**Commercial Formulary**

# Commercial Prior Authorization

PLEASE NOTE: Preferred brand drugs may move to non-preferred status if a generic version becomes available during the year. The list may be subject to change. Not all drugs listed are covered by all prescription-drug benefit programs. For specific questions about your coverage, please call the phone number printed on your member ID card or visit elixirsolutions.com

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# ACTEMRA SC

## Products Affected

- ACTEMRA
- ACTEMRA ACTPEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid Arthritis (RA), Giant Cell Arteritis (GCA), Polyarticular Juvenile Idiopathic Arthritis (PJIA), Systemic Juvenile Idiopathic Arthritis (SJIA), Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq], PDE-4 inhibitor [e.g., Otezla) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO [PJIA]: THREE AGENTS: ADALIMUMAB (-ADAZ, HUMIRA, SIMLANDI), ENBREL, RINVOQ LQ, XELJANZ (TRIED A TNF PRIOR TO RINVOQ/XELJANZ). [SJIA]: TYENNE. [RA]: THREE AGENTS: ADALIMUMAB (-ADAZ, HUMIRA, SIMLANDI), ENBREL, RINVOQ TAB, OR XELJANZ (XR) (TRIED A TNF PRIOR TO RINVOQ/XELJANZ). [GCA]: ONE AGENT: RINVOQ, TYENNE (TRIED RINVOQ PRIOR TO TYENNE). INITIAL: (A) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (B) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Patient had a trial or contraindication to 3-months of treatment with one conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, or sulfasalazine. (C) SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS: (1) Diagnosis of SJIA. (D) GIANT CELL ARTERITIS (GCA): (1) Diagnosis of GCA AND (2) Patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone). (E) SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSC-ILD): (1) Diagnosis of SSc according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) AND (2) Patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as |

| PA Criteria | Criteria Details |
|---|---|
| | mixed connective tissue disease [MCTD]). SEE OTHER CRITERIA |
| **Age Restrictions** | [PJIA, SJIA, CRS]: 2 years of age or older. [RA, GCA, SSc-ILD]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [RA, PJIA, SJIA, SSC-ILD]: rheumatologist. [SIJA]: dermatologist, or immunologist. [SSC-ILD]: pulmonologist. [GCA]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [RA, PIJA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [SJIA]: (3a) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy OR (3b) Patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis). [SSc-ILD]: (3) Patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline. PA Automated |

# ACTHAR HP

## Products Affected

- ACTHAR
- ACTHAR GEL
- CORTROPHIN
- CORTROPHIN GEL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Infantile spasms |
| **Exclusion Criteria** | Acthar pre-filled SelfJect or Cortrophin pre-filled syringe |
| **Required Medical Information** | INITIAL: (A) INFANTILE SPASM: (1) Diagnosis of infantile spasms. |
| **Age Restrictions** | Less than 2 years of age. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | 28 days |
| **Other Criteria** | PA Automation |

# ACTIMMUNE

## Products Affected

- ACTIMMUNE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic granulomatous disease (CGD), Severe malignant osteopetrosis (SMO) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.CHRONIC GRANULOMATOUS DISEASE (CGD): INITIAL: (1) Diagnosis of CGD. B. SEVERE MALIGNANT OSTEOPETROSIS (SMO): INITIAL: (1) Diagnosis of SMO. CONTINUATION OF THERAPY: (1) Patient is stable on therapy for at least 30 days AND (2) Diagnosis of approvable indicationRENEWAL: (1) Patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections) AND (2) Patient has NOT received hematopoietic cell transplantation |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [CGD]: hematologist, infectious disease specialist, or immunologist [SMO]: endocrinologist or hematologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | N/A |

# ADALIMUMAB

## Products Affected

- ABRILADA (1 PEN)
- ABRILADA (2 PEN)
- ABRILADA (2 SYRINGE)
- *adalimumab-aacf (2 pen)*
- *adalimumab-aacf (2 syringe)*
- *adalimumab-aacf(cd/uc/hs strt)*
- *adalimumab-aacf(ps/uv starter)*
- *adalimumab-aaty (1 pen)*
- *adalimumab-aaty (2 pen)*
- *adalimumab-aaty (2 syringe)*
- *adalimumab-aaty cd/uc/hs start*
- *adalimumab-adbm (2 pen)*
- *adalimumab-adbm (2 syringe)*
- *adalimumab-fkjp (2 pen)*
- *adalimumab-fkjp (2 syringe)*
- AMJEVITA
- AMJEVITA-PED 10KG TO <15KG
- AMJEVITA-PED 15KG TO <30KG
- CYLTEZO (2 PEN)
- CYLTEZO (2 SYRINGE)
- CYLTEZO-CD/UC/HS STARTER
- CYLTEZO-PSORIASIS/UV STARTER
- HADLIMA
- HADLIMA PUSHTOUCH
- HULIO (2 PEN)
- HULIO (2 SYRINGE)
- YUFLYMA (1 PEN)
- YUFLYMA (2 PEN)
- YUFLYMA (2 SYRINGE)
- YUFLYMA-CD/UC/HS STARTER
- YUSIMRY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Crohn disease (CD), Hidradenitis suppurativa (HS), Polyarticular juvenile idiopathic arthritis (PJIA), Plaque psoriasis (PsO), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC), Intermediate, posterior, and panuveitis |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT ALL INDICATIONS: (1) Tried or contraindicated to ONE adalimumab (-adaz, Humira, Simlandi) AND [AS]: (2) TWO agents: Bimzelx, Enbrel, Rinvoq tab, Taltz, Xeljanz (XR) (Tried TNF prior to Rinvoz/Xeljanz) [PJIA]: (2) TWO agents: Enbrel, Rinvoq LQ, Xeljanz (Tried TNF prior to Rinvoq/Xeljanz) [PsA]: (2) TWO agents: Bimzelx, Enbrel, Otezla, Rinvoq tab/LQ, Skyrizi, Taltz, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek), Xeljanz (XR) (Tried TNF prior to Rinvoq/Xeljanz) [RA]: (2) TWO agents: Enbrel, Rinvoq tab, Xeljanz (XR) (Tried TNF prior to Rinvoq/Xeljanz) [HS]: (2) ONE agent: Bimzelx [PsO]: (2) TWO agents: Bimzelx, Enbrel, Otezla, Skyrizi, Sotyktu, Taltz Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) [CD]: (2) TWO agents: Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) (Tried TNF prior to Rinvoq) [UC]: (2) TWO agents: Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) (Tried TNF prior to |

| PA Criteria | Criteria Details |
|---|---|
| | Rinvoq/Xeljanz). INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to a NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (C) HIDRADENITIS SUPPURATIVA (HS): (1) Diagnosis of moderate to severe HS. (D) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (E) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to adalimumab AND (3a) A 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA for the treatment of PsO OR (3b) Contraindicated/intolerance to both immunosuppressants AND PUVA used in the treatment of PsO OR SEE OTHER CRITERIA |
| **Age Restrictions** | [CD]: 6 years of age or older. [PJIA, Uveitis]: 2 years of age or older. [HS]: 12 years of age or older. [AS, PsA, PsO, RA]: 18 years of age or older. [UC]: 5 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, PJIA, PsA, RA]: rheumatologist. [HS, PsO, PsA]: dermatologist. [UC, CD]: gastroenterologist. [UV]: ophthalmologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (3c) Switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for same indication. (F) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (G) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Tried or contraindicated to at least 3 months of treatment with ONE conventional synthetic DMARD (e.g., methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine). (H) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. (I) UVEITIS: (1) Diagnosis of non-infectious intermediate, posterior and panuveitis AND (2) Patient does NOT have isolated anterior uveitis. CONTINUING THERAPY: Treat as Initial. RENEWAL: (1) Diagnosis of approvable indication AND (2) Requested drug will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [AS]: (3) Patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy [HS]: (3) Patient has shown improvement |

| PA Criteria | Criteria Details |
| --- | --- |
| | while on therapy [PIJA, PsA, RA]: (3) Patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy [PsO]: (3) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy [Uveitis]: (3) Patient has NOT experienced treatment failure, defined as ONE of the following: (3a) Development of new inflammatory chorioretinal or retinal vascular lesions OR (3b) A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade OR (3c) A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved. No PA Auto |

# ADBRY

## Products Affected

- ADBRY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate-to-severe atopic dermatitis (AD). |
| **Exclusion Criteria** | Used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis |
| **Required Medical Information** | INITIAL: (A) ATOPIC DERMATITIS (AD): (1) Diagnosis of moderate to severe AD AND (2) Meets one of the following:(2a) Patient has AD involving at least 10% body surface area (BSA) OR (2b) Patient has AD affecting the face, head, neck hands, feet, groin, or intertriginous areas OR (2c) Patient was previously stable on another biologic (e.g., Dupixent, Rinvoq) and is switching to Adbry AND (3) Tried or contraindicated to one of the following: (3a) Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate) OR (3b) topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]) OR (3c) Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole]) OR (3d) Topical JAK inhibitor (e.g., Opzelura [ruxolitinib]) OR (3e) Phototherapy. CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Diagnosed by appropriate specialist AND (4) Adbry will NOT be used concurrently with other systemic biologics or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of atopic dermatitis. RENEWAL: (1) Diagnosis of approvable indication AND (2) Adbry will NOT be used concurrently with other systemic biologics or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of atopic dermatitis AND (3) Patient has shown improvement while on Adbry. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, dermatologist, immunologist. |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automation |

# ADDYI

## Products Affected

- ADDYI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD]). |
| **Exclusion Criteria** | Used concurrently with Vyleesi (bremelanotide). |
| **Required Medical Information** | INITIAL: (A) HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD): (1) Diagnosis of acquired, generalized HSDD (also referred to as female sexual interest/arousal disorder [FSIAD]) AND (2) Addyi (flibanserin) is a covered benefit AND (3) Patient has persistently or recurrently deficient sexual fantasies and desire for sexual activity that has persisted for at least 6 months AND (4) Patients HSDD is NOT a result of a co-existing medical or psychiatric condition, a problem within the relationship, or the effects of a medication or drug substance AND (5) Patients HSDD symptom causes marked distress or interpersonal difficulty AND (6) Patient is a female AND (7) Tried or contraindicated to bupropion.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Requested is a covered benefit AND (4) Not used concurrently with Vyleesi (bremelanotide).<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months AND (3) Patient is a female AND (4) HSDD is NOT a result of a co-existing medical or psychiatric condition, a problem within the relationship, or the effects of a medication or drug substance AND (5) HSDD symptom causes marked distress or interpersonal difficulty AND (6) Not currently using Vyleesi AND (7) Patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress). |
| **Age Restrictions** | 18 to 64 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# ADEMPAS

## Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4). |
| **Exclusion Criteria** | Used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline) |
| **Required Medical Information** | A. INITIAL: CTEPH: (1) Diagnosis of persistent/recurrent CTEPH (WHO Group 4) AND (2) Patient has NYHA-WHO Functional Class II to IV symptoms AND (3a) Patient has recurrent or persistent disease after surgical treatment OR (3b) Not a candidate for surgery OR (3c) has inoperable CTEPH. B. PAH: INITIAL: (1) Diagnosis of PAH (WHO Group 1) AND (2) PAH diagnosis confirmed by right heart catheterization with ALL of the following: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUATION OF THERAPY: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient will not use Adempas concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra, Cialis, Levitra), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline).RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient will not use Adempas concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra, Cialis, Levitra), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated |

# AFREZZA

## Products Affected

- AFREZZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diabetes mellitus, type 1 or type 2. |
| **Exclusion Criteria** | Chronic lung disease (i.e., asthma or chronic obstructive pulmonary disease), active lung cancer, currently in diabetic ketoacidosis, smokes or has quit smoking within the past 6 months. |
| **Required Medical Information** | STEP ALERT: Tried ONE preferred rapid-acting insulin: insulin lispro (Humalog), Lyumjev. INITIAL: (A) TYPE 1: (1) Diagnosis of type 1 diabetes mellitus AND (2) Patient had a baseline spirometry performed to measure FEV1 AND (3) Concurrently using a long-acting insulin (e.g. Toujeo, Tresiba, Semglee). (B) TYPE 2: Diagnosis of type 2 diabetes mellitus AND (2) Patient had a baseline spirometry performed to measure FEV1 AND (3) Prescriber has indicated that the patient is physically unable to or unwilling to administer injectable insulin.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient had a spirometry performed to measure FEV1 in the past 12 months.<br><br>RENEWAL: (1a) Diagnosis of type 1 diabetes mellitus AND currently on a long-acting insulin (e.g., Toujeo, Tresiba, Semglee) OR (1b) Diagnosis of type 2 diabetes mellitus AND (2) A follow-up spirometry to measure FEV1 performed after 6 months of treatment then annually thereafter [Note: if FEV1 not performed, allow a 1 month approval to allow for FEV1 test to be completed] AND (3) Patients FEV1 declined by 20% or more from baseline. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# AGAMREE

## Products Affected

- AGAMREE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Duchenne muscular dystrophy, Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A.DISEASE: Duchenne Muscular Dystrophy (DMD): INITIAL: (1) Prescriber attest to diagnosis of DMD confirmed with genetic testing AND (2) A trial and failure of prednisone or prednisolone for at least 6 months and meet one of the following criteria AND (2a) Request due to lack of efficacy of prednisone or prednisolone and meet all of the following criteria: Patient is not pre-symptomatic phase AND deterioration in ambulation, functional status or pulmonary function while on prednisone or prednisolone using standard measures over time (such as a 6 minute walking distance (6MQD), ascending 4 stairs, descending 4 stairs, rise from floor time, 10 meter run or walk time, North Star Ambulatory Assessment (NSAA) consistent with advancing disease (stage 2 to a higher) AND steroid myopathy has been ruled out. OR (2b) Physician attestation that patient has experienced a significant adverse effect (e.g. weight gain) on prednisone or prednisolone such that it is negatively impacting a comorbid condition. CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a neurologist specializing in treatment of DMD at a DMD treatment center. |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA AUTO |

