Examples of GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet), AND b) Kisqali will be used in combination with anastrozole, exemestane, or letrozole, OR ii. Kisqali will be used in combination with fulvestrant.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ONCOLOGY- LAPATINIB PRIOR AUTHORIZATION POLICY

### **Products Affected**

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• LAPATINIB 250 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Head and Neck, Squamous Cell Carcinoma. Urothelial Carcinoma.
Required Medical Information	1. Breast Cancer: A) Patient has human epidermal growth factor receptor 2 (HER2)-positive disease AND B) Patient has recurrent or metastatic breast cancer AND C) Patient meets one of the following criteria (i or ii): i. The patient meets both of the following criteria (a and b): a) The medication will be used in combination with capecitabine or trastuzumab AND b) Patient has tried at least three prior anti-HER2 based regimens [Note: Examples of anti-HER2 regimens include: Perjeta (pertuzumab intravenous infusion) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel, Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion), Kadcyla (ado-trastuzumab emtansine intravenous infusion), Tukysa (tucatinib tablet) + trastuzumab + capecitabine.] OR ii. medication will be used in combination with an aromatase inhibitor (that is, letrozole, anastrozole, or exemestane) AND patient meets the following criteria: a) Patient has hormone receptor-positive (HR+) [i.e., estrogen receptor positive [ER+]-and/or progesterone receptor positive [PR+]]disease AND b) One of the following ([1] [2] or [3]) applies: 1. Patient is a postmenopausal woman OR 2. Patient is a premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, surgical bilateral oophorectomy, or ovarian irradiation [Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous inplant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).]
Age Restrictions	18 years of age or older

PA Criteria	Criteria Details
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	2. Bone Cancer: A) Patient has recurrent chordoma AND B) Patient has epidermal growth-factor receptor (EGFR)-positive disease. 3. Colon or Rectal Cancer: A) Patient has unresectable, advanced, or metastatic disease AND B) Patient has human epidermal receptor2 (HER2)-amplified disease AND C) Patient has wild-type RAS and BRAF disease AND D) Patient meets ONE of the following (i or ii): i. Patient has tried at least one chemotherapy regimen [Note: Examples of chemotherapy are fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine, oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5- FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin)]. OR ii. Patient is not a candidate for intensive therapy, according to the prescriber AND E) The medication is used in combination with trastuzumab AND F) Patient has not been previously treated with a HER2-inhibitor. Note: Examples of HER2-inhibitors are trastuzumab products, Nerlynx (neratinib tablets), Kadcyla (ado-trastuzumab emtansine intravenous infusion) Perjeta (pertuzumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone Cancer. Colon or Rectal Cancer.

### **ONCOLOGY- LENALIDOMIDE PRIOR AUTHORIZATION POLICY**

- LENALIDOMIDE 10 MG CAPSULE
- LENALIDOMIDE 15 MG CAPSULE
- LENALIDOMIDE 25 MG CAPSULE
- LENALIDOMIDE 5 MG CAPSULE
- REVLIMID 10 MG CAPSULE
- REVLIMID 15 MG CAPSULE
- REVLIMID 2.5 MG CAPSULE
- REVLIMID 20 MG CAPSULE
- REVLIMID 25 MG CAPSULE
- REVLIMID 5 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	<ul> <li>1. Follicular Lymphoma: A) Patient meets one of the following: i. Patient is using lenalidomide in combination with rituximab OR ii. Patient has tried at least one other regimen. Examples include bendamustine plus Gazyva (obinutuzumab intravenous infusion) or rituximab, bendamustine plus Gazyva, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus Gazyva or rituximab, CVP (cyclophosphamide, vincristine, prednisone) plus Gazyva or rituximab, chlorambucil with or without rituximab, cyclophosphamide with or without rituximab, rituximab, Gazyva, or Aliqopa (copanlisib intravenous infusion). 2. Mantle Cell Lymphoma: A) Patient meets one of the following: i. Patient is using lenalidomide in combination with rituximab OR ii. Patient has tried at least two other regimens. Examples include HyperCVAD (cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine) + rituximab, the NORDIC regimen (dose-intensified induction immunochemotherapy with rituximab + cyclophosphamide, vincristine, doxorubicin, vincristine, prednisone), bendamustine injection plus rituximab, RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin), Imbruvica (ibrutinib capsules), or Brukinsa (zanubrutinib capsules). 3. Marginal Zone Lymphoma: A) Patient meets one of the following: i. Patient is using</li> </ul>

PA Criteria	Criteria Details
	lenalidomide in combination with rituximab, OR ii. Patient has tried least one other regimen. Examples include CHOP + rituximab, bendamustine + rituximab, CVP + rituximab, rituximab, chlorambucil with or without rituximab, cyclophosphamide with or without rituximab, bendamustine + Gazyva (obinutuzumab IV infusion), Copiktra (duvelisib capsules), Aliqopa (copanlisib IV infusion), or Zydelig (idelalisib capsules).
Age Restrictions	18 years of age and older for all indications EXCEPT Langerhans Cell Histiocytosis
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	4. Multiple Myeloma. 5. Myelodysplastic Syndrome: A) Patient meets one of the following: i. Patient has symptomatic anemia, OR ii. Patient has transfusion-dependent anemia, OR iii. Patient has anemia that is not controlled with an erythropoiesis-stimulating agent. Examples include Epogen/Procrit (epoetin alfa injection), Aranesp (darbepoetin alfa injection). 6. B-Cell-Lymphomas (Other): Patient has tried at least one other regimen, examples include RCHOP, dose-adjusted EPOCH with rituximab, RCEPP, DHA plus platinum (carboplatin, cisplatin, oxaliplatin) with or without rituximab, ICE with or without rituximab, RGCVP, GDP with/without rituximab or gemcitabine, dexamethasone, carboplatin with/without rituximab, R-HyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose methotrexate and cytarabine), or bendamustine with/without rituximab. 7. Kaposi Sarcoma: A) Patient has relapsed or refractory disease, B) Patient has tried at least one other medication, Examples include liposomal doxorubicin, paclitaxel, Pomalyst, Thalomid, and imatinib. 8. Castlemans Disease: relapsed/refractory or progressive disease. 9. Central Nervous System Lymphoma: Per prescriber the patient has tried at least three other regimens. Examples include ABVD, BEACOPP, Adcetris (brentuximab vedotin intravenous infusion), Adcetris + AVD, DHAP, ICE, or GVD. 11. Langerhans Cell Histiocytosis: patients with multifocal skin disease. 12. Myelofibrosis: A) Patient meets the following: i. According to the prescriber the patient has anemia AND ii. Patient has serum erythropoietin levels ≥ 500 mU/mL. B) Patient meets the following: i. According to the prescriber the patient has anemia, AND ii. Patient has experienced no response or loss of response to an erythropoiesis-

PA Criteria	Criteria Details
	stimulating agent. 13. Peripheral T-Cell Lymphomas: A) Patient has tried at least one other regimen, examples of regimens include Beleodaq, Adcetris, DHAP, ESHAP, GDP, GemOX (gemcitabine, oxaliplatin), ICE, or Istodax. 14. POEMS Syndrome AND 15. Systemic Light Chain Amyloidosis: Use of lenalidomide in combination with dexamethasone. 16. T-Cell Leukemia/Lymphoma: Patient has tried at least one other regimen, Examples include Adcetris plus CHP (cyclophosphamide, doxorubicin, and prednisone), CHOP, CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, and prednisone), dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin), HyperCVAD alternating with high-dose methotrexate and cytarabine, or Beleodaq.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	B-Cell-Lymphomas (Other). Kaposi Sarcoma. Castleman's Disease. Central Nervous System Lymphoma. Hodgkin Lymphoma, Classical. Langerhans Cell Histiocytosis. Myelofibrosis. Peripheral T-Cell Lymphomas. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome. Systemic Light Chain Amyloidosis. T-Cell Leukemia/Lymphoma.

### ONCOLOGY- LENVIMA PRIOR AUTHORIZATION POLICY

- LENVIMA 10 MG DAILY DOSE INNER
- LENVIMA 12 MG DAILY DOSE OUTER
- LENVIMA 14 MG DAILY DOSE INNER
- LENVIMA 18 MG DAILY DOSE OUTER
- LENVIMA 20 MG DAILY DOSE INNER
- LENVIMA 24 MG DAILY DOSE INNER
- LENVIMA 4 MG CAPSULE OUTER
- LENVIMA 8 MG DAILY DOSE OUTER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Endometrial Carcinoma: 1) Patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), AND 2) The medication is used in combination with Keytruda (pembrolizumab intravenous injection), AND 3) Patient has tried at least one systemic therapy (Examples of systemic therapy include carboplatin, paclitaxel, docetaxel, cisplatin, doxorubicin, or ifosfamide), AND 4) Patient is not a candidate for curative surgery or radiation. 2. Hepatocellular Cancer: 1) Patient has unresectable or metastatic disease. 3. Renal Cell Cancer: 1) Patient has advanced disease, AND 2) Patient meets ONE of the following (i or ii):i. Lenvima is being used in combination with Keytruda (pembrolizumab intravenous infusion) OR ii. Lenvima is being used in combination with everolimus tablets/Afinitor Disperz (everolimus tablets for oral suspension) AND patient meets one of the following (a or b): a) Patient has clear cell histology and patient has tried one

PA Criteria	Criteria Details
	antiangiogenic therapy (Examples of antiangiogenic therapy include Inlyta (axitinib tablets), Votrient (pazopanib tablets), sunitinib, or Cabometyx (cabozantinib tablets)), por b) Patient has non-clear cell histology. 4. Thyroid Carcinoma, Differentiated: 1) Patient has differentiated thyroid carcinoma (Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hurthle cell carcinoma)) AND 2) The disease is refractory to radioactive iodine therapy. 5. Melanoma: 1) Patient has unresectable or metastatic melanoma, AND 2) The medication is used in combination with Keytruda (pembrolizumab intravenous injection), AND 3) Patient has disease progression on anti- programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)- based therapy (Examples of anti-PD-1/PD-L1 therapies include Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdualag (nivolumab and relatlimab-rmbw intravenous infusion), Keytruda, Opdivo). 6. Thymic Carcinoma: 1) Patient has tried at least one chemotherapy regimen (Examples of a chemotherapy regimen include carboplatin plus paclitaxel, cisplatin, doxorubicin plus cyclophosphamide, cisplatin plus etoposide). 7. Thyroid Carcinoma, Medullary: 1) Patient has tried at least one systemic therapy (Examples of systemic therapy include Caprelsa (vandetanib tablets), Cometriq (cabozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules)).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Melanoma. Thymic Carcinoma. Thyroid Carcinoma, Medullary.

# ONCOLOGY- LORBRENA PRIOR AUTHORIZATION POLICY

- LORBRENA 100 MG TABLET
- LORBRENA 25 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Non-Small Cell Lung Cancer - Anaplastic Lymphoma Kinase (ALK)- Positive: A) Patient has advanced or metastatic disease AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease AND C) The mutation was detected by an approved test. 2. Erdheim-Chester Disease: A) Patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. 3. Inflammatory Myofibroblastic Tumor: A) Patient has anaplastic lymphoma kinase (ALK)-positive disease, B) Patient meets one of the following criteria (i or ii): i. Patient has advanced, recurrent, or metastatic disease OR ii. The tumor is inoperable. 4. Non-Small Cell Lung Cancer - ROS1 Rearrangement-Positive: A) Patient has advanced or metastatic disease AND B) Patient has ROS1 rearrangement-positive disease AND C) Patient has tried at least one of Xalkori (crizotinib capsules), Zykadia (ceritinib capsules or tablets), or Rozlytrek (entrectinib capsules).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Erdheim-Chester Disease. Inflammatory Myofibroblastic Tumor. Non- Small Cell Lung Cancer - ROS1 Rearrangement-Positive.