# ALHEMO

## Products Affected

- ALHEMO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hemophilia A (congenital factor VIII deficiency), Hemophilia B (congenital factor IX deficiency) |
| **Exclusion Criteria** | Used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq]). |
| **Required Medical Information** | INITIAL: (A) HEMOPHILIA A: (1) Diagnosis of hemophilia A (congenital factor VIII deficiency) AND (2) Patients hemophilia has FVIII inhibitors AND (3) Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes. (B) HEMOPHILIA B: (1) Diagnosis of hemophilia B (congenital factor IX deficiency) AND (2) Patients hemophilia has FIX inhibitors AND (3) Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra, Hympavzi) AND [HEMOPHILIA A]: Patients hemophilia has FVIII inhibitors [HEMOPHILIA B]: Patients hemophilia has FIX inhibitors. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has shown a clinical benefit compared to baseline (3) Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra, Hympavzi) AND [HEMOPHILIA A]: (4) Patients hemophilia has FVIII inhibitors OR [HEMOPHILIA B]: (4) Patients hemophilia has FIX inhibitors. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None. |

# ALKINDI

## Products Affected

- ALKINDI SPRINKLE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Replacement therapy in pediatric patients with adrenocortical insufficiency, medically accepted indication. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADRENOCORTICAL INSUFFICIENCY: INTIIAL: (1) Prescriber attests to a documented, adrenocortical insufficiency requiring hydrocortisone treatment AND (2) Prescriber attests patient has a need for dosage strengths and titration flexibility that are not available with other available formulations of hydrocortisone. RENEWAL: (1) Prescriber attests that member cannot switch to hydrocortisone tablet to achieve desired treatment effects AND (2) Prescriber attests that patient adrenal insufficiency is being best managed by ALKINDI SPRINKLES. |
| **Age Restrictions** | Less than 18 years of age |
| **Prescriber Restrictions** | Prescribed by or in conjunction with an endocrinologist or pediatrician |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ALPHA1 PROTEINASE INHIBITORS

## Products Affected

- ARALAST NP
- GLASSIA
- PROLASTIN-C
- ZEMAIRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin [AAT] deficiency). |
| **Exclusion Criteria** | Used concurrently with another alpha-1-proteinase inhibitor (e.g., Glassia, Prolastin C, Aralast NP, Zemaira). |
| **Required Medical Information** | INITIAL: (A) ALPHA1-ANTITRYPSIN [AAT] DEFICIENCY (Alpha1-PI): (1) Diagnosis of clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI AND (2) Requested medication will be used as chronic augmentation or maintenance therapy AND (3) FEV1 less than or equal to 65 percent AND (4) Patient is not currently smoking AND (5) Patient alpha-1 antitrypsin deficiency genotype does not include a normal M gene (e.g. MZ) AND (6) Documented pre-treatment AAT levels less than or equal to 57 mg/dL or 11 micromol/L AND (7) Patient does not have an IgA deficiency.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for 90 days AND (2) Diagnosis of approvable indication AND (3) Confirmation of emphysema with established airflow obstruction AND (4) Patient is NOT currently smoking AND (5) Requested medication is not used concurrently with another alpha-1-proteinase inhibitor.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has shown clinical benefit (maintained or slowed progression of emphysema) AND (3) Patient is not currently smoking AND (4) Requested medication is not used concurrently with another alpha-1-proteinase inhibitor. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist, allergist, or immunologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# ALVAIZ

## Products Affected

- ALVAIZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Persistent or chronic immune (idiopathic) thrombocytopenia, thrombocytopenia due to chronic hepatitis C, severe aplastic anemia |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to Promacta. INITIAL: (A) IMMUNE THROMBOCYTOPENIA (ITP): (1) Diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia AND (2) Patient tried or contraindicated to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy AND (3) Alvaiz will not be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim]) AND (4) Patient has a platelet count of less than 30 x 10^9/L OR the patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event. (B) CHRONIC HEPATITIS C: (1) Diagnosis of thrombocytopenia due to chronic hepatitis C AND (2) Patients thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. (C) APLASTIC ANEMIA: (1) Diagnosis of severe aplastic anemia AND (2) Patient had an insufficient response to immunosuppressive therapy. CONTINUING THERAPY / RENEWAL: (1) Patient has been stable on therapy AND (2) Diagnosis of approvable indication AND [ITP]: (3) Alvaiz will NOT be used concurrently with other TPO-RAs AND (4) Patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events. |
| **Age Restrictions** | [ITP]: 6 years of age and older. [HEP C, ANEMIA]: 18 years of age and older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | [ITP]: Initial: 2 months, Renewal: 12 months. [OTHER]: Initial: 12 months. |
| **Other Criteria** | PA Automated. |

# ALYFTREK

## Products Affected

- ALYFTREK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic fibrosis (CF). |
| **Exclusion Criteria** | Used in combination with another CFTR modulator (e.g., products containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Required Medical Information** | A. INITIAL: CYSTIC FIBROSIS (CF): (1) Diagnosis of CF AND (2) Patient meets one of the following (2a) Patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene OR (2b) Patient has a responsive mutation in the CFTR gene.CONTINUATION OF THERAPY: Patient is stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient will not use in combination with another CFTR modulator. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in clinical status AND (3) Patient will not use in combination with another CFTR modulator. |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cystic fibrosis expert |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None. |

# AMPYRA

## Products Affected

- *dalfampridine er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Multiple sclerosis |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. FOR MULTIPLE SCLEROSIS (MS): INITIAL: (1) Patient has a diagnosis of MS AND (2) Patient has symptoms of a walking disability such as mild to moderate bilateral lower extremity weakness or unilateral weakness plus lower extremity or truncal ataxia. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced at least a 15% improvement in walking ability |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | Initial: 3 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# AMVUTTRA

## Products Affected

- AMVUTTRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN), cardiomyopathy of wild-type transthyretin-mediated amyloidosis, cardiomyopathy of hereditary transthyretin-mediated amyloidosis (ATTR-CM). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HEREDITARY TRANSTHYRETIN-MEDIATED AMLYOIDOSIS-POLYNEUROPATHY (hATTR-PN): (1) Diagnosis of hATTR-PN AND (2) Patient is ambulatory (i.e. Familial Amyloid Polyneuropathy [FAP] stage 1  2 OR Polyneuropathy Disability [PND] stage I  IIIb polyneuropathy) AND (3) Amvuttra will not be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran]) AND (4) Diagnosis is confirmed by one of the following: (4a) Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR (transthyretin) protein OR (4b) DNA genetic sequencing to confirm hATTR mutation. (B) CARDIOMYOPATHY: (1) Diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis or hereditary transthyretin-mediated amyloidosis (ATTR-CM) AND (2) Patient has New York Heart Association (NYHA) Class I, II, or III heart failure AND (3) Diagnosis is confirmed by one of the following (3a) Bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system) OR (3b) Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein. CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND [hATTR-PN]: (3) Patient has not progressed to FAP stage 3 or PND Stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden) AND (4) Amvuttra will not be used concurrently with other hATTR-PN agents. |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a [hATTR-PN]: neurologist, cardiologist, hATTR specialist, or medical geneticist. [CARDIOMYOPATHY]: cardiologist, ATTR specialist, or medical geneticist. |
| **Coverage Duration** | [hATTR-PN]: Initial: 6 months, Renewal: 12 mos; [CARDIOMYOPATHY]: Initial: 12 mos, Renewal: 12 mos. |
| **Other Criteria** | PA Automation |

# ANDEMBRY

## Products Affected

- ANDEMBRY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE). |
| **Exclusion Criteria** | Used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo]). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: Cinryze, Haegarda, Takhzyro, Orladeyo. INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Andembry will be used for prophylaxis against HAE attacks AND (3) Patient meets one of the following: (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Andembry will NOT be used concurrently with an alternative prophylactic agent for HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Andembry will NOT be used concurrently with an alternative prophylactic agent for HAE attacks AND (3) Patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline. |
| **Age Restrictions** | 12 years of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ANZUPGO

## Products Affected

- ANZUPGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe chronic hand eczema (CHE). |
| **Exclusion Criteria** | Used concurrently with ANY of the following for the treatment of atopic dermatitis: Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)], JAK inhibitors [e.g., Opzelura (ruxolitinib)], AhR agonists [e.g., Vtama (tapinarof)]) OR, systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm]), OR other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib]), OR potent immunosuppressants (e.g., azathioprine, cyclosporine). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to TWO agent: Eucrisa, Opzelura, Zoryve 0.15% cream, Vtama. INITIAL: (A) CHRONIC HAND ECZEMA (CHE): (1) Diagnosis of moderate to severe CHE AND (2) Patient has a modified Investigators Global Assessment for Chronic Hand Eczema (IGA-CHE) score of 3 or 4 AND (3) Tried or contraindicated to a topical corticosteroid of medium potency or greater (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Anzupgo will not be used concurrently with any of the following for the treatment of atopic dermatitis: Other non-steroidal topicals, systemic therapeutic biologics, potent immunosuppressants, other JAK inhibitors.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has had improvement of symptoms AND (3) Anzupgo will not be used concurrently with any of the following for the treatment of atopic dermatitis: Other non-steroidal topicals, systemic therapeutic biologics, potent immunosuppressants, other JAK inhibitors. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# APOKYN

## Products Affected

- APOKYN
- *apomorphine hcl subcutaneous*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced Parkinson disease (PD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARKINSONS DISEASE (PD): (1) Diagnosis of advanced PD AND (2) Apokyn will be used for the acute, intermittent treatment of hypomobility, OFF episodes associated with advanced PD AND (3) Prescriber has optimized drug therapy as evidenced by BOTH of the following: change in levodopa/carbidopa dosing strategy for formulation AND (4) Tried or contraindicated to TWO Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND Patient has experienced improvement with motor fluctuations during OFF episodes with the use of Apokyn (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair). |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# AQNEURSA

## Products Affected

- AQNEURSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Niemann-Pick disease type C (NPC) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL: NIEMANN-PICK DISEASE TYPE C (1) Diagnosis of Niemann-Pick disease type C (NPC).CONTINUATION OF THERAPY: (1) Patient has been on therapy for 90 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Patient has experienced improvement or a slowing of disease progression. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a geneticist or neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal:  12 months |
| **Other Criteria** | None |

# AQVESME

## Products Affected

- AQVESME

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Alpha-thalassemia or beta-thalassemia. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) THALASSEMIA: (1) Diagnosis of alpha-thalassemia or beta-thalassemia AND (2) Aqvesme will be used for the treatment of anemia.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Aqvesme will be used for the treatment of anemia. |
| **Age Restrictions** | 18 years of age and older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ARANESP

## Products Affected

- ARANESP (ALBUMIN FREE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Anemia due to chronic kidney disease, chemotherapy in patients with cancer, or hepatitis C. |
| **Exclusion Criteria** | Used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat]). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to Retacrit. INITIAL: (A) CHRONIC KIDNEY DISEASE (CKD) (1) Diagnosis of anemia associated with CKD AND (2) Hemoglobin level is less than 10g/dL. (B) CHEMOTHERAPY INDUCED ANEMIA: Diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy AND (2) Patient meets one of the following: (2a) Hemoglobin level is less than 11g/dL OR (2b) Hemoglobin level has decreased at least 2g/dL below baseline level. (C) HEPATITIS C: (1) Diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa AND (2) Hemoglobin level is less than 10g/dL AND (3) Trial of or contraindication to ribavirin dose reduction. CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication (3) Aranesp will not be used concurrently with another ESA or HIF-PHI AND (4a) [CKD Pediatric]: hemoglobin level is less than 10g/dL OR hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions OR (4b) [CKD Adult]: NOT on dialysis: hemoglobin level is less than 10g/dL OR hemoglobin level has reached 10g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions OR (4c) [CKD Adult]: ON dialysis: hemoglobin level is less than 11g/dL OR hemoglobin level has reached 11g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions. [HEP C]: (4) Hemoglobin level is between 10g/dL and 12g/dL OR [CHEMOTHERAPY]: (4) Patients a hemoglobin level is between 10g/dL and 12g/dL. |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial/Renewal: Hep C: 6 months, All other indications: 12 months. |
| **Other Criteria** | PA Automation |

# ARBLI

## Products Affected

- ARBLI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypertension, hypertension with left ventricular hypertrophy, type 2 diabetes with diabetic nephropathy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HYPERTENSION: (1) Diagnosis hypertension or hypertension with left ventricular hypertrophy AND (2) Patient has a contraindication or is unable to swallow losartan tablets. (B) TYPE 2 DIABETES: (1) Diagnosis of type 2 diabetes with diabetic nephropathy AND (2) Patient has a history of hypertension AND (3) Patient has an elevated serum creatinine level and proteinuria (urinary albumin to creattinine ratio of at least 300mg/g) AND (4) Patient has a contraindication or is unable to swallow losartan tablets. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has a contraindication or is unable to swallow losartan tablets. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ARCALYST

## Products Affected

- ARCALYST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), treatment or reduction in risk of recurrent pericarditis (RP) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication |
| **Required Medical Information** | A.CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS), FAMILIAL COLD AUTOINFLAMMATORY SYNDROME (FCAS), MUCKLE-WELLS SYNDROME (MWS): INITIAL: (1) Diagnosis of CAPS, FCAS, or MWS AND (2) Patient has genetic testing for gain-of-function mutations in the NLRP3 gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein [SAA] or S100 proteins) AND (2) Patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities. B. DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA): INITIAL: (1) Diagnosis of DIRA AND (2) Patient has genetic testing for gain-of-function mutations in the IL1RN gene OR has inflammatory markers (i.e., elevated CRP, ESR) AND (3) Patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis). C. RECURRENT PERICARDITIS (RP): INITIAL: Treatment or reduction in risk of RP AND (2) Patient had an episode of acute pericarditis AND (3) Patient has been symptom-free for an interval of 4 to 6 weeks AND (4) Patient has TWO of the following: chest pain consistent with pericarditis, pericardial friction rub, ECG showing diffuse ST-segment elevation or PR-segment depression, and new or worsening pericardial effusion AND (5) Patient had a trial of or contraindication to two NSAIDs (e.g., ibuprofen, indomethacin) AND colchicine SEE OTHER CRITERIA |
| **Age Restrictions** | CAPS, FCAS, MWS, RP: 12 years of age and older; DIRA: None. |
| **Prescriber** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUATION OF THERAPY/RENEWAL: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient will not use concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication. PA automated. |

# ARIKAYCE

## Products Affected

- ARIKAYCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Refractory Mycobacterium avium complex (MAC) lung disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. REFRACTORY MYCOBACTERIUM AVIUM COMPLEX (MAC): INITIAL: (1) Prescriber attests that patient has a documented refractory MAC lung disease AND (2) Prescriber attests that patient has been on a combination antibacterial drug regimen (i.e. macrolide, rifampin (or rifabutin), ethambutol) and did NOT achieve negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy RENEWAL: (1) Prescriber attests that patient has achieved at least one negative sputum culture AND (2) Prescriber attests that patient continues to receive appropriate monitoring (i.e. monthly sputum cultures) AND (3) Prescriber attests patient continues to receive a multi-drug regimen |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with infectious disease specialist, pulmonologist, or a prescriber specializing in HIV treatment. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ATTRUBY

## Products Affected

- ATTRUBY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cardiomyopathy of wild-type transthyretin-mediated amyloidosis or variant transthyretin-mediated amyloidosis (ATTR-CM) |
| **Exclusion Criteria** | Used concurrently with other ATTR-CM TTR (transthyretin) stabilizers (e.g., tafamidis [Vyndaqel, Vyndamax]) |
| **Required Medical Information** | INITIAL: (A) AMYLOIDOSIS: (1) Diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis or variant transthyretin-mediated amyloidosis (ATTR-CM) AND (2) Patient has New York Heart Association (NYHA) Class I, II, or III heart failure AND (3) Diagnosis is confirmed by one of the following: (3a) Bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system) OR (3b) Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein. CONTINUING THERAPY: Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Attruby will not be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers. RENEWAL: (1) Diagnosis of approvable indication AND (2) Attruby will not be used concurrently with other ATTR-CM TTR (transthyretin) stabilizers. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# AUSTEDO

## Products Affected

- AUSTEDO
- AUSTEDO XR
- AUSTEDO XR PATIENT TITRATION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chorea associated with Huntingtons Disease (Huntingtons Chorea), Tardive Dyskinesia. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHOREA ASSOCIATED WITH HUNTINGTONS DISEASE: INITIAL: (1) Prescriber attests to a diagnosis Huntingtons disease AND (2) Presence of involuntary (choreiform) movements. TARDIVE DYSKINESIA (TD): (1) Prescriber attests to a diagnosis of moderate to severe tardive dyskinesia AND (2) The patients TD has been present for at least 3 months AND (3) The patient has a prior history of using antipsychotic medications (e.g., aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if the patient is 60 years of age or older). CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, or movement disorder specialist, or psychiatrist |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# BACLOFEN

## Products Affected

- *baclofen oral suspension*
- FLEQSUVY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | None. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (1) Patient has a contraindication to is or is unable to swallow baclofen oral tablets.<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# BAXDELA

## Products Affected

- BAXDELA ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute bacterial skin or skin structure infection (ABSSSI) or community-acquired bacterial pneumonia (CABP). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PRESCRIBER ONLY: (1) Prescribed by or in consultation with an Infectious Disease (ID) specialist. OR (B) ACUTE BACTERIAL SKIN (ABSSSI): (1) Diagnosis of acute bacterial skin or skin structure infection (ABSSSI) AND (2) 18 years of age or older AND (3) Patients ABSSSI infection is caused by any of the following susceptible microorganisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, or Pseudomonas aeruginosa AND (4) Baxdela is NOT being used for an animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitus ulcer formation, myonecrosis or ecthyma gangrenosum AND (5) Patient has had an antimicrobial susceptibility test been performed AND (5a) Results from the infection site culture indicate pathogenic organism(s) with resistance to ONE standard of care agent for acute bacterial skin or skin structure infections (ABSSSI) (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin) AND (5a.i) Results from the infection site culture indicate pathogenic organism(s) with susceptibility to Baxdela OR (5b) Antimicrobial susceptibility results are unavailable AND (5b.i) Tried or contraindicated to ONE of the following agents: gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin), penicillin antibiotic (e.g., amoxicillin), fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin), cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin). SEE OTHER CRITERIA |
| **Age Restrictions** | See RMI. |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | See RMI. |
| **Coverage Duration** | Initial: 1 month |
| **Other Criteria** | PA Automated. |

# BENLYSTA

## Products Affected

- BENLYSTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Systemic lupus erythematosus, lupus nephritis (LN) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Saphnelo [anifrolumab-fnia]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE. |
| **Required Medical Information** | A. SYSTEMIC LUPUS ERYTHEMATOSUS: INITIAL: (1) Diagnosis of systemic lupus erythematosus AND (2) Patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives. B. LUPUS NEPHRITIS (LN): INITIAL: (1) Diagnosis of lupus nephritis AND (2) Patient is receiving standard therapy (e.g., steroids, antimalarials, NSAIDs, immunosuppressives). CONTINUATION OF THERAPY: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by an appropriate specialist AND (4) Benlysta will not be used concurrently with another systemic biologic (e.g., Saphnelo [anifrolumab-fnia]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLERENEWAL: [SLE]: (1) Patient has had clinical improvement while on Benlysta. [LUPUS NEPHRITIS]: Patient has had clinical improvement in renal response as compared to baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)) |
| **Age Restrictions** | [SQ PFS]: 18 years of age or older; [IV, SQ Autoinjector]: 5 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with [LN]: a rheumatologist or nephrologist. [SLE] a rheumatologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# BERINERT

## Products Affected

- BERINERT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Berinert will be used for treatment of acute attacks of hereditary angioedema AND (3) Patient meets one of the following (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Berinert will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a reduction in the severity or duration of HAE attacks AND (3) Berinert will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# BESREMI

## Products Affected

- BESREMI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of polycythemia vera in adults, Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation or suicide attempt, hepatic impairment (Child-Pugh B or C), History or presence of active serious or untreated autoimmune disease, Immunosuppressed transplant recipients |
| **Required Medical Information** | A. POLYCYTHEMIA VERA (PV): INITIAL : (1) Diagnosis of PV AND (2) Prescriber confirms patient is at high risk for PV by at least one of the following: (2a) greater than 60 years of age OR (2b) history of thrombosis OR (3) Prescriber attests patient is low risk for PV but is symptomatic and has an indication for cytoreductive therapy such as one of the following: (3a) New thrombosis or disease-related major bleeding OR (3b) Frequent phlebotomy or intolerant of phlebotomy OR (3c) Splenomegaly OR (3d) Progressive thrombocytosis and/or leukocytosis OR (3e) Disease-related symptoms (ie. pruritus, night sweats, fatigue) AND (4) Prescriber attests to documented resistance or contraindication to hydroxyurea (HU) for those with High-Risk PV OR Presence of HU side effects at any dose of HU RENEWAL: (1) Prescriber attests to stabilization or improvement in lab parameters in relation to thrombosis risk |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a hematologist or an oncologist. |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# BIMZELX

## Products Affected

- BIMZELX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (PsO), Psoriatic arthritis (PsA), Non-radiographic axial spondyloarthritis (nr-axSpA), Ankylosing spondylitis (AS), Hidradenitis Suppurativa (HS) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2) Patient is a candidate for system therapy or phototherapy AND (3a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (3b) Patient has psoriatic lesions (rashes) involving the face, hands, feet, genital area, or scalp OR (3c) Patient was previously stable on another biologic and is switching to Bimzelx AND (4) Patient meets one of the following: (4a) Patient has tried at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (4b) Contraindication or intolerance to both immunosuppressant AND PUVA [phototherapy] for the treatment of PsO OR (4c) Patient is switching from a different biologic (e.g., Humira [adalimumab], PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (B) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (C) NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA): (1) Diagnosis of nr-axSpA AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, naproxen, meloxicam) AND (3) One of the following objective signs of inflammation (3a) C-reactive protein (CRP) levels above the upper limit of normal OR (3b) Sacroiliitis on magnetic resonance imaging (MRI) OR (3c) Patient was previously stable on another biologic and is switching to Bimzelx. (D) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, naproxen, meloxicam). (E) HIDRADENITIS SUPPURATIVA (HS): (1) Diagnosis of moderate to severe HS. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber** | Prescribed by or in consultation with a [PsO, HS]: dermatologist. [PsA]: |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | dermatologist or rheumatologist. [nr-axSpA, AS]: rheumatologist. |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Bimzelx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Bimzelx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [PsO]: (3) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. [PsA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [nr-axSpA, AS]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. [HS]: (3) Patient has shown improvement in HS symptoms. PA Automated. |

# BLUJEPA

## Products Affected

- BLUJEPA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Uncomplicated urinary tract infection (uUTI), uncomplicated urogenital gonorrhea. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) URINARY TRACT INFECTION (uUTI): (1) Diagnosis of uncomplicated uUTI AND (2) Patient is female AND (3) Patients infection is caused by susceptible Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis AND (4) Meets one of the following: (4a) Prescribed by or in consultation with an infectious disease (ID) specialist OR (4b) Patient has a documented culture demonstrating uUTI is caused by a bacteria with sensitivity to gepotidacin AND resistance or contraindication to all alternatives (e.g. Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g., ciprofloxacin]). (B) UROGENITAL GONORRHEA: (1) Diagnosis of uncomplicated urogenital gonorrhea AND (2) Patients infection has limited or no alternative treatment options AND (3) Patients infection is caused by a susceptible strain of Neisseria gonorrhoeae AND (4) Tried or contraindicated to the clinical standard of care agent: ceftriaxone.<br><br>CONTINUING THERAPY: [UROGENITAL GONORRHEA]: Treat as Initial. (1) Diagnosis of approvable indication AND (2) Request is for continuation of Blujepa therapy from an inpatient setting (3) Patient is female AND (4) Patient is 12 years of age or older AND (5) Patients infection is caused by susceptible Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis. |
| **Age Restrictions** | 12 years of age and older. |
| **Prescriber Restrictions** | See RMI. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 1 week |
| **Other Criteria** | PA Automated. |

# BOTOX

## Products Affected

- BOTOX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic migraines, overactive bladder (OAB), urinary incontinence, neurogenic detrusor overactivity (NDO), spasticity, cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles), severe axillary hyperhidrosis, blepharospasm, strabismus. |
| **Exclusion Criteria** | Request is for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines). |
| **Required Medical Information** | STEP ALERT: [CERVICAL DYSTONIA]: Tried or contraindicated to TWO preferred agents: Dysport, Myobloc, Xeomin. INITIAL: (A) CHRONIC MIGRAINES: (1) Diagnosis of chronic migraines (15 or more headache days per month, lasting 4 hours a day or longer) AND (2) Botox is prescribed for the prophylaxis of headaches AND (3) Patient is 18 years of age or older AND (4) Tried TWO of the following prophylactic migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, metoprolol. (B) OVERACTIVE BLADDER (OAB): (1) Diagnosis of OAB AND (2) Patient is 18 years of age or older AND (3) Tried or contraindicated to an anticholinergic medication (e.g., oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura). (C) URINARY INCONTINENCE: (1) Diagnosis of urinary incontinence AND (2) Patient has detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury [SCI], multiple sclerosis [MS]) AND (3) Patient is 18 years of age or older AND (4) Tried or contraindicated to an anticholinergic medication (e.g., oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura). (D) NEUROGENIC DETRUSOR OVERACTIVITY (NDO): (1) Diagnosis of NDO AND (2) Patient is 5 years of age or older AND (3) An inadequate response or is intolerant of anticholinergic medication (e.g., oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura). (E) SPASTICITY: (1) Diagnosis of spasticity AND (2) Patient is 2 years of age or older. (F) CERVICAL DYSTONIA: (1) Diagnosis of cervical dystonia AND (2) Patient is 18 years of age or older. (G) AXILLARY HYPERHIDROSIS: (1) Diagnosis of severe axillary hyperhidrosis AND (2) Patient is 18 years of age or older. (H) BLEPHAROSPASM: (1) Diagnosis of blepharospasm AND (2) Patient is 12 years of age or older. (J) STRABISMUS: (1) Diagnosis of strabismus AND (2) Patient is 12 |

| PA Criteria | Criteria Details |
|---|---|
| | years of age or older. |
| **Age Restrictions** | See RMI. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication.<br>RENEWAL: [All indications but migraines]: Treat as Initial. (1) Diagnosis of chronic migraines AND (2) Request is not for a cosmetic indication AND (3) Patient has experienced a reduction in one of the following (3a) Migraine or headache frequency of at least 2 days per month, (3b) Migraine severity, or (3c) Migraine duration. PA Automated. |