# ONCOLOGY- LYNPARZA PRIOR AUTHORIZATION POLICY

- LYNPARZA 100 MG TABLET
- LYNPARZA 150 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	1. Breast Cancer (Adjuvant Therapy): Patient has germline BRCA mutation-positive breast cancer, AND Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer, AND Patient meets one of the following criteria (i or ii): i. Patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease and meets one of the following (a or b): a) Patient did not have a pathologic complete response to neoadjuvant therapy, OR b) Patient has node positive disease after receiving adjuvant therapy, OR ii. Patient has node positive disease after receiving adjuvant therapy, OR ii. Patient has hormone receptor negative disease (HR-) and meets both of the following (a and b): a) Patient has tried neoadjuvant or adjuvant therapy, AND b) Patient has residual disease. 2. Breast Cancer (Recurrent or Metastatic Disease): Patient has recurrent or metastatic disease, AND Patient has germline BRCA mutation-positive breast cancer, AND Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer. 3. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Maintenance, Monotherapy): Patient meets ONE of the following (i or ii): i. Patient meets both of the following criteria for first-line maintenance therapy (a and b): a) Patient has a germline or somatic BRCA mutation- positive disease as confirmed by an approved test, AND b) Patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Note: Examples are carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin, OR ii. Patient is in complete or partial response after at least two platinum-based chemotherapy regimens. Note: Examples of platinum-based chemotherapy are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None

PA Criteria	Criteria Details
Coverage Duration	1 year
Other Criteria	4. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Maintenance, Combination Therapy): The medication is used in combination with bevacizumab, AND Patient has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test. Note: HRD-positive disease includes patients with BRCA mutation-positive disease, AND Patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Note: Examples of chemotherapy regimens are carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin. 5. Pancreatic Cancer (Maintenance Therapy): Patient has a germline BRCA mutation-positive metastatic disease, AND The disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. 6. Prostate Cancer: Patient has metastatic castration resistant prostate cancer, AND Patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog. Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Natorelin acetate subcutaneous injection), Orgovyx (relugolix tablets), OR ii. Patient has had a bilateral orchiectomy, AND Patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test. Note: HRR gene mutations include BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L, AND Patient does not have a PPP2R2A mutation, AND Patient has been previously treated with at least one androgen receptor-directed therapy. Note: Androgen-receptor-directed therapy includes: abiraterone, Xtandi (enzalutamide tablets), 7. Ovarian Cancer (Treatment: Note: This also includes fallopian tube, or primary peritoneal cancer): Patient has a progressed on two or more
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Ovarian Cancer - Treatment. Uterine Leiomyosarcoma

# **ONCOLOGY- NILUTAMIDE PRIOR AUTHORIZATION POLICY**

### **Products Affected**

• NILUTAMIDE 150 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	Prostate Cancer: nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist. Note: Examples are Lupron (leuprolide subcutaneous injection), Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **ONCOLOGY- NUBEQA PRIOR AUTHORIZATION POLICY**

#### **Products Affected**

• NUBEQA 300 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Prostate Cancer - Metastatic, Castration-Sensitive: A) The medication is used concurrently with docetaxel AND B) Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist [Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).] OR ii. The medication is used concurrently with Firmagon (degarelix subcutaneous injection) OR iii. Patient has had a bilateral orchiectomy. 2. Prostate Cancer - Non- Metastatic, Castration-Resistant: A) Patient meets one of the following criteria (i, ii, or iii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist [Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).] OR ii. The medication is used concurrently with Firmagon (degarelix subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).] OR ii. The medication is used concurrently with Firmagon (degarelix subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).] OR ii. The medication is used concurrently with Firmagon (degarelix subcutaneous injection) OR iii. Patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

# ONCOLOGY- ODOMZO PRIOR AUTHORIZATION POLICY

#### **Products Affected**

• ODOMZO 200 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	Basal Cell Carcinoma (Locally Advanced or Metastatic), in a Patient with Disease Progression While on Erivedge (vismodegib capsules). Note: This does not apply to a patient already started on Odomzo. Refer to criteria for Basal Cell Carcinoma, Locally Advanced for a Patient Currently Receiving Odomzo.
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Basal Cell Carcinoma, Locally Advanced. Initial: Patient meets one of the following (a or b): a) Patient has recurrent basal cell carcinoma following surgery or radiation therapy, OR b) Patient meets BOTH of the following [(1) and (2)]: (1) Patient is not a candidate for surgery, AND (2) According to the prescriber, the patient is not a candidate for radiation therapy. Renewal: Patient is Currently Receiving Odomzo. 2. Basal Cell Carcinoma, Metastatic. A. Disease is limited to nodal metastases. Note: This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Basal Cell Carcinoma, Metastatic.

# ONCOLOGY- POMALYST PRIOR AUTHORIZATION POLICY

- POMALYST 1 MG CAPSULE
- POMALYST 2 MG CAPSULE
- POMALYST 3 MG CAPSULE
- POMALYST 4 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older: all indications EXCEPT Central Nervous System Lymphoma
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Kaposi Sarcoma: Patient meets one of the following (i or ii): i. Patient is Human Immunodeficiency Virus (HIV)-negative OR ii. Patient meets both of the following (a and b): a) Patient is HIV-positive AND b) Patient continues to receive highly active antiretroviral therapy. 2. Multiple Myeloma: Patient has received at least one other lenalidomide containing regimen. 3. Central Nervous System Lymphoma: Patient has relapsed or refractory disease. 4. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome: Use of Pomalyst is in combination with dexamethasone. 5. Systemic Light Chain Amyloidosis: A) Use of Pomalyst is in combination with dexamethasone AND B) Patient has tried at least one other regimen. Note: Examples of regimens include lenalidomide plus dexamethasone/ Velcade (bortezomib injection for intravenous or subcutaneous use), lenalidomide, cyclophosphamide, and dexamethasone, Velcade with or without dexamethasone/ Velcade, lenalidomide, and dexamethasone/ melphalan and dexamethasone, Velcade, cyclophosphamide, and dexamethasone, and

PA Criteria	Criteria Details
	Darzalex (daratumumab intravenous infusion)/Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Lymphoma. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome. Systemic Light Chain Amyloidosis.

# **ONCOLOGY- SORAFENIB (GENERIC TABLETS) PRIOR AUTHORIZATION POLICY**

### **Products Affected**

• SORAFENIB 200 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	1. Hepatocellular Cancer: Patient has unresectable or metastatic disease. 2. Renal Cell Cancer: Patient has relapsed or advanced disease, AND Patient has clear cell histology, AND Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include Inlyta (axitinib tablets), Votrient (pazopanib tablets), Sutent (sunitinib capsules), Cabometyx (cabozantinib tablets). 3. Thyroid Carcinoma, Differentiated: Patient has differentiated thyroid carcinoma. Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hurthle cell carcinoma), AND The disease is refractory to radioactive iodine therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	4. Acute Myeloid Leukemia: Patient has FLT3-ITD mutation-positive disease as detected by an approved test, AND Patient meets one of the following criteria (i or ii): i. This medication is used in combination with azacitidine or decitabine, OR ii. Patient has had an allogeneic stem cell transplant and is in remission. 5. Bone Cancer: Patient meets ONE of the following criteria (i or ii): i. Patient has recurrent chordoma, OR ii. Patient meets both of the following criteria (a and b): a) Patient has osteosarcoma, AND b) Patient has tried one systemic chemotherapy regimen. Note: Examples of a systemic chemotherapy regimen contain one of more of the following products: cisplastin, doxorubicin, methotrexate, or ifosfamide. 6. Gastrointestinal Stromal Tumor: Patient has previously tried each of the following (i, ii, iii, and iv): i. One of imatinib or Ayvakit (avapritinib tablets), AND ii. One of Sutent (sunitinib capsules) or Sprycel (dasatinib tablets), AND iii. Stivarga (regorafenib tablets), AND iv. Qinlock

PA Criteria	Criteria Details
	<ul> <li>(ripretinib tablets). 7. Myeloid/Lymphoid Neoplasms with Eosinophilia: The tumor has an FLT3 rearrangement. 8. Ovarian, Fallopian Tube, Primary Peritoneal Cancer: Patient has platinum-resistant disease, AND Nexavar is used in combination with topotecan. 9. Soft Tissue Sarcoma: Patient has ONE of the following diagnoses (i, ii, or iii): i. Angiosarcoma, OR ii. Desmoid tumors (aggressive fibromatosis), OR iii. Solitary Fibrous Tumor/Hemangiopericytoma. 10. Thyroid Carcinoma, Medullary: Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include: Caprelsa (vandetanib tablets), Cometriq (cabozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).</li> </ul>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute Myeloid Leukemia. Bone Cancer. Gastrointestinal Stromal Tumor. Myeloid/Lymphoid Neoplasms with Eosinophilia. Ovarian, Fallopian Tube, Primary Peritoneal Cancer. Soft Tissue Sarcoma. Thyroid Carcinoma, Medullary.

# ONCOLOGY- SPRYCEL PRIOR AUTHORIZATION POLICY

- SPRYCEL 100 MG TABLET
- SPRYCEL 140 MG TABLET
- SPRYCEL 20 MG TABLET
- SPRYCEL 50 MG TABLET
- SPRYCEL 70 MG TABLET
- SPRYCEL 80 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older for Chondrosarcoma or Chordoma, Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	A. Patient has ONE of the following: 1. Acute Lymphoblastic Leukemia 2. Chronic Myeloid Leukemia 3. Bone cancer 4. Gastrointestinal Stromal Tumor 5. Myeloid/Lymphoid Neoplasms with Eosinophilia. 6. 5. Melanoma, Cutaneous. B. Acute Lymphoblastic Leukemia: 1. Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia. C. Chronic Myeloid Leukemia: 1. Patient has Philadelphia chromosome- positive chronic myeloid leukemia. D. Gastrointestinal Stromal Tumor: 1. Patient has tried imatinib or Ayvakit (avapritinib tablets). E. Myeloid/Lymphoid Neoplasms with Eosinophilia: 1. The tumor has an ABL1 rearrangement. F. Bone cancer: Patient has chondrosarcoma or chordoma. G. 5. Melanoma, Cutaneous: 1. B) Patient has metastatic or unresectable disease, AND 2. C) Patient has an activating KIT mutation, AND 3. D) Patient has tried at least one systemic regimen. Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) +

PA Criteria	Criteria Details
	Yervoy (ipilimumab intravenous infusion), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Chondrosarcoma or Chordoma, Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia

# **ONCOLOGY- SUTENT PRIOR AUTHORIZATION POLICY**

- SUNITINIB MALATE 12.5 MG CAP
- SUNITINIB MALATE 25 MG CAPSULE
- SUNITINIB MALATE 37.5 MG CAP
- SUNITINIB MALATE 50 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Gastrointestinal Stromal Tumor: Patient meets one of the following criteria (i or ii): i. Patient has tried imatinib or Ayvakit (avapritinib tablets) OR ii. Patient has succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor. 2. Neuroendocrine Tumors of the Pancreas: Patient has advanced or metastatic disease. 3. Renal Cell Cancer: Patient meets one of the following criteria (i or ii): i. Patient has clear cell histology and meets the following criteria (a and b): a) Patient has high risk of recurrence following nephrectomy AND b) Sutent is being used as adjuvant therapy OR ii. Patient has relapsed or advanced disease. 4. Bone Cancer: Patient has recurrent chordoma. 5. Meningioma: Patient has recurrent or progressive disease. 6. Myeloid/Lymphoid Neoplasms: A) Patient has eosinophilia AND B) The tumor has an FLT3 rearrangement. 7. Pheochromocytoma/Paraganglioma: Patient has one of the following diagnosis (i, ii, or iii): i. Alveolar soft part sarcoma OR ii. Angiosarcoma OR iii. Solitary fibrous tumor/Hemangiopericytoma. 9. Thymic Carcinoma: Patient has tried at least one systemic chemotherapy regimen. Note: Examples of a systemic chemotherapy regimen include one or more of the

PA Criteria	Criteria Details
	following products: carboplatin, paclitaxel, cisplatin, doxorubicin, cyclophosphamide, or etoposide. 10. Thyroid Carcinoma, Differentiated: A) Patient has differentiated thyroid carcinoma [Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hürthle cell thyroid carcinoma.] AND B) Patient is refractory to radioactive iodine therapy. 11. Thyroid Carcinoma, Medullary: Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include: Caprelsa (vandetanib tablets), Cometriq (cabozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Bone Cancer. Meningioma. Myeloid/Lymphoid Neoplasms. Pheochromocytoma/Paraganglioma. Soft Tissue Sarcoma. Thymic Carcinoma. Thyroid Carcinoma, Differentiated. Thyroid Carcinoma, Medullary.