# BREAST CANCER PST

## Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced or metastatic breast cancer, medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Request is for experimental or investigational use, Member is enrolled in a clinical trial. |
| **Required Medical Information** | STEP ALERT (NEW STARTS ONLY): TRIED, FAILED OR CONTRAINDICATED TO KISQALI, KISQALI FEMARA OR VERZENIO PRIOR TO SECONDARY AGENT: IBRANCE A. FOR ALL INDICATIONS: INITIAL: (1) Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1, 2a, 2b only) and Clinical Pharmacology (strong recommendation) AND (2) Documentation of dose and dates of all previous therapies and the resulting outcomes AND (3) Documentation that the proper succession of the therapies have been tried and failed (i.e. intolerance, contraindication, or progression) AND (4) Chart notes detailing the members current clinical status AND (5) Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment AND NOTE: For stage four advanced metastatic cancer, members are not required to step through other treatment options prior to requested therapy RENEWAL: (1) Current chart notes detailing response and adherence to therapy AND (2) Documented clinically significant improvements in the disease state and stability on the medication. |
| **Age Restrictions** | As noted in the package insert and approved compendia |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, an oncologist, hematologist, or other specialist treating cancer. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# BRINSUPRI

## Products Affected

- BRINSUPRI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-cystic fibrosis bronchiectasis (NCFB). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) NON-CYSTIC FIBROSIS BRONCHIECTASIS (NCFB): (1) Diagnosis of NCFB. CONTINUING THERAPY: Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# BRIXADI

## Products Affected

- BRIXADI
- BRIXADI (WEEKLY)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Opioid use disorder. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) OPIOID USE DISORDER: Diagnosis of moderate to severe opioid use disorder AND (2a) Patient initiated treatment with a single dose of a transmucosal buprenorphine product (e.g., Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]) OR (2b) Patient is already being treated with buprenorphine. CONTINUING THERAPY / RENEWAL: Treat as initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# BRONCHITOL

## Products Affected

- BRONCHITOL
- BRONCHITOL TOLERANCE TEST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis, medically accepted indication. |
| **Exclusion Criteria** | Failure to pass the Bronchitol Tolerance Test |
| **Required Medical Information** | A. CYSTIC FIBROSIS, INITIAL: (1) Prescriber attests to a diagnosis of cystic fibrosis with pulmonary symptoms requiring airway clearance AND (2) Prescriber attests that patients airway clearance is not being adequately managed by dornase alfa and/or hypertonic saline alone or the patient has a contraindication to dornase alfa and/or hypertonic saline AND (3) Prescriber attests that the patient has an oral short-acting bronchodilator on hand to be used prior to administration of BRONCHITOL CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | Elixir Quantity Limit Applies. PA Automated |

# BYLVAY

## Products Affected

- BYLVAY
- BYLVAY (PELLETS)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cholestatic pruritus associated with Alagille syndrome (ALGS), Cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC). |
| **Exclusion Criteria** | Used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat]). |
| **Required Medical Information** | INITIAL: (A) PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS (PFIC) (1) Diagnosis of cholestatic pruritus associated with PFIC AND (2) If patient is 12 months of age or older, patient has tried or contraindicated to Livmarli (maralixibat). (B) ALAGILLE SYNDROME (ALGS) (1) Diagnosis of cholestatic pruritus associated with ALGS AND (2) Patient has tried or contraindicated to Livmarli (maralixibat). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Bylvay will NOT be used concurrently with another IBAT inhibitor. RENEWAL: (1) Diagnosis of approvable indication AND (2) Bylvay will not be used with another IBAT inhibitor AND (3) Patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline AND [PFIC]: (4) Patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) protein. |
| **Age Restrictions** | [PFIC]: 3 years of age and older. [ALGS]: 12 months of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in [PFIC]: PFIC cholestasis. [ALGS]: ALGS cholestasis. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# BYNFEZIA

## Products Affected

- BYNFEZIA PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly, metastatic carcinoid tumor, vasoactive intestinal peptide tumor (VIPoma). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE generic octreotide product (e.g., octreotide acetate). INITIAL: (A) ACROMEGALY: (1) Diagnosis of acromegaly AND (2) Patient had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. (B) CARCINOID TUMOR: (1) Diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumor. (C) VASOACTIVE INTESTINAL PEPTIDE TUMOR (VIPoma): Diagnosis of profuse watery diarrhea associated with VIPoma.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND [Acromegaly]: Patient has a reduction, normalization or maintenance of IGF-1 levels based on age and gender AND (3) Patient has shown improvement or sustained remission of clinical symptoms of acromegaly. [Carcinoid, VIPomas]: (2) Patient has improvement or sustained remission of clinical symptoms. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an [Acromegaly]: endocrinologist. [Carcinoid, VIPoma]: None. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# CABLIVI

## Products Affected

- CABLIVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acquired thrombotic thrombocytopenic purpura. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) ACQUIRED THROMBOTIC THROMBOCYTOPENIC PURPURA (aTTP): (1) Diagnosis of aTTP AND (2) Patient has not experienced more than 2 recurrences of aTTP (i.e., new drop in platelet (type of blood cell) count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (PEX) and up to 28 days of extended therapy AND (3) One of the following: (3a) Request for continuation of Cablivi therapy from an inpatient (hospital) setting AND (3a.i) Cablivi was previously initiated as part of an FDA-approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within the inpatient setting OR (3b) Request for continuation of Cablivi therapy after initial 30-day treatment course (e.g., with no break in therapy) AND (3b.i) Patient is receiving immunosuppressive therapy (treatment that weakens the immune system) AND (3b.ii) Patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [also known as von Willebrand factor-cleaving protease (VWFCP)] activity level remains present). |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | Initial: 1 month |
| **Other Criteria** | PA Automated |

# CAMZYOS

## Products Affected

- CAMZYOS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Obstructive hypertrophic cardiomyopathy (HCM). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) OBSTRUCTIVE HYPERTROPHIC CARDIOMYOPATHY (HCM): (1) Diagnosis of symptomatic obstructive HCM AND (2) Patient has New York Heart Association (NYHA) functional class II or III AND (2) Patient has a peak left ventricular outflow tract (LVOT) gradient of at least 50 mmHG at rest or with provocation AND (3) Tried or contraindicated to beta-blockers (e.g., metoprolol, carvediolol) AND non-dihydropyridine calcium channel blockers (e.g., verapamil, diltiazem). CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has experienced continued clinical benefit (e.g., reduction of symptoms, NYHA classification improvement). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# CARBAGLU

## Products Affected

- CARBAGLU
- *carglumic acid*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hyperammonemia, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. HYPERAMMONEMIA: INITIAL: (1a) Prescriber attests to an indication of adjunctive treatment for acute hyperammonemia due to hepatic enzyme N-acetylglutamate synthase deficiency OR (1b) Prescriber attests to an indication for maintenance therapy of chronic hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) OR (1c) Prescriber attests to adjunctive therapy to standard of care for treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemica (MMA) AND (2) Prescriber attests to an elevation of ammonia in plasma AND (3) Member must be utilizing a protein restricted diet. RENEWAL: (1) Patient continues to meet initial criteria AND (2) Prescriber attests to continued monitoring of plasma ammonia levels |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician specializing in metabolic disorders or genetics |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# CAYSTON

## Products Affected

- CAYSTON

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Patients colonized with Burkholderia cepacia |
| **Required Medical Information** | A. CYSTIC FIBROSIS: INITIAL: (1) Prescriber attests a diagnosis of Cystic Fibrosis AND (2) Prescriber attests to colonization of Pseudomonas aeruginosa in the lungs AND (3) Prescriber attests to a FEV1 greater than 25% or less than 75% predicted CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist |
| **Age Restrictions** | 7 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or infectious disease specialist |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | Elixir Quantity Limit Applies. PA Automated |

# CD20 AGENTS FOR MULTIPLE SCLEROSIS (IV)

## Products Affected

- BRIUMVI
- OCREVUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, [Ocrevus only]: Primary progressive multiple sclerosis (PPMS). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) RELAPSING FORM OF MULTIPLE SCLEROSIS (MS) [BRIUMVI AND OCREVUS]: (1) Diagnosis of relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease AND (2) Tried or contraindicated to Kesimpta. (B) PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS (PPMS) [OCREVUS]: (1) Diagnosis of PPMS.<br>CONTINUING THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been on therapy for at least 30 days. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# CHENODIOL

## Products Affected

- CTEXLI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cerebrotendinous xanthomatosis (CTX), radiolucent gallstone(s). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) CEREBROTENDINOUS XANTHOMATOSIS (CTX): (1) Diagnosis of CTX. (B) RADIOLUCENT GALLSTONE: (1) Diagnosis of radiolucent gallstone(s) AND (2) Request is for Chenodal AND (3) Patient has tried or contraindicated to ursodiol AND (4) Patient has NOT previously received a total duration of chenodiol therapy exceeding 24 months. CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND [CTX]: (3) Patient has experienced improvement as defined by ONE of the following (3a) Patient has normalization of elevated serum or urine bile alcohols (3b) Patient has normalization of elevated serum cholestanol levels (3c) Patient has shown improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs). [GALLSTONE]: (3) Request is for Chenodal AND (4) Patient has NOT previously received a total duration of chenodiol therapy exceeding 24 months AND (4) Patient has NOT experienced complete or zero gallstone dissolution, as seen on imaging (e.g., oral cholecystogram, ultrasonogram) after 12 months of therapy AND (5) Patient has experienced partial gallstone dissolution, as seen on imaging (e.g., oral cholecystogram, ultrasonogram) after 12 months of therapy. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months. [GALLSTONE]: Lifetime total: 24 months |
| **Other Criteria** | PA Automation |

# CHOLBAM

## Products Affected

- CHOLBAM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Bile acid synthesis disorder, peroxisomal disorder (Zellweger spectrum disorder). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) BILE ACID SYNTHESIS, PERIXISOMAL DISORDER: (1) Diagnosis of bile acid synthesis disorder or peroxisomal disorder (Zellweger spectrum disorder) AND (2) Patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in liver function as defined by one of the following: (2a) Patients ALT (alanine aminotransferase) or AST (aspartate transaminase) values have been reduced to less than 50 U/L or the patients baseline levels have been reduced by 80% (2b) Patients total bilirubin values have been reduced to less than 1 mg/dL (2c) There is no evidence of cholestasis on liver biopsy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or hepatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# CIALIS

## Products Affected

- CIALIS TABLET 5 MG ORAL
- *tadalafil tablet 2.5 mg oral*
- *tadalafil tablet 5 mg oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Benign prostatic hyperplasia (BPH), erectile dysfunction. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) BENIGN PROSTATIC HYPERPLASIA (BPH): (1) Diagnosis of BPH AND (2) Tried or contraindicated to ONE preferred formulary 5-alpha-reductase inhibitor (e.g., finasteride, dutasteride) AND (3) Tried or contraindicated to ONE preferred formulary alpha blocker (e.g., doxazosin, terazosin, tamsulosin, alfuzosin). (B) ERECTILE DYSFUNCTION: (1) Diagnosis of erectile dysfunction AND (2) Erectile dysfunction is a covered benefit.<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# CIBINQO

## Products Affected

- CIBINQO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe atopic dermatitis |
| **Exclusion Criteria** | Used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO THREE AGENTS: ADBRY, EBGLYSS, DUPIXENT, AND RINVOQ INITIAL: (A) ATOPIC DERMATITIS (AD): (1) Diagnosis of moderate to AD AND (2) Patient has at least TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living AND (3a) Patient has AD involving at least 10% body surface area (BSA) OR (3b) Patient has AD affecting the face, head, neck hands, feet, groin, or intertriginous areas. CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Cibinqo will NOT be used concurrently with other systemic biologics or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of atopic dermatitis.RENEWAL: (1) Diagnosis of approvable indication AND (2) Cibinqo will NOT be used concurrently with other systemic biologics or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of atopic dermatitis AND (3) Patient has shown improvement while on Cibinqo. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist/immunologist or dermatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# CIMZIA

## Products Affected

- CIMZIA
- CIMZIA (1 SYRINGE)
- CIMZIA (2 SYRINGE)
- CIMZIA-STARTER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), Crohns disease (CD), Polyarticular juvenile idiopathic arthritis (pJIA), Plaque Psoriasis (PsO), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Patient is pregnant, breastfeeding, or trying to become pregnant OR Tried or contraindicated to [AS]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Rinvoq, Taltz, Xeljanz (Tried a TNF prior to Rinvoq/Xeljanz). [PsA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Rinvoq, Skyrizi, Taltz, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek), Xeljanz (Tried a TNF prior to Rinvoq/Xeljanz). [PJIA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Enbrel, Rinvoq, Xeljanz (Tried a TNF prior to Rinvoq/Xeljanz). [PsO]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, , Enbrel, Otezla, Skyrizi, Sotyktu, Taltz, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek). [RA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Enbrel, Rinvoq, Xeljanz (Tried a TNF prior to Rinvoq/Xeljanz). [CD]: ONE agent: adalimumab-adaz, Humira, Omvoh, Rinvoq, Simlandi, Skyrizi, Tremfya, Stegeyma, ustekinumab-aekn, Yesintek (Tried a TNF prior to Rinvoq). INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Patient has tried or contraindicated to an NSAID (e.g., ibuprofen, meloxicam, naproxen) (B) NON-RADIOGRAPHIC AXIAL SpA (nr-axSpA): (1) Diagnosis of nr-axSpA AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, meloxicam, naproxen AND (3) Patient meets one of the following: (3a) C-reactive protein (CRP) levels above upper limit of normal OR (2b) Confirmation of sacroiliitis on MRI OR (3c) Previously stable on another biologic and is switching to Cimzia. (C) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [RA, PsA, AS, nr-axSpA]: rheumatologist. [PsO, PsA]: dermatologist. [CD]: gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (D) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Psoriasis covering 3 percent or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (3b) Patient has a contraindication or intolerance to both immunosuppressants AND PUVA used in the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira), PDE-4 inhibitor (e.g., Otezla), or JAK inhibitor for the same indication (E) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (F) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Tried or contraindicated to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug) such as: methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine AND (3) Patient meets STEP requirements OR (3a) Patient has tried a TNF inhibitor AND the physician has indicated the patient cannot use a JAK inhibitor due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events. (G) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Cimzia will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Cimzia will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication AND [AS, nr-axSpA]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. [PsO]: (3) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. [PJIA, PsA, RA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. PA Auto |

# CINQAIR

## Products Affected

- CINQAIR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe eosinophilic asthma |
| **Exclusion Criteria** | Cinqair will be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma |
| **Required Medical Information** | FORMULARY ALERT: TRIED, FAILED OR INTOLERANT TO PRIMARY TREATMENT DUPIXENT, FASENRA, NUCALA OR TEZSPIRE PRIOR TO SECONDARY TREATMENT CINQAIR. ASTHMA: INITIAL: (1) Diagnosis of severe asthma AND (2) Blood eosinophilic level of 150 cells/microliter within the past 12 months AND (3) Cinqair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (beclomethasone, budesonide, mometasone) AND at least ONE other maintenance medication (long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline) AND (4) Patient meets one of the following: (4a) Patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR (4b) Patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months OR (4c) Patient have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week, any activity limitation due to asthma. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an allergist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has an approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Patient must not be taking with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma AND (5) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid). RENEWAL: (1) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid) AND (2) Patient must not be taking with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma AND (3) Patient has shown a clinical response as evidenced by ONE of the following: (3a) Reduction in asthma exacerbations from baseline OR (3b) Decreased utilization of rescue medications (e.g., albuterol OR (3c) Increase in percent predicted FEV1 from pre-treatment baseline OR (3d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing). PA Automated |

# CINRYZE

## Products Affected

- CINRYZE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnoses of HAE AND (2) Cinryze will be used for prophylaxis against HAE attacks AND (3) Patient meets one of the following (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE attacks AND (3) Patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline. |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# CONJUPRI

## Products Affected

- CONJUPRI
- *levamlodipine maleate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypertension. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HYPERTENSION: (1) Diagnosis of hypertension AND (2) Tried or contraindicated to TWO generic dihydropyridine calcium channel blockers (e.g., amlodipine, felodipine, nicardipine) AND (3) Tried or contraindicated to TWO other antihypertensive agents in another class (e.g., hydrochlorothiazide, lisinopril, losartan).<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | 6 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# CONTINUOUS GLUCOSE MONITORS

## Products Affected

- EVERSENSE 365 SENSOR/HOLDER
- EVERSENSE 365 SMART TRANSMIT
- EVERSENSE SENSOR/HOLDER
- EVERSENSE SMART TRANSMITTER
- GUARDIAN 4 GLUCOSE SENSOR
- GUARDIAN 4 TRANSMITTER
- GUARDIAN LINK 3 TRANSMITTER
- GUARDIAN SENSOR (3)
- *guardian sensor 3*
- SIMPLERA SENSOR
- SIMPLERA SYNC SENSOR
- SIMPLERA SYSTEM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Blood glucose monitoring |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) BLOOD GLUCOSE MONITORING: (1) Patient has a diagnosis of type 1, type 2, or gestational diabetes AND (2) Patient meets one of the following (2a) Patient is being treated with insulin (e.g., Humalog [insulin lispro], Lantus [insulin glargine]) OR (2b) Patient has a clinical need that cannot be managed with self-monitoring of blood glucose (SMBG) (e.g., frequent hypoglycemia, hypoglycemic unawareness, unable to achieve control of diabetes) AND (3) Patient meets one of the following: (3a) Tried or contraindicated to Dexcom G6 or G7 OR (3b) Tried or contraindicated to Freestyle Libre OR (4c) Dexcom G6, G7, and Freestyle Libre are not compatible with the patient's current insulin pump. CONTINUING THERAPY: (1) Patient is currently stable on the requested agent while covered by their current or previous health plan AND (2) Diagnosis of approvable indication. RENEWAL: (1) Patient continues to require continuous glucose monitoring. |
| **Age Restrictions** | [Dexcom G4 or G5]: 2 years of age and older. [Guardian Connect]: age 14 to 75. [Guardian 3 or 4, Simplera, Simplera Sync]: 7 years of age and older. [Eversense, Eversense E3 Smart Transmitter]: 18 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# COSENTYX

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Plaque psoriasis (PsO), Psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA), Enthesitis-Related Arthritis, Hidradenitis Suppurativa (HS) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [AS]: THREE agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Rinvoq, Taltz, Xeljanz (Tried TNF prior to Rinvoq/Xeljanz). [HS]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx. [nr-axSpA]: TWO agents: Bimzelx, Cimzia, Rinvoq, Taltz (Tried TNF prior to Rinvoq). [PsO]: FOUR agents: adalimumab (-adaz, Humira, Simlandi) Bimzelx, Enbrel, Otezla, Skyrizi, Sotyktu, Taltz, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek). [PsA]: THREE agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Rinvoq, Skyrizi, Taltz, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek), Xeljanz (Tried TNF prior to Rinvoq/Xeljanz). INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (3) Patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA): (1) Diagnosis of nr-axSpA AND (2) Patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, meloxicam, naproxen AND (3) Patient has ONE of the following objective signs of inflammation (3a) C-reactive protein (CRP) levels above upper limit of normal OR (3b) Sacroiliitis on magnetic resonance imaging (MRI). (C) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patient has psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (3b) Contraindication or intolerance to both immunosuppressants AND PUVA for the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira |

| PA Criteria | Criteria Details |
|---|---|
| | [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (D) PSORATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. SEE OTHER CRITERIA |
| **Age Restrictions** | [AS, HS, nr-axSpA]: 18 years of age or older, [ERA]: 4 years of or older, [PsO]: 6 years of age or older, [PsA]: 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, ERA, nr-axSpA, PsA]: rheumatologist. [HS, PsO, PsA]: dermatologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (E) ENTHESITIS-RELATED ARTHRITIS (ERA): (1) Diagnosis of ERA AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, meloxicam, naproxen), methotrexate, or sulfasalazine. (F) HIDRADENITIS SUPPURATIVA (HS): (1) Diagnosis of moderate to severe HS AND (2) Tried or contraindicated to ONE topical therapy (e.g., clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (e.g., tetracycline, dapsone). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication AND (5) Meets step alert.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication AND (3) Meets step alert AND [AS, nr-axSpA]: (4) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. [HS]: (4) Patient has shown improvement on therapy. [PsA] (4) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [PsO]: (4) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. [ERA]: (4) Patient has experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion. PA Automated. |

# CRENESSITY

## Products Affected

- CRENESSITY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Classic congenital adrenal hyperplasia (CAH). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) CONGENITAL ADRENAL HYPERPLASIA (CAH): (1) Diagnosis of classic CAH AND (2) Will be used as adjunctive treatment with glucocorticoid replacement therapy AND (2) For Crenessity solution: patient is unable to swallow Crenessity capsules.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Will be used as adjunctive treatment with glucocorticoid replacement therapy.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced clinical benefit (e.g., decreased androstenedione levels, reduction in glucocorticoid daily dose from baseline, improvement or stabilization in CAH symptoms). |
| **Age Restrictions** | 4 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# CRYSVITA

## Products Affected

- CRYSVITA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | X-linked Hypophosphatemia, tumor induced osteomalacia, medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Use with oral phosphate and active vitamin D analogs, patients with severe renal impairment or end stage renal disease. |
| **Required Medical Information** | A. X-LINKED HYPOPHOSPHATEMIA (XLH): INITIAL: (1) Diagnosis of X-linked hypophosphatemia that has been confirmed by one of the following: genetic testing or elevated serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL. AND (2) Serum phosphorus is below the normal range for age (reference ranges provided) B. TUMOR-INDUCED OSTEOMALACIA (TIO): INITIAL: (1) Diagnosis of TIO confirmed with elevated serum FGF23 level greater than 30 pg/mL AND (2) Confirmation TIO cannot be cured with surgical removal AND (3) Serum phosphorus is below the normal range for age CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Prescribed by or in consultation with an endocrinologist, nephrologist, oncologist, or specialist experienced in the treatment of metabolic bone disorders |
| **Age Restrictions** | XLH: 6 months of age or older, TIO: 2 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, nephrologist , oncologist, or specialist experienced in the treatment of metabolic bone disorders |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# CUPRIMINE_DEPEN

## Products Affected

- CUPRIMINE
- DEPEN TITRATABS
- *penicillamine oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Wilson's disease, Cystinuria, Rheumatoid arthritis, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Women who are pregnant or breastfeeding (except Wilsons Disease), patients with a history of penicillamine-related aplastic anemia or agranulocytosis should not be restarted on penicillamine, penicillamine should not be administered to patients with a history or other evidence of renal insufficiency, juvenile rheumatoid arthritis |
| **Required Medical Information** | A. WILSONS DISEASE: INITIAL: (1) Prescriber attests to a documented diagnosis of Wilsons disease confirmed by: genetic testing OR the presence of the following diagnostic features: a) If presence of Kayser-Fleisher rings, serum ceruloplasmin (CPN) less than 20 mg /dL AND 24 hour urine copper greater than 40 mcg b) If no presence of Kayser-Fleisher rings, serum ceruloplasmin (CPN) less than 20 mg/dL AND 24 hour urine copper greater than 100 mcg OR Liver biopsy with copper dry weight greater than 250 mcg/g AND (2) Prescriber attests that patient must adhere to a low copper diet B. CYSTINURIA: INITIAL: (1) Prescriber attests to a documented diagnosis of Cystinuria AND (2) Must have failed to respond or have a contraindication to urinary alkalization therapy with potassium citrate or potassium bicarbonate in the last 180 days. C. RHEUMATOID ARTHRITIS: (1) Prescriber attests to a documented diagnosis of rheumatoid arthritis AND (2) Must have tried and failed, have an intolerance, or a contraindication to at least TWO of the following DMARDs: Hydroxychloroquine, Leflunomide, Methotrexate, Sulfasalazine AND (3) Prior trial and failure of TWO of the following treatment regimens defined by no improvement in disease activity in 3 months OR low disease activity not reached by 6 months: TNF inhibitor (i.e. Humira, Cimzia, Enbrel, Simponi, Remicade) with or without MTX OR Non-TNF biologic (i.e. Orencia, Rituxan, Actemra) with or without MTX OR Xeljanz/XR (tofacitinib) with or without MTX RENEWAL FOR ALL INDICATIONS: (1) Patient continues to meet initial criteria AND (2) Prescriber attests that the patients condition has stabilized or improved during therapy. |
| **Age Restrictions** | Wilsons Disease - none, Cystinuria - 1 year of age or older. Rheumatoid Arthritis - 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Rheumatoid Arthritis -Prescribed by, or in conjunction with, a rheumatologist. Wilsons Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant prescriber. CYSTINURIA: Prescribed by or in consultation with a physician specializing in metabolic disorders or genetics |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# CYSTADANE

## Products Affected

- *betaine*
- CYSTADANE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Homocystinuria including cystathionine beta-synthase [CBS] deficiency, 5,10-methylenetetrahydrofolate reductase [MTHFR] deficiency, cobalamin cofactor metabolism [cbl] defect). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HOMOCYSTINURIA: (1) Diagnosis of homocystinuria (including cystathionine beta-synthase [CBS] deficiency, 5,10-methylenetetrahydrofolate reductase [MTHFR] deficiency, cobalamin cofactor metabolism [cbl] defect).<br><br>CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# DARAPRIM

## Products Affected

- DARAPRIM
- *pyrimethamine oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Toxoplasmosis, Isosporiasis, Pneumocystis pneumonia prophylaxis. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Pneumocystis pneumonia treatment. Use of drug in patients with documented megaloblastic anemia due to folate deficiency. |
| **Required Medical Information** | A. TOXOPLASMOSIS - PRIMARY PROPHYLAXIS, INITIAL (1) Prescriber attests to patient being Toxoplasma-seropositive (IgG labs must be submitted) AND (2) Prescriber attests that CD4 count less than 100 cells/mm3 AND (3) Prescriber attest that patient has had must have trial, failure, or contraindication to TMP-SMX AND (4) Prescriber has informed patient importance of, and will monitor, adherence to antiretroviral therapy. RENEWAL: (1) Prescriber attests that indications for discontinuation of prophylaxis have been evaluated, including: a. CD4 count greater than 200 cells/mm3 for at least 3 months. B. TOXOPLASMOSIS ACUTE TREATMENT: (1) Prescriber attests to patient being Toxoplasma-seropositive (IgG labs must be submitted) AND (2) Will not be used as monotherapy. C. TOXOPLASMOSIS SECONDARY PROPHYLAXIS (maintenance treatment), INITIAL: (1) Must have completed initial treatment regimen AND (2) Prescriber attests that CD4 count less than 200 cells/mm3 AND (3) Prescriber has informed patient importance of, and will monitor, adherence to antiretroviral therapy RENEWAL: (1) Prescriber attests that indications for discontinuation of prophylaxis have been evaluated, including: Remain asymptomatic and CD4 count greater than 200 cells/mm3 for at least 3 months. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Primary prophylaxis : 6 months, Treatment and secondary prophylaxis : 12 months |
| **Other Criteria** | No PA Automation |

# DAWNZERA

## Products Affected

- DAWNZERA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE). |
| **Exclusion Criteria** | Used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii]). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: Cinryze, Haegarda, Takhzyro, Orladeyo. INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Dawnzera will be used for prophylaxis against HAE attacks AND (3) Patient meets one of the following (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Dawnzera will NOT be used concurrently with an alternative prophylactic agent for HAE. RENEWAL: (1) Diagnosis of approvable indication AND (2) Dawnzera will NOT be used concurrently with an alternative prophylactic agent for HAE AND (3) Patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline. |
| **Age Restrictions** | 12 years of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# DAXXIFY

## Products Affected

- DAXXIFY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles). |
| **Exclusion Criteria** | Request is for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to TWO of the following preferred agents: Dysport, Myobloc, Xeomin. INITIAL: (A) CERVICAL DYSTONIA: (1) Diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# DAYBUE