# ONCOLOGY- TALZENNA PRIOR AUTHORIZATION POLICY

- TALZENNA 0.25 MG CAPSULE
- TALZENNA 0.5 MG CAPSULE
- TALZENNA 0.75 MG CAPSULE
- TALZENNA 1 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	Breast Cancer: Patient has recurrent or metastatic breast cancer, AND Patient has germline BRCA mutation-positive disease, AND Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ONCOLOGY- TASIGNA PRIOR AUTHORIZATION POLICY

- TASIGNA 150 MG CAPSULE INNER
- TASIGNA 200 MG CAPSULE INNER PACK
- TASIGNA 50 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	Acute Lymphoblastic Leukemia, Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia: 18 years of age and older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	A. Patient has ONE of the following: 1. Chronic Myeloid Leukemia 2. Acute Lymphoblastic Leukemia 3. Gastrointestinal Stromal Tumor 4. Myeloid/Lymphoid Neoplasms with Eosinophilia 5. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. 6. Melanoma, Cutaneous. B. Chronic Myeloid Leukemia: Patient has Philadelphia chromosome-positive chronic myeloid leukemia. C. Acute Lymphoblastic Leukemia: Patient has Philadelphia chromosome-positive acute lymphoblastic leukemia. D. Gastrointestinal Stromal Tumor: 1. Patient has tried each of the following (i, ii, iii, and iv): i. Imatinib or Ayvakit (avapritinib tablets), AND ii. Sutent (sunitinib capsules) or Sprycel (dasatinib tablets), AND iii. Stivarga (regorafinib tablets), AND iv. Qinlock (ripretinib tablets). E. Myeloid/Lymphoid Neoplasms with Eosinophilia: 1. The tumor has an ABL1 rearrangement. F. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor: 1. Patient meets one of the following: a) Patient has tried Turalio (pexidartinib capsules), OR b) Patient cannot take Turalio, according to the prescriber. Note: Examples of reasons for not being able to take Turalio include patients with

PA Criteria	Criteria Details
	elevated liver enzymes or concomitant use of medications that are associated with hepatotoxicity. G. Melanoma, Cutaneous: a) Patient has metastatic or unresectable disease, AND b) C) Patient has an activating KIT mutation, AND c) D) Patient has tried at least one systemic regimen. Note: Examples of a systemic regimen include: Opdivo (nivolumab intravenous infusion) + Yervoy (ipilimumab intravenous infusion), Opdivo + Opdualag (nivolumab/relatlimab-rmbw intravenous infusion), Keytruda (pembrolizumab intravenous infusion), Opdivo, Tafinlar (dabrafenib capsules) + Mekinist (trametinib tablets), Zelboraf (vemurafenib tablets) + Cotellic (cobimetinib tablets), Braftovi (encorafenib capsules) + Mektovi (binimetinib tablets).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Acute Lymphoblastic Leukemia, Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia, Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor

# ONCOLOGY- THALOMID PRIOR AUTHORIZATION POLICY

- THALOMID 100 MG CAPSULE
- THALOMID 150 MG CAPSULE
- THALOMID 200 MG CAPSULE
- THALOMID 50 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	Cancer Cachexia. Crohns Disease.
Required Medical Information	N/A
Age Restrictions	Multiple Myeloma and Myelofibrosis: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	1. Erythema Nodosum Leprosum. 2. Multiple Myeloma: Thalomid is being taken in combination with at least two other medications. (Note: Examples of medications include Velcade (bortezomib injection for subcutaneous or intravenous use), dexamethasone, cisplatin, doxorubicin, cyclophosphamide, etoposide, and Kyprolis (carfilzomib injection for intravenous use).) 3. Castlemans Disease: A) Patient has relapsed/refractory or progressive disease OR B) Patient meets the following criteria (i and ii): i. Patient has multi-centric Castlemans disease AND ii. Patient is negative for the human immunodeficiency virus and human herpesvirus-8. 4. Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus: Patient has tried at least two other medications. (Note: Examples of medications include corticosteroids (oral, topical, intralesional), antimalarial agents (e.g., hydroxychloroquine), topical calcineurin inhibitors (e.g., Protopic [tacrolimus ointment], Elidel [pimecrolimus cream]), azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, dapsone, and Soriatane (acitretin capsules).) 5. Kaposi Sarcoma: A) Patient has tried at least one medication (Note: Examples include liposomal doxorubicin, paclitaxel, Pomalyst (pomalidomide

PA Criteria	Criteria Details
	capsules), lenalidomide, and imatinib.) AND B) Patient has relapsed or refractory disease. 6. Langerhans Cell Histiocytosis: Patient has multifocal skin disease. 7. Myelofibrosis: A) Patient meets the following criteria: i. According to the prescriber the patient has anemia AND iii. Patient has serum erythropoietin levels greater than or equal to 500 mU/mL OR B) Patient meets the following criteria: i. According to the prescriber the patient has anemia AND ii. Patient has serum erythropoietin levels less than 500 mU/mL AND iii. Patient has experienced no response or loss of response to an erythropoiesis-stimulating agent. 8. Prurigo Nodularis: Patient has tried at least two other medications. (Note: Examples of medications include topical steroids, intralesional steroids, systemic steroids, topical tar, cyclosporine, macrolides, azathioprine, methotrexate, topical calcineurin inhibitors (Elidel [pimecrolimus cream], Protopic [tacrolimus ointment]), retinoids, antihistamines, hydroxyzine, dapsone, capsaicin, psoralen plus ultraviolet A therapy, and ultraviolet B therapy.) 9. Recurrent Aphthous Ulcers or Aphthous Stomatitis: Patient has tried at least two other medications. (Note: Examples of medications include topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics (e.g., lidocaine 2% viscous solution, benzocaine lozenges), antimicrobial mouthwashes (e.g., tetracycline, chlorhexidine), topical sucralfate, acyclovir, pentoxifylline, dapsone, colchicine, and azathioprine.) 10. Rosai-Dorfman Disease: Patient has cutaneous disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Castleman's Disease. Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus. Kaposi Sarcoma. Langerhans Cell Histiocytosis. Myelofibrosis. Prurigo Nodularis. Recurrent Aphthous Ulcers or Aphthous Stomatitis. Rosai-Dorfman Disease.

# ONCOLOGY- VERZENIO PRIOR AUTHORIZATION POLICY

- VERZENIO 100 MG TABLET
- VERZENIO 150 MG TABLET
- VERZENIO 200 MG TABLET
- VERZENIO 50 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	1. Breast Cancer (Early): A. Patient has hormone receptor positive (HR+) [such as, estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease, AND B. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer, AND C. Patient has node- positive disease at high risk of recurrence. Note: High risk includes patients with 4 or more positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size greater than or equal to 5 cm, or a Ki-67 score of greater than or equal to 20%, AND D. ONE of the following criteria (i or ii): i. Will be used in combination with anastrozole, exemestane, or letrozole AND one of the following (a ,b, or c): a. Postmenopausal woman, OR b. Pre/perimenopausual woman and one of the following [(1) or (2)]: (1) Receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist. Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection), OR (2) Patient had surgical bilateral oophorectomy or ovarian irradiation, OR c. Patient is a man and receiving a GnRH analog. Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection), OR (2) Patient had surgical bilateral oophorectomy or ovarian irradiation, OR c. Patient is a man and receiving a GnRH analog. Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet), OR ii. Will be used in combination with tamoxifen AND one of the following (a or b): a. Postmenopausal wo
Age Restrictions	18 years of age and older

PA Criteria	Criteria Details
Prescriber Restrictions	None
Coverage Duration	Breast Cancer - Early: 2 years. All others: 1 year
Other Criteria	2. Breast Cancer (Recurrent or Metastatic in Women): A. Recurrent or metastatic breast cancer, AND B. Patient has hormone receptor positive (HR+) [such as, estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer, AND D. ONE of the following criteria (i or ii): i. Postmenopausal OR ii. Patient is pre/perimenopausal and one of the following (a or b): a. Receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist. Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), OR b. Patient had surgical bilateral oophorectomy or ovarian irradiation, AND E. ONE of the following criteria (i, ii, or iii): i. Will be used in combination with fulvestrant, OR iii. Patient meets the following conditions (a, b, and c): a. Will be used as monotherapy, AND b. Patients breast cancer has progressed on at least one prior endocrine therapy. Note: Examples of prior endocrine therapy include anastrozole, exemestane, letrozole, tamoxifen, toremifene, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol, AND c. Patient has HER2-negative breast cancer, AND D. ONE of the following cinclude leuprolide acetate; no positive (HR+), AND C. Patient has HER2-negative breast cancer, AND D. ONE of the following cinclude leuprolide acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Coladex (goserelin acetate subcutaneous inplant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet), AND b. Verzenio will be used in combination with fulvestrant, OR iii. Patient meets the following conditions (a, b, and c): a. Verzenio will be used as monotherapy, AND b. Patient has hormone receptor positive (HR+

PA Criteria	Criteria Details
	identity or gender expression, and men are defined as individuals with the biological traits of a man, regardless of the individuals gender identity or gender expression.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ONCOLOGY- VIZIMPRO PRIOR AUTHORIZATION POLICY

- VIZIMPRO 15 MG TABLET
- VIZIMPRO 30 MG TABLET
- VIZIMPRO 45 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Non-Small Cell Lung Cancer: A) Patient has advanced or metastatic disease AND B) Patient has sensitizing EGFR mutation-positive non-small cell lung cancer as detected by an approved test. [Note: Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.]
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ONCOLOGY- XALKORI PRIOR AUTHORIZATION POLICY

- XALKORI 200 MG CAPSULE
- XALKORI 250 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	Anaplastic Large Cell Lymphoma and Inflammatory Myofibroblastic Tumor: 1 year of age or older. All other indications: 18 years of age or older.
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Anaplastic Large Cell Lymphoma: Patient has anaplastic lymphoma kinase (ALK)-positive disease, AND Patient meets one of the following criteria (i or ii): i. Patient has relapsed disease, OR ii. Patient has refractory disease. 2. Inflammatory Myofibroblastic Tumor: A) Patient has anaplastic lymphoma kinase (ALK)-positive disease, AND B) Patient meets one of the following criteria (i or ii): i. Patient has advanced, recurrent, or metastatic disease, OR ii. The tumor is inoperable. 3. Non-Small Cell Lung Cancer (Anaplastic Lymphoma Kinase [ALK])-Positive: Patient has advanced or metastatic disease, AND Patient has anaplastic lymphoma kinase (ALK)-positive disease, AND The mutation was detected by an approved test. 4. Non-Small Cell Lung Cancer, ROS1 Rearrangement- Positive: Patient has advanced or metastatic disease, AND The mutation was detected by an approved test. 5. Histiocytic Neoplasm: Patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease, AND Patient meets one of the following criteria (i, ii, or iii): i. Patient has Langerhans cell histiocytosis, OR ii. Patient had Erdheim-Chester disease, OR iii. Patient has Rosai-Dorfman disease. 6. Non-Small Cell Lung Cancer

PA Criteria	Criteria Details
	with Mesenchymal Epithelial Transition (MET) Mutation: Patient meets one of the following criteria (i or ii): i. Patient has non-small cell lung cancer with high level MET amplification, OR ii. Patient has non-small cell lung cancer with MET exon 14 skipping mutation. 7. Melanoma, Cutaneous: A) Patient meets one of the following criteria (i or ii): i. Patient has anaplastic lymphoma kinase (ALK) fusion disease OR ii. Patient has ROS1 fusion disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Histiocytic Neoplasm. Non-Small Cell Lung Cancer with Mesenchymal Epithelial Transition (MET) Mutation. Melanoma, Cutaneous.

# ONCOLOGY- XTANDI PRIOR AUTHORIZATION POLICY

- XTANDI 40 MG CAPSULE
- XTANDI 40 MG TABLET
- XTANDI 80 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Prostate Cancer - Castration-Resistant (Metastatic or Non-Metastatic): A) Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist [Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).] OR ii. The medication is concurrently used with Firmagon (degarelix subcutaneous injection) OR iii. Patient has had a bilateral orchiectomy. 2. Prostate Cancer - Metastatic, Castration-Sensitive: A) Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist [Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).] OR ii. The medication is (histrelin acetate subcutaneous implant).] OR ii. The medication is concurrently used with Firmagon (degarelix subcutaneous injection) OR iii. Patient has had a bilateral orchiectomy.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ONCOLOGY- YONSA PRIOR AUTHORIZATION POLICY

#### **Products Affected**

• YONSA 125 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	Prostate Cancer (Metastatic, Castration-Resistant): The medication is used in combination with methylprednisolone or dexamethasone, AND Patient meets ONE of the following criteria (i, ii, or iii): i. The medication is concurrently used with a gonadotropin-releasing hormone agonist. Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), or Vantas (histrelin acetate subcutaneous implant), OR ii. The medication is concurrently used with Firmagon (degarelix subcutaneous injection), OR iii. Patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **ONCOLOGY- ZEJULA PRIOR AUTHORIZATION POLICY**

#### **Products Affected**

• ZEJULA 100 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance Therapy: A) Patient is in complete or partial response after a platinum- based chemotherapy regimen. Note: Examples of chemotherapy regimens are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine AND B) Patient meets one of the following criteria (i or ii): i. Patient meets both of the following criteria (a and b): a) Patient has recurrent disease AND b) Patient has a BRCA mutation OR ii. Patient is in complete or partial response to first-line primary treatment. 2. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Treatment: A) Patient has tried at least three prior chemotherapy regimens. Note: Examples of chemotherapy regimens are carboplatin/gemcitabine, carboplatin/liposomal doxorubicin, carboplatin/paclitaxel, cisplatin/gemcitabine, capecitabine, irinotecan. AND B) Patient has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test. Note: HRD- positive disease includes patients with BRCA mutation-positive disease. 3. Uterine Leiomyosarcoma: A) Patient has a BRCA2 mutation, AND B) Patient has tried one systemic regimen. Note: Examples of a systemic regimen include one or more of the following products: dacarbazine, docetaxel, doxorubicin, epirubicin, gemcitabine, ifosfamide, vinorelbine.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Treatment. Uterine Leiomyosarcoma.

# ONCOLOGY- ZYKADIA PRIOR AUTHORIZATION POLICY

#### **Products Affected**

• ZYKADIA 150 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 year
Other Criteria	1. Non-Small Cell Lung Cancer (NSCLC)- Anaplastic Lymphoma Kinase (ALK)-Positive: A) Patient has advanced or metastatic disease, AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease, AND C) The mutation is detected by an approved test. 2. Erdheim-Chester Disease: A) Patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion- positive disease. 3. Inflammatory Myofibroblastic Tumor: A) Patient has anaplastic lymphoma kinase (ALK)-positive disease, AND B) Patient meets one of the following criteria (i or ii): i. Patient has advanced, recurrent, or metastatic disease, OR ii. The tumor is inoperable. 4. Non- Small Cell Lung Cancer with ROS1 Rearrangement: A) Patient has advanced or metastatic disease, AND B) Patient has ROS1 rearrangement- positive disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Erdheim-Chester Disease. Non-Small Cell Lung Cancer (NSCLC) with ROS1 Rearrangement. Inflammatory Myofibroblastic Tumor.

## PALIPERIDONE TAB ER

- PALIPERIDONE ER 1.5 MG TABLET
- PALIPERIDONE ER 3 MG TABLET F/C
- PALIPERIDONE ER 6 MG TABLET F/C
- PALIPERIDONE ER 9 MG TABLET F/C

PA Criteria	Criteria Details
Exclusion Criteria	Hypersensitivity to risperidone
Required Medical Information	None
Age Restrictions	12 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of schizophrenia or schizoaffective disorder AND Patient has had a trial and failure, intolerance, or contraindication to at least TWO (2) of the following: risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## PALIVIZUMAB

- SYNAGIS 100 MG/ML VIAL
- SYNAGIS 50 MG/0.5 ML VIAL

PA Criteria	Criteria Details
Exclusion Criteria	(1) Patient is an infant with cardiac lesions adequately corrected by surgery (unless pharmacological management is required for CHF) OR (2) Patient is an infant with chronic lung disease (CLD) not requiring medical support in the 2nd year of life OR (3) Patient is an infant with mild cardiomyopathy that does not require pharmacotherapy OR (4) Synagis will be used as routine prophylaxis for ANY of the following conditions: (4a) Down syndrome (unless qualifying heart disease, CLD/BPD, airway clearance issues or prematurity [less than 29 weeks, 0 day's gestation] is present) OR (4b) Nosocomial disease prevention OR (4c) Primary asthma prevention (or for reduction of subsequent wheezing episodes) in infants and children OR (5) Synagis will be used as prophylaxis in ANY of the following scenarios: (5a) Outside of RSV season as defined by Centers for Disease and Prevention (CDC) surveillance reports or state or local health departments OR (5b) Dosing in excess of 5 doses per single RSV "season" as defined by Centers for Disease and Prevention (CDC) surveillance reports or state or local health departments OR (5c) Monthly Synagis administration as prophylaxis post breakthrough RSV hospitalization during the current season (if child had met criteria for palivizumab) OR (6) Synagis will be used for the treatment of symptomatic RSV disease.
Required Medical Information	The request is for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in a pediatric patient who meets ANY of the following: A. Request is for an early preterm infant AND patient was born before 29 weeks, 0 days gestation and is younger than 12 months of age at the start of RSV season OR B. Patient has a diagnosis of chronic lung disease of prematurity (CLD)/bronchopulmonary dysplasia (BPD) OR C. Patient has a diagnosis of hemodynamically significant congenital heart disease (CHD) OR D. Patient has a diagnosis of anatomic pulmonary abnormalities or neuromuscular disorder OR E. Request is for a patient who is immunocompromised OR F. Patient has a diagnosis of cystic fibrosis.
Age Restrictions	Less than 24 months
Prescriber Restrictions	N/A

PA Criteria	Criteria Details
Coverage Duration	5 months
Other Criteria	A. CLD/BPD: (1) Request is for an infant younger than 12 months of age at the start of RSV season AND meets BOTH of the following: (1a) Patient is a preterm infant who developed CLD/BPD of prematurity (defined as gestational age less than 32 weeks, 0 days AND (1b) Patient requires more than 21% of oxygen for at least the first 28 days after birth) OR (2) Requess for an infant between 12-24 months of age at the start of RSV season who meets ALL of the following: (2a) Patient is a preterm infant who developed CLD/BPD of prematurity (defined as gestational age less than 32 weeks, 0 days AND (2b) Patient requires more than 21% of oxygen for at least the first 28 days after birth) AND (2c) Patient continues to require medical intervention (e.g., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) within the 6-month period before the start of the childs second RSV season. B. Hemodynamically significant congenital heart disease (CHD): Patient is an infant younger than 24 months of age at the start of RSV season with ONE of the following: (1) Patient has acyanotic heart disease and is receiving medication to control congestive heart failure (CHF) AND will require a cardiac surgical procedure OR (2) Patient has a cyanotic heart defect OR (3) Patient has moderate to severe pulmonary hypertension OR (4) Patient will undergo cardiac transplantation during RSV season. C. Anatomic pulmonary abnormalities or neuromuscular disorder: (1) Patient is an infant younger than 12 months of age at the start of RSV season AND (2) Patient has a neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough/swallow. D. Request for a patient who is immunocompromised: (1) Patient is an infant younger than 24 months of age at the start of RSV season (Examples of severe immunodeficiencies include: severe combined immunodeficiency, severe acquired immunodeficiency syndrome, acute myeloid leukemia/acute lymphoblastic leukemia, chemotherapy, solid or

PA Criteria	Criteria Details
	(iii) Weight for length less than the 10th percentile on a pediatric growth chart.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PARICALCITOL

- PARICALCITOL 1 MCG CAPSULE
- PARICALCITOL 2 MCG CAPSULE
- PARICALCITOL 4 MCG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: Hypercalcemia, Vitamin D toxicity
Required Medical Information	INITIAL: 1. Patients intact parathyroid hormone (iPTH) levels are greater than 240 pg/mL AND 2. Corrected serum calcium less than 10.5 mg/dL AND 3. Corrected serum Ca x (times) serum phosphorus less than 70. RENEWAL: 1. Patients intact iPTH levels are greater than 120 pg/mL (or 2 times the upper limit of normal) AND 2. Corrected serum calcium less than 11.5 mg/dL AND 3. Corrected serum Ca x (times) serum phosphorus less than 75.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Initial: Patient has a documented diagnosis of secondary hyperparathyroidism due to chronic kidney disease (CKD) AND Patients with CKD stage 5 are currently receiving hemodialysis (HD) or peritoneal dialysis (PD) AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to calcitriol or Hectorol oral or injection therapy by demonstrating iPTH level greater than 180 pg/mL. Renewal: Patient has a diagnosis of secondary hyperparathyroidism due to chronic kidney disease (CKD).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- REPATHA 140 MG/ML SURECLICK P/F, SUV
- REPATHA 140 MG/ML SYRINGE P/F, SUV
- REPATHA 420 MG/3.5 ML PUSHTRONX P/F, SUV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: Documented diagnosis of HeFH confirmed by ONE Simon Broome criteria listed below: Prescriber reports TC greater than 290mg/dL or greater than 260mg/dL in patients less than 16 years of age, OR LDL cholesterol greater than 190mg/dL or greater than 155mg/dL in patients less than 16 years of age, AND Documentation of a history of tendon xanthomas in ONE of the following: the patient, AND/OR patients first degree relative, AND/OR patients second degree relative, OR Documentation of ONE of the following: Family history of myocardial infarction in a first degree relative less than 60 years of age, AND/OR Family history of myocardial infarction in a second degree relative less than 50 years of age, AND/OR Family history of LDL-C greater than 190mg/dL in a first or second degree relative, OR Documentation of a history of arcus cornealis before age of 45 in ONE of the following: the patient, AND/OR first of second degree relative, AND HeFH diagnosis confirmed by genetic testing of an LDL receptor mutation, familiar defective apoB, or a PCSK9 mutation. HoFH: Diagnosis of HoFH confirmed by clinical diagnosis based on ANY one the following: Patient has a documented history of untreated LDL-C greater than 400 mg/dL AND 1 or both parents having clinical diagnosed familial hypercholesterolemia, or documented treatment for LDL-C greater than 300mg/dL, OR Prescriber attests to genetic evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation or autosomal recessive FH, OR LDL-C greater than 400mg/dL with aortic valve disease, OR LDL-C greater than 400mg/dL with xanthomata at less than 20 years of age. CLINICAL ASCVD OR PRIMARY HYPERLIPIDEMIA AT HIGH RISK FOR ASCVD: Prescriber reports: baseline and current LDL-C, AND One of the following: baseline LDL-C is between 70-189mg/dL, OR patient requires greater than 25 percent additional lowering of LDL-C.
Age Restrictions	REPATHA: CVD: 18 years of age or older, HeFH and HoFH: 10 years of age or older.