## Products Affected

- DAYBUE
- DAYBUE STIX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rett Syndrome |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) RETT SYNDROME: (1) Diagnosis of Rett Syndrome.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# DEMSER

## Products Affected

- *metyrosine*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pheochromocytoma. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PHEOCHROMOCYTOMA: (1) Diagnosis of pheochromocytoma AND (2) Requested medication will be used for one of the following: (2a) Preoperative preparation for surgery OR (2b) Management of malignant pheochromocytoma when surgery is contraindicated OR (2c) Chronic treatment of patients with malignant pheochromocytoma AND (3) Patient has a non-metastatic pheochromocytoma AND (4) IF patient is awaiting surgery, requested medication will be used in combination with an alpha-adrenergic receptor blocker (e.g., doxazosin, terazosin, prazosin, phenoxybenzamine). CONTINUING THERAPY / RENEWAL: [Prior to surgery]: Treat as Initial. [Non-surgical]: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Requested medication will be used for one of the following: (3a) Management of malignant pheochromocytoma when surgery is contraindicated OR (3b) Chronic treatment of patients with malignant pheochromocytoma AND (4) Patient is stable or has shown clinical improvement while on therapy. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, endocrine surgeon, or hematologist-oncologist. |
| **Coverage Duration** | [PRIOR TO SURGERY]: 1 month, [NON-SURGICAL]: Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# DIACOMIT

## Products Affected

- DIACOMIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Seizures associated with Dravet syndrome. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) DRAVET SYNDROME: (1) Diagnosis of seizures associated with Dravet syndrome AND (2) Patient is currently being treated with clobazam AND (3) Tried or contraindicated to valproic acid or derivatives. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient is currently being treated with clobazam. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient is currently being treated with clobazam. |
| **Age Restrictions** | 6 months of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# DIBENZYLINE

## Products Affected

- *phenoxybenzamine hcl oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pheochromocytoma |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PHEOCHROMOCYTOMA: (1) Diagnosis of pheochromocytoma AND (2) Requested medication is used prior to pheochromocytoma resection/removal AND (3) Patient has tried or contraindicated to an alpha-1 selective adrenergic receptor blocker (e.g., doxazosin, terazosin, or prazosin). CONTINUING THERAPY / RENWAL: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, endocrine surgeon, or hematologist-oncologist. |
| **Coverage Duration** | PRIOR TO SURGERY: 1 month |
| **Other Criteria** | PA Automation |

# DICLOFENAC 3%

## Products Affected

- *diclofenac sodium gel 3 % external*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Actinic keratosis, medically accepted indication will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACTINIIC OR SOLAR KERATOSIS: INITIAL: (1) Prescriber attests to a diagnosis of Actinic or Solar keratosis AND (2) Prescriber attests to a trail, failure or intolerance to ONE of the following: 5-fluoruoracil 5% cream (Efudex) OR Imiquimod 5% cream (Aldara) RENEWAL: (1) Prescriber attests that patient has had disease stabilization or improvement. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# DIHYDROERGOTAMINE AND ERGOTAMINE

## Products Affected

- *dihydroergotamine mesylate nasal*
- ERGOMAR
- MIGERGOT
- TRUDHESA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ALL TREATMENTS: Acute treatment of migraine headaches with or without aura, medically accepted indication will also be considered for approval DHE45, MIGERGOT, ERGOMAR ONLY: Acute treatment of cluster headaches. |
| **Exclusion Criteria** | DHE 45, MIGRANAL, ERGOMAR, MIGERGOT: peripheral vascular disease; hepatic or renal impairment; coronary heart disease; hypertension; sepsis; concomitant use of ergot alkaloids with strong inhibitors of CYP3A4 (includes HIV and HCV protease inhibitors, cobicistat azole antifungals, and some macrolide antibiotics); pregnancy. DHE 45, MIGRANAL ONLY: ischemic heart disease, angina pectoris, history of MI, silent ischemia, or coronary artery vasospasm including Prinzmetal angina; breastfeeding |
| **Required Medical Information** | A. MIGRAINE HEADACHE: INITIAL (1) Prescriber attests to a diagnosis of migraine headaches AND (2) Prescriber attests that patient has tried and failed (or is intolerant to) at least TWO triptans AND (3) Patient is not on concurrent therapy with other ergot products. RENEWAL: (1) Prescriber attests that patient is tolerating therapy and has had disease improvement or stabilization with therapy B. CLUSTER HEADACHE: INITIAL: (1) Prescriber attests to a diagnosis of cluster headaches. AND (2) Prescriber attests (2a) tried and failed (or is intolerant) to injectable sumitriptanOR (2b) if patient unable to use injectable sumatriptan (e.g. needle phobia, etc.) patient has tried and failed nasal zolmitriptan or nasal sumitriptan AND (3) Patient is not on concurrent therapy with other ergot products RENEWAL: (1) Prescriber attests that patient is tolerating therapy and has had disease improvement or stabilization with therapy |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | CLUSTER HEADACHE: Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# DOPTELET

## Products Affected

- DOPTELET
- DOPTELET SPRINKLE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Thrombocytopenia in chronic liver disease, chronic immune thrombocytopenia (cITP). |
| **Exclusion Criteria** | Doptelet will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag]). |
| **Required Medical Information** | INITIAL: (A) CHRONIC IMMUNE THROMBOCYTOPENIA (cITP): (1) Diagnosis of cITP AND (2) Tried or contraindicated to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy AND (3) AND (4) Patient meets one of the following (4a) Platelet count of less than 30 x 10^9/L OR (4b) Platelet count of less than 50 x 10^9/L AND a prior bleeding event. (B) CHRONIC LIVER DISEASE (1) Diagnosis of thrombocytopenia in chronic liver disease AND (2) Patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy AND (3) Patient has a platelet count of less than 50 x 109/L. CONTINUING THERAPY / RENEWAL: [LIVER]: Treat as Initial. [cITP]: (1) Patient has been stable on therapy AND (2) Diagnosis of approvable indication AND (3) Doptelet will NOT be used concurrently with other TPO-RAs AND (4) Patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events. |
| **Age Restrictions** | [Liver]: 18 years of age or older. [cITP]: 1 year of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | [Liver]: Initial: 1 month. [cITP]: Initial: 2 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# DUOPA

## Products Affected

- DUOPA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced Parkinson disease (PD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARKINSONS DISEASE (PD): (1) Diagnosis of advanced PD. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# DUPIXENT

## Products Affected

- DUPIXENT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe atopic dermatitis (AD), moderate-to-severe asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis (PN), chronic obstructive pulmonary disease (COPD), bullous pemphigoid (BP), chronic spontaneous urticaria (also called chronic idiopathic urticaria). |
| **Exclusion Criteria** | [All except BP]: Used concurrently with another systemic biologic [benralizumab (Fasenra), mepolizumab (Nucala). omalizumab (Xolair), resilizumab (Cinqair), or tezepelumab-ekko (Tezspire)] or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication. |
| **Required Medical Information** | INITIAL: (A) AD: (1) Diagnosis of moderate to severe AD AND (2a) AD involving at least 10% body surface area (BSA) OR (2b) AD affecting the face, head, neck hands, feet, groin, or intertriginous areas OR (2c) Previously stable on another biologic and is switching to Dupixent AND tried or contraindicated to ONE of the following: (3a) topical corticosteroid OR (3b) topical calcineurin inhibitor OR (3c) Topical PDE-4 inhibitor OR (3d) Topical JAK inhibitor OR (3e) Phototherapy. (B) ASTHMA: (1) Diagnosis of (1a) mod to severe oral corticosteroid-dependent asthma OR (1b) mod to severe asthma with eosinophilic phenotype AND (1b.i) Pretreatment blood eosinophilic level of 150 to 1500 cells/microliter AND (2) Patient is currently being treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid AND at least ONE other maintenance medication (long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist, theophylline) AND (3) Meets one of the following: (3a) Has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR (3b) Has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months OR (3c) Has poor symptom control despite current therapy as evidenced by at least 3 of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist reliever for symptoms more than twice per week, any activity limitation due to asthma. (C) CRSwNP: (1) Diagnosis of CRSwNP AND (2) Evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan AND (3) Inadequately controlled disease AND (4) Tried ONE |

| PA Criteria | Criteria Details |
|---|---|
| | intranasal corticosteroid for a 56-day trial AND (5) Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids). |
| **Age Restrictions** | [ASTHMA]: 6 years of age or older. [AD]: 6 months of age or older. [BP, COPD, PN]: 18 years of age or older. [CRSwNP, CSU]: 12 years of age or older. [EoE]: 1 year of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AD, PN, CSU]: dermatologist, allergist, or immunologist. [ASTHMA]: allergist or pulmonologist. [COPD]: pulmonologist. [CRSwNP]: allergist, immunologist, or otolaryngologist. [EoE]: allergist, immunologist, or gastroenterologist. [BP]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (D) EoE: (1) Diagnosis of EoE AND (2) Patient weighs at least 15 kg AND (3) Tried or contraindicated to dietary therapy AND (4) Tried or contraindicated to a proton pump inhibitor. (E) PN: (1) Diagnosis of PN AND (2) Presence of multiple PN lesions AND (3) Tried or contraindicated to ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids, antidepressants, k-/mu-opioid receptor antagonists, thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine. (F) COPD: (1) Diagnosis of COPD AND (2) Has an eosinophilic phenotype COPD AND (3) Used in combo with a long-acting muscarinic antagonist/long-acting beta-2-agonist/ICS. (G) BP: (1) Diagnosis of BP. (H) CSU: (1) Diagnosis of CSU/CIU AND (2) Still experiences hives or angioedema on most days of the week for at least 6 weeks AND (3) Trial of and is maintained on OR has a contraindication to 4-times the maximally labeled dose of a second generation H1 antihistamine. CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND [ALL except BP]: (3) Diagnosis confirmed by an appropriate specialist AND (4) Patient will not take another systemic biologic or targeted small molecules for the same indication AND [ASTHMA]: (5) Will continue to use an ICS AND at least ONE other maintenance medication. [COPD]: (5) Patient has an eosinophilic phenotype COPD AND (6) Dupixent will be used in combo with a LAMA/ LABA/ICS. [CSU]: (5) Tried and is maintained on OR contraindicated to 4-times the maximally labeled dose of a second generation H1 antihistamine. RENEWAL: [BP]: Treat as Initial. (1) Diagnosis of approvable indication AND (2) Patient will not take another systemic |

| PA Criteria | Criteria Details |
| --- | --- |
| | biologic or targeted small molecules for the same indication AND [AD]: (3) Patient has shown improvement. [ASTHMA]: (3) Patient will continue to use an ICS AND at least ONE other maintenance medication AND (4) Patient has shown clinical response as evidenced by ONE of the following: Reduction in asthma exacerbations from baseline, decreased utilization of rescue medications, increase in percent predicted FEV1 from pretreatment baseline, reduction in severity or frequency of asthma-related symptoms. [CRSwNP]: (3) Shown clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps). [EoE]: (3) Shown improvement (e.g., symptom improvement or achieving histological remission). [PN]: (3) Patient has had PN improvement (reduction) of pruritus or pruriginous lesions. [COPD]: (3) Patient has an eosinophilic phenotype COPD AND (4) Dupixent will be used in combo with a LAMA/LABA/ICS. [CSU]: (4) Diagnosis confirmed by appropriate specialist AND (5) Tried and is maintained on OR has a contraindication to, 4-times the maximally labeled dose of a second generation H1 antihistamine. PA Auto |

# DUVYZAT

## Products Affected

- DUVYZAT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Duchenne muscular dystrophy (DMD) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL: DUCHENNE MUSCULAR DYSTROPHY (DMD) (1) Prescriber attests to a diagnosis of DMD confirmed by genetic testing AND (2) Prescriber attests patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat. CONTINUATION OF THERAPY: (1) Diagnosis of an approvable indication AND (2) Patient has been stable on therapy for at least 30 days AND (3) Prescriber attests patient will continue steroid therapy with Duvyzat.RENEWAL: (1) Prescriber attests patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat AND (2) Prescriber attests the patient has shown improvement since starting Duvyzat, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gowers maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA]) if ambulatory OR (3) Prescriber attests the patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since starting Duvyzat, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength) if non-ambulatory. |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a neurologist specializing in DMD at a DMD treatment center |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None |

# DYSPORT

## Products Affected

- DYSPORT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles), spasticity. |
| **Exclusion Criteria** | Request is for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines). |
| **Required Medical Information** | INITIAL: (A) CERVICAL DYSTONIA: (1) Diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) AND (2) Patient is 18 years of age or older AND (B) SPASTICITY: (1) Diagnosis of spasticity AND (2) Patient is 2 years of age or older.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | See RMI. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# EBGLYSS

## Products Affected

- EBGLYSS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Atopic dermatitis |
| **Exclusion Criteria** | Used concurrently with other systemic biologics (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of atopic dermatitis |
| **Required Medical Information** | INITIAL: (A) ATOPIC DERMATITS (AD): (1) Diagnosis of moderate to severe AD AND (2) Weighs at least 40 kg (88 lbs) AND (3) Meets one of the following: (3a) Patient has AD involving at least 10 percent of body surface area (BSA) OR (3b) AD affecting the face, head, neck, hands, feet, groin, or intertriginous areas OR (3c) Patient was previously stable on another biologic (e.g., Adbry, Dupixent) and is switching to Ebglyss AND (4) Tried or contraindicated to ONE of the following: (4a) Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate) (4b) Topical calcineurin inhibitor (e.g., Protopic, Elidel) (4c) Topical PDE-4 inhibitor (e.g., Eucrisa) (4d) Topical JAK inhibitor (e.g., Opzelura) (4e) Phototherapy. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosed by appropriate specialist AND (4) Ebglyss not be used concurrently with other systemic biologics or targeted small molecules for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has shown improvement while on Ebglyss AND (3) Ebglyss not be used concurrently with other systemic biologics or targeted small molecules for an autoimmune indication |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist, allergist, or immunologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None |

# EKTERLY

## Products Affected

- EKTERLY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide]) |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: Kalbitor, Berinert, Ruconest, generic icatibant. INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Ekterly will be used for the treatment of acute attacks of HAE AND (3) Patient meets one of the following: (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Ekterly will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Ekterly will NOT be used concurrently with an alternative prophylactic agent for HAE attacks AND (3) Patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline. |
| **Age Restrictions** | 12 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ELAPRASE

## Products Affected

- ELAPRASE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mucopolysaccharidosis type II [MPS II] (Hunter Syndrome), Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. FOR MPS II, INITIAL: (1) Prescriber attests to a diagnosis of MPS II (Hunter Syndrome) confirmed by iduronate-2-sulfatase (I2S) activity OR genetic testing confirming mutations in the IDS gene AND (2) The patient must have TWO of the below symptoms: a decline in developmental skills ( usually between ages 18 months and 3 years), coarse facial features, including thickening of the lips, protruding tongue and nostrils and a broad nose, carpal tunnel syndrome, claw-like hands, diarrhea, bone deformities, hepatosplenomegaly, recurrent otitis media, macrocephaly, recurrent sinopulmonary infections, sleep apnea, cardiac abnormalities and valvular disease, impaired vision, skin lesions on the back and upper arms, impaired hearing, aggressive behavior, short stature ( usually after age 4 or 5), joint stiffness and reduced range of motion, reduced pulmonary function AND (3) Prescriber attests to obtain baseline urinary glycosaminoglycan (uGAG) AND (4) Prescriber attests to obtain baseline 6-minute walk test (6-MWT) AND (5) Prescriber attests to obtain a baseline forced vital capacity (FVC). RENEWAL: (1) Prescriber attests to a clinical response to both of the following: (a) Improvement in walking capacity with greater than 30 meter or 29% increase in 6-minute walk test (6MWT) or improvement or stabilization of FVC AND (b) Decrease in urinary glycosaminoglycan (GAG) from baseline. |
| **Age Restrictions** | 16 months of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician specializing in metabolic disorders or genetics |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | Elixir Quantity Limit Applies. No PA Automation |

# ELFABRIO

## Products Affected

- ELFABRIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Fabry Disease. |
| **Exclusion Criteria** | Used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Galafold [migalastat]). |
| **Required Medical Information** | INITIAL: (A) FABRY DISEASE:(1) Diagnosis of Fabry disease AND (2) Patient is symptomatic OR has evidence of injury to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI) AND [FEMALE]: (3) Patient has a galactosidase alpha (GLA) gene mutation via genetic testing. [MALE]: (3) Patient meets one of the following: (3a) An alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay OR A galactosidase alpha (GLA) gene mutation via genetic testing.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Elfabrio will NOT be used concurrently with another Fabry disease therapy.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Elfabrio will NOT be used concurrently with another Fabry disease therapy AND (3) One of the following: (3a) Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss) OR (3b) Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound) OR (3c) Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ELIGARD

## Products Affected

- ELIGARD
- VABRINTY KIT 22.5 MG SUBCUTANEOUS
- VABRINTY KIT 30 MG SUBCUTANEOUS
- VABRINTY KIT 45 MG SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Gender dysphoria, advanced prostate cancer. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) GENDER DYSPHORIA (1) Diagnosis of gender dysphoria AND (2) Gender dysphoria is not restricted from coverage under the patient's benefit. (B) PROSTATE CANCER: (1) Diagnosis of advanced prostate cancer. CONTINUING THERAPY / RENEWAL: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ELYXYB

## Products Affected

- ELYXYB

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute treatment of migraines. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ACUTE MIGRAINES: (1) Diagnosis of acute treatment of migraines AND (2) Patient is unable to swallow tablets or capsules AND (3) Patient has tried or contraindicated to generic ibuprofen oral liquid formulation.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient is unable to swallow tablets or capsules. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# EMFLAZA

## Products Affected

- *deflazacort*
- EMFLAZA
- *jaythari oral tablet*
- KYMBEE
- PYQUVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Duchenne muscular dystrophy (DMD). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) DUCHENNE MUSCULAR DYSTROPHY (DMD): (1) Diagnosis of DMD AND (2) Diagnosis of DMD is confirmed by genetic testing AND (3) Tried prednisone or prednisolone for at least 6 months AND (4) One of the following: (4a) Prednisone or Prednisolone did not work for the patient AND meets all of the following: (4a.i) Patient is not in Stage 1 of the disease AND (4a.ii) Steroid myopathy has been ruled out AND (4a.iii) Patient has experienced deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone that is consistent with advancing disease (stage 2 or higher) and assessed using standard measures over time (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessment [PGA], pulmonary function tests [FVC, PFTs], upper limb strength [propelling a wheelchair 30 feet]) OR (4b) Patient experienced a significant adverse effect (e.g., weight gain) on prednisone or prednisolone that is negatively impacting a comorbid condition (e.g., diabetes). SEE OTHER CRITERIA |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) One of the following (3a) Patient is currently ambulatory AND Patient has shown function or improvement since being on requested medication, as assessed by a standard set of ambulatory or functional status measures |

| PA Criteria | Criteria Details |
| --- | --- |
| | (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessment [PGA]) OR (3b) Patient is currently non-ambulatory AND Patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since being on requested medication, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength measures [propelling a wheelchair 30 feet], Physician Global Assessment [PGA]).PA Automation |

# EMPAVELI

## Products Affected

- EMPAVELI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Paroxysmal nocturnal hemoglobinuria (PNH), Complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria. |
| **Exclusion Criteria** | [PNH]: Used concurrently with C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]) or Factor B inhibitor (e.g., Fabhalta [iptacopan]).[C3G, IC-MPGN]: Used concurrently with another complement inhibitor (e.g., Fabhalta). |
| **Required Medical Information** | INITIAL: (A) PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): (1) Diagnosis of PNH AND (2) Patient has flow cytometry demonstrating (2a) at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND (2b) PNH granulocyte clone size of at least 10 percent. (B) COMPLEMENT 3 GLOMERULOPATHY (C3G) or Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN): Diagnosis of C3G OR primary IC-MPGN AND (2) Diagnosis confirmed by renal biopsy AND (3) Urine protein creatine ratio (UCPR) of greater than 1g/g AND (4) Has an eGFR of at least 30 mL/min/1.73m2 AND (5) Tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to BOTH drug classes. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) [PNH] Empaveli will NOT be used concurrently with C5 complement inhibitor therapy or Factor B inhibitor. [C3G, IC-MPGN]: Empaveli will NOT be used concurrently with another complement inhibitor. RENEWAL: (1) Diagnosis of approvable indication AND (2) [PNH]: Patient experienced a clinical benefit while on Empaveli (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline (baseline defined as patient condition post treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz]) AND (3) Empaveli will NOT be used concurrently with a C5 complement inhibitor therapy or Factor B inhibitor. [C3G, IC-MPGN]: (2) Patient has had a reduction in proteinuria OR has improved, or stable kidney function compared to baseline AND (3) Empaveli will NOT |

| PA Criteria | Criteria Details |
|---|---|
| | be used concurrently with another complement inhibitor. |
| **Age Restrictions** | [C3G, IC-MPGN]: 12 years of age or older. [PNH]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [PNH]: hematologist. [C3G, IC-MPGN]: nephrologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# EMROSI

## Products Affected

- EMROSI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rosacea |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL (A) ROSACEA: (1) Diagnosis of rosacea AND (2) Patient has inflammatory lesions (papules and pustules) associated with rosacea AND (2) Tried or contraindicated to ONE generic minocycline or doxycycline. CONTINUING THERAPY: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 16 weeks. |
| **Other Criteria** | PA Automated |

# ENBREL

## Products Affected

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Plaque psoriasis (PsO), Polyarticular juvenile idiopathic arthritis (PJIA), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Patient has had a trial of or contraindication to an NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3 percent or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to Enbrel AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (3b) Patient has a contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] used in the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g.,Otezla [apremilast]), or JAK inhibitor for same indication. (C) PJIA: (1) Diagnosis of moderate to severe PJIA. (D) PsA: (1) Diagnosis of PsA. (E) RA: (1) Diagnosis of moderate to severe RA AND (2) Patient had a trial of or contraindication to at least 3 months of treatment with one conventional synthetic DMARD (disease-modifying anti-rheumatic drug) (such as: methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Enbrel will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. SEE OTHER CRITERIA |
| **Age Restrictions** | [PJIA, PsA]: 2 years or older, [PsO]: 4 years or older, [RA, AS]: 18 years |

| PA Criteria | Criteria Details |
|---|---|
| | or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [RA, PsA, AS, PJIA]: rheumatologist. [PsO, PsA]: dermatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | RENEWAL: (1) Diagnosis of approvable indication AND (2) Enbrel will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [AS]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. [PsO]: (3) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. [PJIA, PsA, RA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. PA Automated |

# ENBUMYST

## Products Affected

- ENBUMYST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Edema associated with congestive heart failure, hepatic disease or renal disease (including nephrotic syndrome) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) EDEMA: (1) Diagnosis of edema associated with congestive heart failure, hepatic disease, or renal disease (including nephrotic syndrome) AND (2) Patient has a contraindication to or is unable to swallow bumetanide tablets. CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist, nephrologist, hepatologist, or gastroenterologist. |
| **Coverage Duration** | Initial: 2 weeks; allows for a 30 day supply |
| **Other Criteria** | PA Automated. |

# ENDARI

## Products Affected

- ENDARI
- *l-glutamine oral packet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Sickle cell disease |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. SICKLE CELL DISEASE (SCD): INITIAL: (1) Prescriber attests to a diagnosis of SCD AND (2) Patient has had a trial of or contraindication to hydroxyurea AND (3) Prescriber attests if the patient is 18 years of age or older one of the following (3a) The patient had at least 2 sickle cell crises in the past year (a sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism, or splenic sequestration) OR (3b) The patient is having sickle-cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living OR (3c) The patient has a history of or has recurrent acute chest syndrome (ACS). CONTINUATION OF THERAPY: (1) Prescriber attests to a diagnosis of approvable indication AND (2) Patient has been stable on therapy 30 days RENEWAL: (3) Prescriber attests the patient has maintained or experienced a reduction in acute complications of sickle -cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS]). |
| **Age Restrictions** | 5 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | Elixir Quantity Limit Applies. PA Automated |

# ENSPRYNG

## Products Affected

- ENSPRYNG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Neuromyelitis optica spectrum disorder (NMOSD) |
| **Exclusion Criteria** | Used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]). |
| **Required Medical Information** | INITIAL: (A) NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD): (1) Diagnosis of a NMOSD AND (2) Patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibody AND (3) Patient has at least ONE of the following core clinical characteristics: Optic neuritis, Acute myelitis, Area postrema syndrome, Acute brainstem syndrome, Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, Symptomatic cerebral syndrome with NMOSD-typical brain lesions.<br>CONTINUING THERAPY: (1) Treat as Initial.<br>RENEWAL: (1) Diagnosis of NMOSD AND (2) Patient had a reduction in relapse frequency from baseline AND (3) Enspryng will NOT be used concurrently with another NMOSD. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or ophthalmologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ENTYVIO

## Products Affected

- ENTYVIO
- ENTYVIO PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Crohns disease (CD), ulcerative colitis (UC) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [CD]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) (Tried a TNF prior to Rinvoq). [UC]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek), Xeljanz (XR) (Tried a TNF prior to Rinvoq /Xeljanz). INITIAL: (A) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (B) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Entyvio will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Entyvio will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# EOHILIA

## Products Affected

- EOHILIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Eosinophilic esophagitis (EoE), Medically accepted indications. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: Eosinophilic esophagitis (EoE) (1) Prescriber attests that the patient has a diagnosis of eosinophilic esophagitis (EoE) AND (2) Prescriber attests patient has evidence of at least 15 eosinophils/hpf in the esophagus as confirmed by a biopsy AND (3) Prescriber attests patient had a trial of or contraindication to one inhaled corticosteroid (e.g., Flovent [fluticasone], Pulmicort [budesonide]) OR one generic proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole).<br>CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy 90 days |
| **Age Restrictions** | 11 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or allergist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None. |

# EPANED

## Products Affected

- *enalapril maleate oral solution*
- EPANED

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Asymptomatic left ventricular dysfunction, hypertension, symptomatic heart failure. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HEART CONDITIONS, HYPERTENSION: (1) Diagnosis of asymptomatic left ventricular dysfunction, hypertension, or symptomatic heart failure AND (2) Patient has a contraindication to is or is unable to swallow enalapril tablets.<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# EPCLUSA