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	INITIAL: 12 months, RENEWAL: 12 months
Other Criteria	INITIAL: A. HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH): Prescriber attests that PCSK-9 will be used in combination with a maximally tolerated statin OR prescriber attests that patient is statin intolerant and can provide rationale to intolerance or contraindication. B. HOMOZYGOUS FAMILIAL HYPERCHOLESTSEROLEMIA (HoFH): Prescriber attests that PCSK-9 will be used in combination with a maximally tolerated statin OR prescriber attests that member is statin intolerant and can provide rationale to intolerance or contraindication. C. CLINICAL ASCVD OR PRIMARY HYPERLIPIDEMIA AT HIGH RISK FOR ASCVD: (1) Patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) OR primary hyperlipidemia at high risk for ASCVD, AND (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, OR (b) myocardial infarction (MI), OR (c) coronary or other arterial revascularization, OR (d) stroke, OR (e) transient ischemic stroke (TIA), OR (f) stable/unstable angina, OR (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 (2) (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 (3) Requires LDL-C reduction after at least a 90-day trial of BOTH of the following: (a) high-intensity statin (atorvastatin 40- 80mg OR rosuvastatin 20-40mg) or documentation of maximally tolerated statin

PA Criteria	Criteria Details
	myositis or myalgia related symptoms with either, rosuvastatin, atorvastatin OR another maximally tolerated statin
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

#### **Products Affected**

• SILDENAFIL 20 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: Documented confirmatory PAH diagnosis based on right heart catheterization
Age Restrictions	REVATIO/SILDENAFIL: 18 years of age or older.
Prescriber Restrictions	Prescribed by or given in consultation with a cardiologist or pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: (1) Has NYHA-WHO Functional Class II to IV symptoms, (2) Not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form, and (3) Not concurrently taking guanylate cyclase stimulators (e.g. Adempas). RENEWAL: One of the following: 1) Improvement from baseline in the 6- minute walk distance test OR 2) Stable 6-minute walk distance test with a stable or improved World Health Organization functional class.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PEGFILGRASTIM

- FULPHILA 6 MG/0.6 ML SYRINGE
- ZIEXTENZO 6 MG/0.6 ML SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

- PEGASYS 180 MCG/0.5 ML SYRINGE
- PEGASYS 180 MCG/ML VIAL RTU,SDV

PA Criteria	Criteria Details
Exclusion Criteria	HEPATITIS B: Cirrhosis
Required Medical Information	HEPATITIS B: (1) Serum HBeAg positive chronic hepatitis B, AND (2) Documented evidence of viral replication with elevated serum ALT. HEPATITIS C: Documented detectable pretreatment HCV RNA level/viral load (Varies by lab assay but is a level typically greater than or equal to 25 IU/mL)
Age Restrictions	Pegasys- HEPATITIS B: 3 years of age or older, HEPATITIS C: 5 years of age or older.
Prescriber Restrictions	HEPATITIS B: Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model. HEPATITS C: Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g., a hepatologist)
Coverage Duration	24-38 weeks
Other Criteria	Pegasys- HEPATITIS C: (1) Use as a part of a combination antiviral treatment regimen.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PENICILLAMINE

## **Products Affected**

• PENICILLAMINE 250 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: WILSONS DISEASE: ONE of the following: (1) Plasma copper-protein ceruloplasmin less than 20mg/dL, (2) Liver biopsy positive for abnormally high amount of copper (greater than 250 mcg/d dry weight) or presence of Kayser-Fleischer rings, OR (3) Diagnosis confirmed by genetic testing for ATP7B mutations. CYSTINURIA: Daily cystine output greater than 300mg per 24 hours following urine cystine excretion testing. RENEWAL-WILSONS DISEASE: Free serum copper level less than 10 mcg/dL. CYSTINURIA: Cystine excretion of less than 200 mg/day
Age Restrictions	N/A
Prescriber Restrictions	WILSONS DISEASE: Prescribed by or given in consultation with a hepatologist, CYSTINURIA: Prescribed by or given in consultation with a nephrologist, RHEUMTATOID ARTHRITIS (RA): Prescribed by or given in consultation with a rheumatologist.
Coverage Duration	INITIAL: 12 months, RENEWAL: Lifetime.
Other Criteria	INITIAL: WILSONS DISEASE:(1) Maintained a low copper diet (less than 2 mg copper per day). CYSTINURIA:(1) Presence of nephrolithiasis and ONE of the following: (a) Stone analysis positive for cystine, (b) Urinalysis positive for pathognomonic hexagonal cystine crystals, (c) Family history of cystinuria with positive cyanide-nitroprusside screen. (2) Failure to respond to an adequate trial of or contraindication to ALL of the following conventional therapies: increased fluid intake, modest reductions in sodium and protein intake, and urinary alkalization. RA:(1) No history of or other evidence of renal insufficiency, (2) Failure to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine. RENEWAL:RA:1) No history of or other evidence of renal

PA Criteria	Criteria Details
	insufficiency 2) Experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PENTOSAN POLYSULFATE

## **Products Affected**

• ELMIRON 100 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	INITIAL: 6 months. RENEWAL: Lifetime
Other Criteria	INITIAL: Interstitial cystitis/bladder pain syndrome ongoing for at least six weeks. RENEWAL: Clinical improvement from baseline secondary to treatment
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## PHENOXYBENZAMINE

## **Products Affected**

• PHENOXYBENZAMINE HCL 10 MG CAP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist/oncologist
Coverage Duration	21 days
Other Criteria	(1) Requested for treatment of pheochromocytoma prior to pheochromocytoma resection/removal. (2) Trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **PHOSPHATE BINDERS**

## **Products Affected**

• SEVELAMER 0.8 GM POWDER PACKET OUTER

• SEVELAMER 2.4 GM POWDER PACKET OUTER

PA Criteria	Criteria Details
Exclusion Criteria	Sevelamer carbonate: Patients with bowel obstruction. Sevelamer carbonate ONLY: Patients with known hypersensitivity to sevelamer carbonate or sevelamer hydrochloride.
Required Medical Information	None
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of chronic kidney disease (CKD), AND Patient is on dialysis, AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to sevelamer carbonate tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## PIRFENIDONE

#### **Products Affected**

• PIRFENIDONE 267 MG TABLET

• PIRFENIDONE 801 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	INITIAL: (1) Documentation showing usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT. (2) Documentation showing predicted forced vital capacity (FVC) of at least 50% at baseline.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INTIAL: (1) No other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer). (2) Patient does not currently smoke cigarettes. RENEWAL: Clinically meaningful improvement or maintenance in annual rate of decline
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PRAZIQUANTEL

## **Products Affected**

• PRAZIQUANTEL 600 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Patients with ocular cysticercosis. Patients taking strong Cytochrome P450 (CYP450) inducers, such as rifampin.
Required Medical Information	None
Age Restrictions	1 year of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist.
Coverage Duration	7 days
Other Criteria	Patient has a documented diagnosis of Schistosomiasis due to a species of schistosoma (for example, Schistosoma mekongi, Schistosoma japonicum, Schistosoma mansoni and Schistosoma haematobium) OR Patient has a documented diagnosis of Clonorchiasis or Opisthorchiasis due to the liver flukes, Clonorchis sinensis/Opisthorchis viverrini.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## PYRAZINAMIDE

## **Products Affected**

• PYRAZINAMIDE 500 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Patients with severe hepatic damage. Patients with acute gout.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, an Infectious Disease specialist
Coverage Duration	2 months
Other Criteria	Patient has a documented diagnosis of active tuberculosis AND pyrazinamide will be used in combination with other antituberculosis agents OR patient had a treatment failure with other primary drugs for active tuberculosis AND prescribed dosing and duration are within the current CDC and American Thoracic Society guidelines
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## PYRIDOSTIGMINE

## **Products Affected**

• PYRIDOSTIGMINE 60 MG/5 ML SOLN

PA Criteria	Criteria Details
Exclusion Criteria	Mechanical intestinal or urinary obstruction
Required Medical Information	N/A
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of myasthenia gravis AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to pyridostigmine oral tablets.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## PYRIMETHAMINE

## **Products Affected**

• PYRIMETHAMINE 25 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Patients with documented megaloblastic anemia due to folate deficiency.
Required Medical Information	TOXOPLASMOSIS 1. PRIMARY PROPHYLAXIS FOR TOXOPLASMIC ENCEPHALITIS: (1a) patient is Toxoplasma IgG positive AND (1b) Patient has a documented CD4 less than or equal to 100 cells/mm3 if initiating prophylaxis OR CD4 less than 100-200 cells/mm3 if reinstituting prophylaxis. (Note: Chart notes/medical records required for documentation).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PRIMARY PROPHYLAXIS:6 mo. TX (TOXOPLASMOSIS), SECONDARY PROPHYLAXIS (TOXOPLASMOSIS, PCP):12 mo
Other Criteria	TOXOPLASMOSIS: Patient has documentation confirming the use of pyrimethamine is supported for patient's diagnosis of (1) Active severe acquired toxoplasmosis (including toxoplasmic encephalitis and congenital toxoplasmosis) OR (2) Secondary prophylaxis of toxoplasmic encephalitis OR (3) Primary prophylaxis for toxoplasmic encephalitis AND (3a) Pyrimethamine will be used in combination with dapsone or atovaquone AND (3b) Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP- SMX) AND (3c) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate OR (3d) Patient has experienced a moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome) and is contraindicated for a re-challenge. PNEUMOCYSTIS PNEUMONIA (PCP): (1a) Pyrimethamine is being used as primary Pneumocystis Pneumonia (PCP) prophylaxis in an HIV infected patient OR (1b) Pyrimethamine is being used as secondary prophylaxis in an HIV infected patient who has been treated for an acute episode of Pneumocystis Pneumonia AND (2) Patient has experienced intolerance to prior

PA Criteria	Criteria Details
	prophylaxis with trimethoprim-sulfamethoxazole (TMP- SMX) AND (3a) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP- SMX) using a desensitization protocol and is still unable to tolerate OR (3b) Patient has experienced a moderately severe or life threatening- reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome) and is contraindicated for a re-challenge. (Note: Chart notes/medical records required for documentation).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Toxoplasmosis (primary and secondary prophylaxis). Pneumocystis Pneumonia (primary and secondary prophylaxis).

## RIFAXIMIN

## **Products Affected**

• XIFAXAN 550 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	N/A
Age Restrictions	HE: Xifaxan 550mg: 18 years of age or older, IBS WITH DIARRHEA: 18 years of age or older, TRAVELERS DIARRHEA: 12 years of age or older.
Prescriber Restrictions	HE: Prescribed by or in consultation with a hepatologist, IBS WITH DIARRHEA: Prescribed by or in consultation with a gastroenterologist, CDI: Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	INITIAL:HE:550mg:12mos, 200mg:10days IBS:12wks TRVLRS DIARR:3days C.DIFF:20days RENEW:HE, IBS:12mos
Other Criteria	INITIAL: HE: ONE of the following: 1) Trial of lactulose or currently on lactulose monotherapy AND request is for Xifaxan 550mg tablets, OR 2) Concurrent use with lactulose AND request is for Xifaxan 200mg tablets. IBS WITH DIARRHEA: (1) Trial or contraindication to tricyclic anti- depressants or dicyclomine, AND (2) Request is for Xifaxan 550mg tablets. TRAVELERS DIARRHEA: (1) Trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin, AND (2) Request is for Xifaxan 200mg tablets. CDI: (1) Had at least one previous occurrence of Clostridium difficile infection, AND (2) Use in combination with vancomycin. RENEWAL - HE: Request is for Xifaxan 550mg tablets. IBS WITH DIARRHEA: 1) At least 6 weeks have passed since the last treatment course of rifaximin AND 2) Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale), AND 3) Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7) AND 4) Request is for Xifaxan 550mg tablets.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	Xifaxan 200mg: Hepatic encephalopathy (HE) treatment, Clostridium difficile infection (CDI)

# **RINVOQ (UPADACITINIB)**

#### **Products Affected**

- RINVOQ ER 15 MG TABLET
- RINVOQ ER 30 MG TABLET
- RINVOQ ER 45 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease- Modifying Antirheumatic Drug (DMARD). Concurrent use with an Anti- Interleukin Monoclonal Antibody. Concurrent use with Other Janus Kinase Inhibitors. Concurrent use with Xolair (omalizumab subcutaneous injection. Concurrent use with Other Potent Immunosuppressants. COVID- 19 (Coronavirus Disease 2019).
Required Medical Information	Initial: AS: Patient has had a 3-month trial of at least ONE TNF-inhibitor, OR Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial. Conventional synthetic DMARDs such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count, AND Patient has tried one of Enbrel or Humira. AD: Patient has had a 3-month trial of at least ONE traditional systemic therapy, OR Patient has tried at least ONE traditional systemic therapy, OR Patient has tried at least ONE traditional systemic therapy but was unable to tolerate a 3- month trial. PsA: Patient has had a 3-month trial of at least ONE TNF- inhibitor, OR Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial. RA: Patient has had a 3-month trial of at least ONE TNF-inhibitor, OR Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial, AND Patient has tried one of Enbrel or Humira. UC: Patient has had a 3-month trial of at least ONE TNF-inhibitor, OR Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial, AND Patient has tried one of Enbrel or Humira. UC: Patient has had a 3-month trial of at least ONE TNF-inhibitor, OR Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial of at least ONE TNF-inhibitor, OR Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial, AND Patient has tried Humira. nr-axSpA: Patient meets BOTH of the following: i. Patient has objective signs of inflammation, defined as at least one of the following: a) CRP elevated beyond the ULN for the reporting laboratory OR b) Sacroilitis reported on MRI AND ii. Patient meets ONE of the following: a) Patient has had a 3-month trial of at least ONE TNF-inhibitor OR b) Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial (Note: Cimzia (certolizumab pegol SQ) is an example of TNF-inhibitor used for non-radiographic axial spondyloarthritis. Conventional synthetic
Age Restrictions	Ankylosing Spondylitis, Psoriatic Arthritis, Rheumatoid Arthritis, Ulcerative Colitis: 18 years of age or older. Atopic Dermatitis: 12 years of age or older

PA Criteria	Criteria Details
Prescriber Restrictions	Ankylosing Spondylitis, RA, nr-axSpA : prescribed by, or in consultation with, a rheumatologist. Psoriatic Arthritis: prescribed by, or in consultation with, a rheumatologist or a dermatologist. Ulcerative Colitis: prescribed by, or in consultation with, a gastroenterologist. Atopic Dermatitis: prescribed by, or in consultation with, an allergist, immunologist, or dermatologist.
Coverage Duration	Initial: AS, nr-axSpA, PsA, RA, UC: 6 months. Atopic Derm: 3 months Renewal: 1 year
Other Criteria	Renew AS (CONT): AND Patient has tried one of Enbrel or Humira, OR Patient has been established on Rinvoq for at least 90 days and prescription claims history indicates at least a 90-day supply of Rinvoq was dispensed within the past 130 days if claims history is not available, per the prescriber. AD: Patient has been on therapy for at least at least 90 days, AND Patient had a beneficial clinical response, defined as improvement from baseline in at least one of the following: estimated body surface area affected, erythema, induration/papulation/cdema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis, AND Compared with baseline, patient had an improvement in at least one symptom. PsA: Patient has been established on therapy for at least 6 months, AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline, OR Compared with baseline, patient experienced an improvement in at least one symptom: improved function or activities of daily living or decreased soft tissue swelling in joints or tendon sheaths, AND Patient has tried one of Enbrel or Humira, OR Patient has been established on Rinvoq for at least 90 days and prescription claims history indicates at least a 90- day supply of Rinvoq was dispensed within the past 130 days if claims history is not available, according to the prescriber. RA: Patient has been on therapy for at least 6 months, AND Patient had a beneficial clinical response when assessed by at least one objective measure, OR Patient had an improvement in at least one symptom, improved function or activities of daily living, decreased soft tissue swelling in joints or tendon sheaths, AND Patient has tried one of Enbrel or Humira, OR Patient has been established on Rinvoq for at least 90 days and prescriptor claims history indicates at least a 90-day supply of Rinvoq was dispensed within the past 130 days if claims history is not available, according to the prescriber. U

PA Criteria	Criteria Details
	prescriber. nr-axSpA: Patient has been on the therapy for at least 6 months AND Patient meets at least one of the following: When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline OR Compared with baseline, patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- ADEMPAS 0.5 MG TABLET
- ADEMPAS 1 MG TABLET
- ADEMPAS 1.5 MG TABLET
- ADEMPAS 2 MG TABLET
- ADEMPAS 2.5 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP I: INITIAL: Documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization. NYHA-WHO functional class II-IV symptoms. CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO GROUP 4: INITIAL: NYHA-WHO functional class II-IV Symptoms.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	<ul> <li>INITIAL: PAH: Not concurrently taking nitrate or nitric oxide donors, phosphodiesterase inhibitors, or non-specific phosphodiesterase inhibitors.</li> <li>CTEPH: (1) Not concurrently taking nitrate or nitric oxide donors, phosphodiesterase inhibitors, or non-specific phosphodiesterase inhibitors.</li> <li>(2) Patient has persistent or recurrent disease after surgical treatment OR is not a candidate for surgery or has inoperable CTEPH. RENEWAL: PAH/CTEPH: (1) Improvement from baseline in the 6-minute walk distance, OR (2) Stable 6-minute walk distance and a stable or improved World Health Organization (WHO) functional class.</li> </ul>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- NEUPRO 1 MG/24 HR PATCH
- NEUPRO 2 MG/24 HR PATCH
- NEUPRO 3 MG/24 HR PATCH
- NEUPRO 4 MG/24 HR PATCH
- NEUPRO 6 MG/24 HR PATCH
- NEUPRO 8 MG/24 HR PATCH

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of Parkinsons disease OR Restless leg syndrome AND meets one of the following criteria: (1) Patient had a trial and therapeutic failure, intolerance, or contraindication to generic oral pramipexole AND oral ropinirole OR (2) Patient is unable to ingest solid oral dosage forms due to ONE of the following: (2a) Oral/motor difficulties OR (2b) Dysphagia.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# SIMPONI (GOLIMUMAB) SQ

- SIMPONI 100 MG/ML PEN INJECTOR
- SIMPONI 100 MG/ML SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	1. Concurrent Use with a Biologic or with a Targeted Synthetic Disease- Modifying Antirheumatic Drug (DMARD). 2. Plaque Psoriasis without Psoriatic Arthritis.
Required Medical Information	Initial: AS: Documentation that the patient has tried 2 of Enbrel, Humira, Taltz, Rinvoq, Xeljanz/XR. RA: Patient has tried 1 conventional synthetic DMARD for at least 3 months, AND Documentation that the patient has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR. UC: Patient has tried 1 systemic therapy, OR Patient meets BOTH of the following: Patient has pouchitis, AND Patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa (mesalamine) enema. PsA: Documentation that the patient has tried 2 of Enbrel, Humira, Otezla, Rinvoq, Skyrizi subcutaneous, Stelara subcutaneous, Taltz, Tremfya, and Xeljanz/XR. UC: Patient has tried Humira. Spondyloarthritis, Other Subtypes: Patient meets 1 of the following (a or b): a) Patient meets both of the following: Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet, AND Patient has tried at least ONE conventional synthetic DMARD, OR b) Patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least one of the following: CRP elevated beyond the upper limit of normal for the reporting laboratory, OR Sacroiliitis reported on MRI. Renewal: AS: Patient has been on therapy for at least 6 months, AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline, OR Compared with baseline, patient had an improvement in function or activities of daily living, AND Patient has tried TWO of Enbrel, Humira, Taltz, and Xeljanz/XR, OR PER the prescriber, the patient has been on Simponi Aria for at least 90 days, OR Patient has been on Simponi subcutaneous for at least 90 days and prescription claims indicates at least a 90-day supply of Simponi subcutaneous was dispensed within the past 130 days [verification required] if claims history is not available, per the prescriber [verification required]
Age Restrictions	UC: 18 years of age or older.

PA Criteria	Criteria Details
Prescriber Restrictions	AS, RA, Spondyloarthritis: prescribed by or in consultation with a rheumatologist. PsA: prescribed by or in consultation with a rheumatologist or a dermatologist. UC: prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Initial: 6 Months, Renewal: 1 year
Other Criteria	PsA: Patient has been on therapy for at least 6 months, AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline, OR Compared with baseline, patient had an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue, improved function or activities of daily living, decreased soft tissue swelling in joints or tendon sheaths, AND Patient has tried TWO of Enbrel, Humira, Otezla, Rinvoq, Stelara subcutaneous, Taltz, Tremfya, and Xeljanz/XR, OR PER the prescriber, the patient has been established on Simponi Aria for at least 90 days OR Patient has been established on Simponi subcutaneous for at least 90 days and prescription claims indicates at least a 90-day supply of Simponi subcutaneous was dispensed within the past 130 days [verification required] if claims history is not available, according to the prescriber [verification required]. RA: Patient has been on therapy for at least 6 months, AND Patient had a beneficial clinical response when assessed by at least one objective measure OR Patient had an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue, improved function or activities of daily living, decreased soft tissue swelling in joints or tendon sheaths, AND Patient has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR OR PER the prescriber; the patient has been established on Simponi Aria for at least 90 days OR Patient has been established on Simponi avia for at least 90 days and prescription claims indicates at least 130 days [verification required]. UC: Patient has been on therapy for at least 6 months, AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient had an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding AND Patient has tried Humira OR PER the prescriber, the patient has been established

PA Criteria	Criteria Details
	on therapy for at least 6 months AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline OR Compared with baseline, patient had an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Spondyloarthritis, other subtypes.

- SIROLIMUS 0.5 MG TABLET
- SIROLIMUS 1 MG TABLET
- SIROLIMUS 1 MG/ML SOLUTION
- SIROLIMUS 2 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	LYMPHANGIOLEIOMYOMATOSIS (LAM): Prescriber attests patient has diagnosis of Lymphangioleiomyomatosis (LAM) confirmed by lung biopsy or HRCT showing cystic lung disease
Age Restrictions	LAM: 18 years of age or older
Prescriber Restrictions	RENAL TRANSPLANT: Prescribed by or in consultation with a transplant specialist. LAM: Prescribed by, or in consultation with, a pulmonologist.
Coverage Duration	12 months
Other Criteria	PROPHYLAXIS OF ORGAN REJECTION IN RENAL TRANSPLANTS: The patient 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. LYMPHANGIOLEIOMYOMATOSIS (LAM): Patient has one of the following conditions: (i) Diagnosis of Tuberous Sclerosis Complex (TSC) (ii) Chylous Pleural Effusion (iii) Angioleiomyoma
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

#### **Products Affected**

- SOVALDI 150 MG PELLET PACKET OUTER
- SOVALDI 200 MG PELLET PACKET OUTER
- SOVALDI 200 MG TABLET
- SOVALDI 400 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	SOVALDI: (1) PT has severe renal impairment (GFR less than 30 mL/min/1.73m2), ESRD, or dialysis (2) PT has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (3) PT is currently taking any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, tipranavir/ritonavir, velpatasvir/sofosbuvir (Epclusa), ledipasvir/sofosbuvir (Harvoni), velpatasvir/sofosbuvir/voxilaprevir (Vosevi), or elbasvir/grazoprevir (Zepatier) (4) PT is using Sovaldi with a direct acting antiviral (e.g., Olysio or Daklinza) AND is concurrently taking amiodarone (5) Adult with compensated cirrhosis. (6) Adult taking Sovaldi with ribavirin OR peginterferon alfa and ribavirin. SOVALDI/OLYSIO REGIMEN: (1) PT has cirrhosis (2) PT completed full course of therapy with 1) any HCV protease inhibitor and has not achieved a sustained virologic response (SVR) OR 2) a regimen containing NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen) (3) PT is concurrently using any of the following with Sovaldi/Olysio which are not recommended by the manufacturer of Olysio: (a) Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical), clarithromycin, telithromycin, itraconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg) (b) Any of the following HIV medications: delavirdine, etravirine, nevirapine, or efavirenz (c) A cobicistat-containing medication (e.g., Stribild or Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir), Evotaz, Prezcobix, or Tybost) (d) An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir).
Required Medical Information	Documentation showing patient has an HCV RNA level within the past 6 months (Note: Chart notes or lab reports required for documentation)

PA Criteria	Criteria Details
Age Restrictions	Genotype 1 or 3: 18 years of age or older, Genotype 2 or 3: 3 to 17 years old
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
Coverage Duration	G3 w/compensated cirrhosis, w/o cirrhosis combo w/ribavirin in patient aged 3-17: 24wks Other:12wks
Other Criteria	FOR ADULT PATIENTS (18 years of age or older), patient meets ALL of the following: (1) Treatment naive or treatment experienced (prior treatment with peginterferon/ribavirin) (2) Patient will be using Sovaldi with Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only) (3) Patient has failed a short trial of the preferred formulary agent or has a contraindication to therapy with the preferred formulary agent(s) (a) For genotype 1 HCV infection: a short trial of Epclusa or Harvoni (e.g., adverse effect early in therapy to Harvoni or Epclusa) or contraindication to BOTH agents (b) For genotype 3 HCV infection: a short trial of Epclusa (e.g., adverse effect early in therapy to Epclusa) or contraindication to this agent (NOTE: An individual who has completed a full course of therapy with the preferred agent that did not achieve SVR will not be approved) FOR PEDIATRIC PATIENTS (Under age 18), Patient has genotype 2 or 3 infection and request must meet the Food and Drug Administration (FDA)- approved indication: treatment naive or treatment experiences patient with compensated cirrhosis (Child-Pugh A) or without cirrhosis AND the requested medication will be used with ribavirin. For Sovaldi with Daklinza, approve if patient will be taking ribavirin together with Sovaldi and Daklinza AND has decompensated cirrhosis or post-liver transplant patient.
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A

## SOFOSBUVIR/VELPATASVIR

- EPCLUSA 150-37.5 MG PELLET PKT OUTER
- EPCLUSA 200 MG-50 MG TABLET
- EPCLUSA 200-50 MG PELLET PACK OUTER
- EPCLUSA 400 MG-100 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	(1) Patient is currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir, topotecan, sofosbuvir (Sovaldi) (as a single agent), ledipasvir/sofosbuvir (Harvoni), elbasvir/grazoprevir (Zepatier), pibrentasvir/glecaprevir (Mavyret), or velpatasvir/sofosbuvir/voxilaprevir (Vosevi). (2) Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
Required Medical Information	Documentation showing patient has a chronic HCV infection documented by at least ONE detectable HCV RNA level within the last 6 months (Note: Chart notes or lab reports required for documentation)
Age Restrictions	3 years of age older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
Coverage Duration	12 weeks
Other Criteria	If patient has a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 WITH decompensated cirrhosis (symptoms related to liver damage), approval also requires that the requested medication will be used with ribavirin. If patient does not have cirrhosis (liver damage) OR has compensated cirrhosis (a condition where liver is extensively scarred, but does not have symptoms of liver damage), approval also requires that patient meets ONE of the following: (1) Treatment naive and genotype 1-6 infection OR (2) Treatment experienced, genotype 1-6 infection, with prior treatment with ONE of the following: (a) peginterferon/ribavirin OR (b) NS3 protease inhibitor triple therapy (Olysio, Incivek or Victrelis with

PA Criteria	Criteria Details
	peginterferon/ribavirin) OR (3) Treatment experienced, genotype 1b or genotype 2 infection, with previous treatment with Sovaldi (sofosbuvir)- containing regimen (e.g., Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio) that does not include an NS5A inhibitor.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

### **Products Affected**

• VOSEVI 400-100-100 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	(1) Patient is currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir, topotecan, sofosbuvir (Sovaldi) (as a single agent), ledipasvir/sofosbuvir (Harvoni), elbasvir/grazoprevir (Zepatier), pibrentasvir/glecaprevir (Mavyret), or velpatasvir/sofosbuvir/voxilaprevir (Vosevi). (2) Patient has moderate or severe hepatic impairment (Child- Pugh B or C). (3) Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
Required Medical Information	Documentation showing patient has a chronic HCV infection documented by at least ONE detectable HCV RNA level within the last 6 months (Note: Chart notes or lab reports required for documentation)
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
Coverage Duration	12 weeks
Other Criteria	Genotype 1-6: treatment experienced and previously failed a full course of therapy with DAA regimen that includes NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination). Genotype 1a or 3: treatment experienced and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (e.g., Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other HCV protease inhibitor in combination with Sovaldi))
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## SUCRALFATE

#### **Products Affected**

• SUCRALFATE 1 GM/10 ML SUSP

PA Criteria	Criteria Details
Exclusion Criteria	Hypersensitivity to sucralfate.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, a gastroenterologist.
Coverage Duration	3 months
Other Criteria	Patient has a diagnosis of active duodenal ulcer AND meets BOTH of the following criteria: (1) Patient had a trial and therapeutic failure, intolerance, or contraindication to generic oral sucralfate tablet AND (2) Request is for short-term (up to 8 weeks) therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **SUMATRIPTAN**

- SUMATRIPTAN 20 MG NASAL SPRAY
- SUMATRIPTAN 5 MG NASAL SPRAY
- SUMATRIPTAN 6 MG/0.5 ML INJECT SDV, OUTER
- SUMATRIPTAN 6 MG/0.5 ML INJECT SUV
- SUMATRIPTAN 6 MG/0.5 ML VIAL INNER, SDV

PA Criteria	Criteria Details
Exclusion Criteria	Prevention of migraine or cluster headache attacks, Ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetals angina, Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders, History of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke, Peripheral vascular disease, Ischemic bowel disease, Uncontrolled hypertension, Recent use (i.e., within 24 hours) of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamine1 (5-HT1) agonist, Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor, Hypersensitivity to sumatriptan, Severe hepatic impairment. Nasal Spray: treatment of cluster headache
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. Patient has a diagnosis or indication for ONE of the following: 1. Acute treatment of migraines 2. Acute treatment of cluster headaches AND B. If the medication is being used for the acute treatment of migraines, approval also requires the following: 1. Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to ALL of the following

PA Criteria	Criteria Details
	(medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history): oral sumatriptan, rizatriptan, naratriptan, almotriptan AND 2. For sumatriptan injection: Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to Sumatriptan Nasal Spray (before injection).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **TEMOZOLOMIDE-PO**

- TEMOZOLOMIDE 100 MG CAPSULE
- TEMOZOLOMIDE 140 MG CAPSULE
- TEMOZOLOMIDE 180 MG CAPSULE
- TEMOZOLOMIDE 20 MG CAPSULE
- TEMOZOLOMIDE 250 MG CAPSULE
- TEMOZOLOMIDE 5 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	A. Patient has one of the following diagnoses: 1. Refractory anaplastic astrocytoma. 2. Glioblastoma multiforme OR 3. Metastatic melanoma. B. If the diagnosis is refractory anaplastic astrocytoma, patient has experienced disease progression on a drug regimen containing nitrosourea and procarbazine. C. If the diagnosis is glioblastoma multiforme, the requested medication is being used at the same time as radiotherapy for a newly diagnosed patient then being used as a maintenance therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Metastatic Melanoma.

### **TESTOSTERONE**

- METHYLTESTOSTERONE 10 MG CAP
- TESTOSTERON ENAN 1,000 MG/5 ML MDV
- TESTOSTERONE 1% (25 MG/2.5 G) PK OUTER
- TESTOSTERONE 1.62% (2.5 G) PKT INNER
- TESTOSTERONE 1.62% GEL PUMP
- TESTOSTERONE 1.62%(1.25 G) PKT OUTER
- TLANDO 112.5 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: MALE HYPOGONADISM: Documented low testosterone levels confirmed by at least ONE of the following laboratory values: 1) Two morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state or 2) Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)
Age Restrictions	GENDER DYSPHORIA: 16 years of age or older. ALL OTHER INDICATIONS: None
Prescriber Restrictions	N/A
Coverage Duration	MALE HYPOGONADISM, GENDER DYSPHORIA:12mos. DELAYED PUBERTY (MALES), FEMALE W/BREAST CANCER: Lifetime
Other Criteria	INITIAL: MALE HYPOGONADISM: Testosterone levels not required for the following patients: 1) Has a previously approved prior authorization for testosterone, OR 2) Receiving any form of testosterone replacement therapy documented by physician attestation or claims history. For requests for TLANDO: patient had a trial and failure, intolerance, or contraindication to TWO formulary alternatives (e.g., testosterone 1% gel (AndroGel 1%), intramuscular testosterone enanthate, testosterone 1.62% gel (AndroGel 1.62%), etc.). For requests for ANDROID OR TESTRED: The patient had a trial and failure, intolerance, or contraindication to Tlando, AND patient had a trial and failure, intolerance, or contraindication to TWO additional formulary alternatives (e.g., testosterone 1% gel (AndroGel 1%), intramuscular testosterone enanthate, testosterone 1% gel (AndroGel 1%), intramuscular testosterone enanthate, testosterone 1% gel (AndroGel 1%), intramuscular testosterone enanthate, testosterone 1.62% gel (AndroGel 1.62%), etc.) DELAYED PUBERTY IN MALES NOT

PA Criteria	Criteria Details
	DUE TO A PATHOLOGICAL DISORDER or FEMALE WITH METASTATIC BREAST CANCER: Requests for methyltestosterone (Testred or Android) require a trial of or contraindication to intramuscular testosterone enanthate. RENEWAL: MALE HYPOGONADISM: (1) Improved symptoms compared to baseline and tolerance to treatment, AND (2) Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)

## TETRABENAZINE

- TETRABENAZINE 12.5 MG TABLET
- TETRABENAZINE 25 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	INITIAL/RENEWAL: Patients who are actively suicidal, or in patients with untreated or inadequately treated depression. Patients with hepatic impairment. Patients taking monoamine oxidase inhibitors (MAOIs) or within a minimum of 14 days of discontinuing therapy with an MAOI. Concomitant therapy with reserpine (at least 20 days should elapse after stopping reserpine before starting tetrabenazine. Concomitant therapy with deutetrabenazine or valbenazine.
Required Medical Information	INITIAL: Patients who require doses of XENAZINE greater than 50 mg/day should be first tested and genotyped to determine if they are poor metabolizers (PMs) or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6 AND Patient is a confirmed extensive metabolizer (poor metabolizer should not exceed a daily dose of 50mg).
Age Restrictions	N/A
Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist that treats Huntington's Disease.
Coverage Duration	INITIAL/RENEWAL: 3 months
Other Criteria	Diagnosis of chorea associated with Huntingtons Disease INITIAL: Patient has had a documented trial and therapeutic failure of at least TWO (2) of the following: amantadine, an antipsychotic (fluphenazine, haloperidol, risperidone, ziprasidone, quetiapine, or olanzapine), riluzole, a benzodiazepine. RENEWAL: (1) Signs and symptoms of chorea must be decreased (2) Adverse reactions such as akathisia, restlessness, parkinsonism, depression, insomnia, anxiety, or sedation occur have not subsided with dose reduction.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **TEZACAFTOR/IVACAFTOR**

- SYMDEKO 100/150 MG-150 MG TABS
- SYMDEKO 50/75 MG-75 MG TABLETS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	INITIAL: (1) Documentation that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, OR (2) Documentation that patient has at least one mutation in the CFTR gene.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
Coverage Duration	INITIAL: 24 weeks. RENEWAL: Lifetime.
Other Criteria	RENEWAL: Improvement in clinical status compared to baseline as shown by Improved, maintained, or demonstrated less than expected decline in ONE of the following: FEV1, or body mass index (BMI), or reduction in rate of pulmonary exacerbations.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## THIOGUANINE

### **Products Affected**

• TABLOID 40 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Patients whose disease has demonstrated prior resistance to mercaptopurine and thioguanine. Use during maintenance therapy or similar long-term continuous treatments for acute nonlymphocytic leukemias. Treatment of chronic lymphocytic leukemia, Hodgkin's lymphoma, multiple myeloma, or solid tumors.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of acute nonlymphocytic leukemias.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **TOBRAMYCIN INHALED**

### **Products Affected**

• TOBRAMYCIN 300 MG/5 ML AMPULE P/F

PA Criteria	Criteria Details
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.
Age Restrictions	6 years of age and older.
Prescriber Restrictions	N/A
Coverage Duration	12 months.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **TOPICAL RETINOIDS**

- TRETINOIN 0.05% CREAM
- TRETINOIN 0.1% CREAM

PA Criteria	Criteria Details
Exclusion Criteria	Request is for a cosmetic condition.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	The medication being requested for a Medical condition (that is, a NON- COSMETIC condition). (Note: Examples of Medical conditions (that is, non-cosmetic conditions) include acanthosis nigricans, acne rosacea, actinic keratosis/precancerous lesions, alopecia areata, basal cell carcinoma (skin cancer), diabetic foot ulcers, dysplasia of cervix, folliculitis (for example, pseudofolliculitis barbae), ichthyosis (e.g., congenital, lamellar, vulgaris, X-linked), keloid scars, keratosis (e.g., keratosis follicularis [Dariers disease], keratosis pilaris), lichen planus, lichen sclerosis, military osteoma cutis, molluscum contagiosum, mucositis, oral leukoplakia, papillomatosis, systemic sclerosis, and warts.
Indications	Some FDA-approved Indications Only.
Off-Label Uses	N/A

### TOREMIFENE

### **Products Affected**

• TOREMIFENE CITRATE 60 MG TAB

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

- ORENITRAM ER 0.125 MG TABLET
- ORENITRAM ER 0.25 MG TABLET
- ORENITRAM ER 1 MG TABLET
- ORENITRAM ER 2.5 MG TABLET
- ORENITRAM ER 5 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	ORENITRAM: Severe hepatic impairment
Required Medical Information	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH) (WHO GROUP 1):Documented confirmatory PAH diagnosis based on right heart catheterization.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or given in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	INITIAL: ORENITRAM- ONE of the following:(1) Continuation of Orenitram (treprostinil) therapy from hospital discharge AND NYHA/WHO FC II, III, or IV symptoms OR (2) New start of Orenitram AND WHO FC II or III symptoms AND trial of or contraindication to TWO of the following agents from different drug classes: (a) oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan), (b) oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil), (c) oral cGMP inhibitor (e.g., riociguat), AND trial of or contraindication to the preferred oral prostanoid: Uptravi. OR (3) New start of Orenitram AND WHO FC III symptoms with evidence of rapid progression/poor prognosis, or WHO FC IV symptoms AND trial of or contraindication to ONE IV/SQ prostacycline (e.g., epoprostenol or treprostinil) AND trial of or contraindication to the preferred oral prostanoid: Uptravi. RENEWAL - ORENITRAM: One of the following:(1) Patient had improvement from baseline in the 6-minute walk distance test OR (2) Patient remained stable from baseline in the 6-minute walk distance test AND the patients World Health Organization (WHO) functional class has improved or remained stable.

PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# **TRETINOIN ORAL**

### **Products Affected**

• TRETINOIN 10 MG CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	Patients with known hypersensitivity to tretinoin or other retinoids.
Required Medical Information	Patient has a documented diagnosis of acute promyelocytic leukemia (APL), French-American-British (FAB) classification M3 (including the M3 variant) confirmed by the presence of the t(15,17) translocation AND/OR the presence of the PML/RARa gene.
Age Restrictions	18 years of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist.
Coverage Duration	12 months.
Other Criteria	Tretinoin will be used for the induction of remission only AND Patient is refractory to, or has relapsed from, anthracycline chemotherapy, or anthracycline-based chemotherapy is contraindicated. Patient will receive an accepted form of remission consolidation and/or maintenance therapy for APL after completion of induction therapy with tretinoin.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# TRIAMCINOLONE AEROSOL

### **Products Affected**

• TRIAMCINOLONE 0.147 MG/G SPRAY

PA Criteria	Criteria Details
rachteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. Patient has corticosteroid-responsive dermatoses, AND B. Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to at least THREE of the following: mometasone 0.1% solution, fluocinonide 0.05% solution, fluocinolone 0.01% solution, clobetasol 0.05% solution.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## **TRIFLURIDINE EYE DROPS**

### **Products Affected**

• TRIFLURIDINE 1% EYE DROPS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	6 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	21 Days
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# VALGANCICLOVIR

### **Products Affected**

• VALGANCICLOVIR 450 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Hypersensitivity to valganciclovir or ganciclovir.
Required Medical Information	PREVENTION OF CMV DISEASE: Donor CMV seropositive/Recipient CMV seronegative [D+/R-]
Age Restrictions	For prevention of CMV disease: Pediatric kidney transplant: 4 months of age and older, Pediatric heart transplant: 1 month of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. Patient has ONE of the following diagnoses: 1. Cytomegalovirus (CMV) Retinitis OR 2. Prevention of CMV Disease in patients with a kidney, heart, and kidney-pancreas transplant AND B. If patient has CYTOMEGALOVIRUS (CMV) RETINITIS: Patient has a documented diagnosis of Cytomegalovirus (CMV) Retinitis AND patient has a documented diagnosis of acquired immunodeficiency syndrome (AIDS) OR C. If medication is being used for PREVENTION OF CMV DISEASE: Valcyte is being used for the prevention of CMV Disease in patients with a kidney, heart, and kidney-pancreas transplant at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]) AND patient meets ONE of the following criteria: 1. Patient is post kidney transplant and is 4 months of age or older OR 2. Patient is post heart transplant and is 1 month of age or older OR 3. Patient is post kidney-pancreas transplant.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

## VORICONAZOLE

- VORICONAZOLE 200 MG TABLET F/C
- VORICONAZOLE 40 MG/ML SUSP
- VORICONAZOLE 50 MG TABLET F/C

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration of cisapride, pimozide, quinidine, ivabradine, Sirolimus, rifampin, carbamazepine, and long-acting barbiturates, efavirenz doses of 400 mg every 24 hours or higher, ritonavir, rifabutin, ergot alkaloids (ergotamine and dihydroergotamine), St. Johns Wort, naloxegol, tolvaptan, venetoclax (at initiation and during the ramp-up phase).
Required Medical Information	Fungal culture and other relevant laboratory studies (including histopathology) need to be obtained to isolate and identify causative organisms
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	12 months
Other Criteria	A. The request is for ONE of the following: 1. Invasive aspergillus OR 2. Candidemia in a non-neutropenic patient OR 3. One of the following Candida infections: disseminated infection in skin or infection in abdomen, kidney, bladder wall, or wound OR 4. Esophageal candidiasis OR 5. A serious fungal infection caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) or Fusarium species including Fusarium solani AND B. If patient has invasive aspergillus, approval also requires: Patient has a diagnosis of clinically documented invasive aspergillosis, that is susceptible to voriconazole confirmed by fungal culture and other relevant laboratory studies (including histopathology) with isolated and identified causative organisms AND Patient has had a trial and therapeutic failure of amphotericin B. AND C. For ALL other indications, approval also requires: 1. Patient had a trial and failure, contraindication, or intolerance to fluconazole.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# XELJANZ, XELJANZ XR (TOFACITINIB)

- XELJANZ 1 MG/ML SOLUTION OUTER
- XELJANZ 10 MG TABLET
- XELJANZ 5 MG TABLET
- XELJANZ XR 11 MG TABLET
- XELJANZ XR 22 MG TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease- Modifying Antirheumatic Drug (DMARD). Concurrent use with Other Potent Immunosuppressants (e.g., azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil). COVID-19 (Coronavirus Disease 2019). Renal Transplantation.
Required Medical Information	Xeljanz solution Initial: JIA: Patient has tried one of Enbrel or Humira. Note: A trial of an infliximab product or Simponi Aria also counts. Renewal: JIA: Patient has tried one of Enbrel or Humira. Note: A trial of an infliximab product or Simponi Aria also counts OR Patient has been established on Xeljanz for at least 90 days and prescription claims history indicates at least a 90-day supply of Xeljanz was dispensed within the past 130 days if claims history is not available, according to the prescriber. Note: In cases when 130 days of the patients prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Xeljanz for at least 90 days AND the patient has been receiving Xeljanz via paid claims. Xeljanz/Xeljanz XR tablets: Initial: AS, RA, PsA: Patient has had a 3- month trial of at least one TNF inhibitor, OR Patient has tried at least one TNF-inhibitor but was unable to tolerate a 3-month trial, AND Patient has tried one of Enbrel or Humira, JIA, UC Patient has had a 3- month trial of at least a 3-month trial of at least one TNF-inhibitor, OR Patient has tried one of Enbrel or Humira.
Age Restrictions	Ankylosing Spondylitis, Psoriatic Arthritis, Rheumatoid Arthritis, Ulcerative Colitis : 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months Renewal: 1 year

PA Criteria	Criteria Details
Other Criteria	Xeljanz/Xeljanz XR tablets Renewal: AS: Patient has been on therapy for at least 6 months, AND When assessed by at least one objective measure, patient had a beneficial clinical response from baseline, OR Compared with baseline patient experienced an improvement in at least one symptom AND Patient and has tried ONE TNF inhibitor for 3 months, OR Patient has been established on Xeljanz/XR for at least 90 days and prescription claims history indicates at least a 90-day supply of Xeljanz/XR was dispensed within the past 130 days if claims history is not available, according to the prescriber. JIA: Patient has been on therapy for at least 6 months, AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline, OR Compared with baseline, patient experienced an improvement in at least one symptom AND Patient has tried ONE TNF inhibitor for 3 months, OR Patient has been established on Xeljanz/XR for at least 90 days and prescription claims history indicates at least a 90-day supply of Xeljanz/XR was dispensed within the past 130 days if claims history is not available, according to the prescriber. Psoriatic Arthritis: Patient has been on therapy for at least 6 months, AND medication will be used in combination with methotrexate or another conventional synthetic DMARD, unless contraindicated AND When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline, OR Compared with baseline, patient experienced an improvement in at least one symptom AND Patient has tried ONE TNF inhibitor for 3 months, OR Patient has been established on Xeljanz/XR for at least 90 days and prescription claims history indicates at least a 90-day supply of Xeljanz/XR was dispensed within the past 130 days if claims history is not available, according to the prescriber RA: Patient has been on therapy for at least 6 months, AND Patient has been established on Xeljanz/XR for at least 90 days and prescripton claims history indicates at east a 9
Indications	All FDA-approved Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A

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