## Products Affected

- EPCLUSA
- *sofosbuvir-velpatasvir*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic Hepatitis C (GT 1, 2, 3, 4, 5, and 6) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to BRAND EPCLUSA prior to generic. INITIAL (A) CHRONIC HEPATITIS C GT 1, 2, 3, 4, 5 or 6: (1) Must have a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5, or 6. AND (2) Must provide HCV RNA level dated within last 6 months AND (3) the patient does NOT meet ANY of the following criteria: (3a) patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions, (3b) Epclusa will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], efavirenz-containing HIV regimens, rosuvastatin at doses greater than 10mg, Aptivus [tipranavir]/ritonavir, topotecan, St. Johns wort), (3c) Epclusa will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier, Mavyret, or Vosevi AND (4) Patient meets ONE of the following criteria: (4a) patient does not have cirrhosis, (4b) patient has compensated cirrhosis (Child-Pugh A), (4c) patient has decompensated cirrhosis (moderate or severe hepatic impairment; Child-Pugh B or C) AND Epclusa will be used with ribavirin OR (5) patient have decompensated cirrhosis and meet ONE of the following criteria: (5a) patient has a contraindication to ribavirin (ribavirin ineligible), (5b) patient has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir/ribavirin) AND Epclusa will be used with ribavirin, (5c) patient has failed prior treatment with an NS5A inhibitor-based regimen (e.g., Harvoni [ledipasvir/sofosbuvir]) AND Epclusa will be used with ribavirin, (5d) patient is post-liver transplant, treatment-experienced, AND Epclusa will be used with ribavirin OR SEE OTHER CRITERIA |
| **Age Restrictions** | 3 years of age or older |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12-24 weeks, See OTHER CRITERIA Field |
| **Other Criteria** | (6) The patient does meet a condition as specified above but the requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.<br><br>Duration of approval is based on recommendations by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.<br><br>No PA Automation. |

# EPOETIN ALPHA

## Products Affected

- EPOGEN
- PROCRIT
- RETACRIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Anemia due to chronic kidney disease (CKD), zidovudine, chemotherapy in patients with cancer, hepatitis C, or for reduction of allogenic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery. |
| **Exclusion Criteria** | Used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat]). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to Retacrit before Epogen, Procrit. INITIAL: (A) CHRONIC KIDNEY DISEASE (CKD): (1) Diagnosis of anemia associated with CKD AND (2) Hemoglobin level is less than 10g/dL. (B) CHEMOTHERAPY INDUCED ANEMIA: Diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy AND (2) Patient meets one of the following: (2a) Hemoglobin level is less than 11g/dL OR (2b) Hemoglobin level has decreased at least 2g/dL below baseline level. (C) HIV - ZIDOVUDINE USE: (1) Diagnosis of anemia related to zidovudine (Retrovir) therapy AND (2) Hemoglobin level is less than 10g/dL. (D) HEPATITIS C: (1) Diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa AND (2) Hemoglobin level is less than 10g/dL AND (3) Tried or contraindicated to ribavirin dose reduction. (E) SURGERY: (1) Patient is undergoing elective, noncardiac, nonvascular surgery AND (2) Hemoglobin level is less than 13g/dL. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial/Renewal: [Hep C]: 6 months. [Surgery]: 1 month. [All other indications]: 12 months. |
| **Other Criteria** | CONTINUING THERAPY / RENEWAL: [PRE-SURGERY]: Treat as Initial. (1) Patient has been on therapy for at least 90 days AND (2) |

| PA Criteria | Criteria Details |
| --- | --- |
| | Diagnosis of approvable indication AND (3) Patient will NOT use concurrently with another ESA OR HIF-PHI AND [CKD Pediatric]: (4a) hemoglobin level is less than 10g/dL OR hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions OR [CKD adult]: (4b) NOT on dialysis: hemoglobin level is less than 10g/dL OR hemoglobin level has reached 10g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions OR [CDK adult]: (4c) ON dialysis: hemoglobin level is less than 11g/dL OR hemoglobin level has reached 11g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions. [CHEMOTHERAPY, ZIDOVUDIN USE, HEP C]: (4) Hemoglobin level is between 10g/dL and 12g/dL. PA Automation |

# EPOPROSTENOL

## Products Affected

- *epoprostenol sodium*
- FLOLAN
- VELETRI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUATION OF THERAPY: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication.RENEWAL: Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# EPRONTIA

## Products Affected

- EPRONTIA
- *topiramate oral solution*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Partial-onset seizures or primary generalized tonic-clonic seizures, seizures associated with Lennox-Gastaut syndrome, migraines. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARTIAL-ONSET/TONIC-CLONIC SEIZURES: (1) Diagnosis of partial-onset seizures or primary generalized tonic-clonic seizures AND (2) Requested medication will be used as initial monotherapy OR adjunctive therapy AND (3) Patient has a contraindication to or is unable to swallow oral topiramate tablets or capsules AND (4) Tried or contraindicated to THREE antiepileptic medications (e.g., carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate tablets or capsules, lamotrigine). (B) LENNOX-GASTAUT SYNDROME: (1) Diagnosis of seizures associated with Lennox-Gastaut syndrome AND (2) Requested medication will be used as adjunctive therapy AND (3) Patient has a contraindication to or is unable to swallow oral topiramate tablets or capsules AND (4) Tried or contraindicated to valproic acid or derivatives AND (5) Tried or contraindicated to TWO of the following antiepileptic medications: Epidiolex, rufinamide, felbamate, clobazam, lamotrigine, clonazepam, generic topiramate tablets or capsules. (C) MIGRAINES: (1) Diagnosis of migraines AND (2) Requested medication will be used as preventative treatment of migraines AND (3) Patient is unable to take oral tablets or capsules AND (4) Tried or contraindicated to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle.<br><br>CONTINUING THERAPY: [Migraines]: Treat as Initial. [Seizures]: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: [Migraines]: Treat as Initial. [Seizures]: (1) Diagnosis of |

| PA Criteria | Criteria Details |
|---|---|
| | approvable indication. |
| **Age Restrictions** | [Seizures]: 2 years of age or older. [Migraines]: 12 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [Seizures]: neurologist. [Migraines]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ESBRIET

## Products Affected

- *pirfenidone*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Idiopathic pulmonary fibrosis (IPF). |
| **Exclusion Criteria** | Used concurrently with Ofev. |
| **Required Medical Information** | INITIAL: (A) IDIOPATHIC PULMONARY FIBROSIS (IPF): (1) Diagnosis of IPF AND (2) Patient does NOT have other known causes of interstitial lung disease (ILD) (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, cancer) AND (3) Patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT AND (4) Patient does NOT currently smoke cigarettes.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Esbriet will not be used concurrently with Ofev.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline AND (3) Esbriet will not be used concurrently with Ofev. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# EUCRISA

## Products Affected

- EUCRISA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Atopic dermatitis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ATOPIC DERMATITIS: (1) Diagnosis of mild to moderate atopic dermatitis AND (2) Tried or contraindicated to a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment AND (3) Tried or contraindicated to the preferred agent: topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# EVENITY

## Products Affected

- EVENITY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postmenopausal osteoporosis |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) POSTMENOPAUSAL OSTEOPOROSIS: (1) Diagnosis of postmenopausal osteoporosis AND (2) Patient meets one of the following (2a) Patient is at high risk for fractures defined as one of the following: (2a.i) History of osteoporotic (i.e., fragility, low trauma) fracture OR (2a.ii) Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.) OR (2a.iii) FRAX score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture AND Patient has no prior treatment for osteoporosis OR (2b) Patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems, lower GI problems, trouble remembering to take oral medications or coordinate oral bisphosphonate with other oral medications) OR (2c) Patient had an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva) AND (3) Patient has NOT previously received 12 months of Evenity therapy. CONTINUING THERAPY: Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has not exceeded 12 months of therapy with Evenity. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Approved for only 12 months of utilization per lifetime |
| **Other Criteria** | PA Automated |

# EVEROLIMUS

## Products Affected

- AFINITOR
- *everolimus tablet 10 mg oral*
- *everolimus tablet 2.5 mg oral*
- *everolimus tablet 5 mg oral*
- *everolimus tablet 7.5 mg oral*
- TORPENZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced breast cancer, progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, advanced renal cell carcinoma (RCC), tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA), tuberous sclerosis complex (TSC)-associated partial-onset seizures. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | Advanced breast cancer, progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, advanced renal cell carcinoma (RCC), tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA), tuberous sclerosis complex (TSC)-associated partial-onset seizures. |
| **Age Restrictions** | [Metastatic, RCC, Angiomyolipoma]: 18 years of age or older. [SEGA]: 1 year of age or older. [Seizures]: 2 years of age or older. [Breast cancer]: None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [Seizures]: neurologist. [Breast cancer, Metastatic, RCC, Angiomyolipoma, SEGA]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# EVEROLIMUS DISPERZ

## Products Affected

- AFINITOR DISPERZ
- *everolimus oral tablet soluble*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA), tuberous sclerosis complex (TSC)-associated partial-onset seizures. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: [Seizures]: Tried or contraindicated to Epidiolex. INITIAL: (A) SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA): (1) Diagnosis of tuberous sclerosis complex (TSC)-associated SEGA AND (2) Patients diagnosis requires therapeutic intervention but cannot be curatively resected. (B) PARTIAL-ONSET SEIZURES: (1) Diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures AND (2) Requested medication will be used as adjunctive treatment AND (3) Tried or contraindicated to ONE antiepileptic medication (e.g., vigabatrin, carbamazepine, levetiracetam, oxcarbazepine, valproic acid derivatives, clobazam, topiramate, lamotrigine). CONTINUING THERAPY: [SEGA]: Refer to initial. [Seizures]: (1) Diagnosis of approvable indication. RENEWAL: [SEGA]: Refer to initial. [Seizures]: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | [SEGA]: 1 year of age or older. [Seizures]: 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [Seizures]: neurologist. [SEGA]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# EVRYSDI

## Products Affected

- EVRYSDI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Spinal muscular atrophy (SMA). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) SPINAL MUSCULAR ATROPHY (SMA): (1) Diagnosis of SMA AND (2) Diagnosis confirmed by gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele]) AND (3) Patient is pre-symptomatic AND (3a) Patient has up to (i.e., no more than) THREE copies of the survival motor neuron 2 (SMN2) gene based on newborn screening OR (4) Patient is symptomatic AND meets all the following (5) Onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age AND (6) Patient had a baseline motor function assessment by a neuromuscular specialist or SMA specialist AND (7) If the patient received prior gene therapy, the patient had a less than expected clinical benefit with gene therapy. CONTINUING THERAPY / RENEWAL: (1) Patient has been stable on therapy for 90 days AND (2) Diagnosis of approvable indication AND (3) Patient meets one of the following: (3a) Patient has improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND) OR (3b) Patient has improved, maintained, or demonstrated a less than expected decline in other muscle function (e.g., pulmonary). |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# EXXUA

## Products Affected

- EXXUA
- EXXUA TITRATION PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Major depressive disorder (MDD). |
| **Exclusion Criteria** | Used concurrently (at the same time) with another 5-HT1A receptor agonist (e.g., buspirone). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to BOTH agents: Fetzima, Trintellix. INITIAL: (A) MAJOR DEPRESSIVE DISORDER (MDD): (1) Diagnosis of MDD. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Exxua will NOT be used concurrently with another 5-HT1A receptor agonist. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has had a response to or remission of depressive symptoms with Exxua AND (3) Exxua will NOT be used concurrently with another 5-HT1A receptor agonist. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# FABHALTA

## Products Affected

- FABHALTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Paroxysmal nocturnal hemoglobinuria (PNH), primary immunoglobulin A nephropathy (IgAN), complement 3 glomerulopathy (C3G). |
| **Exclusion Criteria** | [PNH]: Used concurrently with a C5 complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]) or Factor D inhibitor (e.g., Voydeya [danicopan]).<br>[IgAN]: None.<br>[C3G]: Used concurrently with another complement inhibitor (e.g., Empaveli [pegcetacoplan]) for the treatment of C3G. |
| **Required Medical Information** | INITIAL: (A) PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH): (1) Diagnosis of PNH AND (2) Diagnosis confirmed by flow cytometry that show PNH granulocyte clone size of at least 10% AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes). (B) PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN): (1) Diagnosis if IgAN AND (2) Patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] of at least 1.5 g/g) AND (3) Diagnosis confirmed by renal biopsy AND (4) Patient has an eGFR of at least 20 mL/min/1.73m2 AND (5) Patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to BOTH drug classes. (C) COMPLEMENT 3 GLOMERULOPATHY (C3G): Diagnosis of C3G AND (2) Diagnosis confirmed by renal biopsy AND (3) Urine protein creatine ratio (UCPR) of at least 1g/g AND (4) Has an eGFR of at least 30 mL/min/1.73m2 AND (5) Tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to BOTH drug classes.<br>CONTINUING THERAPY: (1) Patient has already started Fabhalta treatment AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber** | Prescribed by or in consultation with a [PNH]: hematologist. [IgAN, C3G]: |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | nephrologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | RENEWAL: (1) Diagnosis of approvable indication AND [PNH]: (2) Patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels) compared to baseline AND (3) Fabhalta will NOT be used concurrently with C5 complement inhibitor therapy, C3 complement inhibitor therapy or Factor D inhibitor therapy. [IgAN, C3G]: (2) Patient has improved, or stable kidney function compared to baseline OR has a reduction in proteinuria AND (3) [C3G]: Fabhalta will NOT be used concurrently with another complement inhibitor for the treatment of C3G. PA Automated |

# FABRAZYME

## Products Affected

- FABRAZYME

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Fabry Disease. |
| **Exclusion Criteria** | Used concurrently with another Fabry disease therapy (e.g., Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat]). |
| **Required Medical Information** | INITIAL: (A) FABRY DISEASE:(1) Diagnosis of Fabry disease AND (2) Patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI) AND [FEMALE]: (3) Patient has a galactosidase alpha (GLA) gene mutation via genetic testing. [MALE]: (3) Patient meets one of the following: (3a) An alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay OR A galactosidase alpha (GLA) gene mutation via genetic testing.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Fabrazyme will NOT be used concurrently with another Fabry disease therapy.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Fabrazyme will NOT be used concurrently with another Fabry disease therapy AND (3) One of the following: (3a) Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss) OR (3b) Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound) OR (3c) Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy). |
| **Age Restrictions** | 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders. |
| **Coverage Duration** | None |
| **Other Criteria** | Initial: 12 months, Renewal: 12 months |

# FASENRA

## Products Affected

- FASENRA
- FASENRA PEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe asthma with an eosinophilic phenotype, eosinophilic granulomatosis with polyangiitis (EGPA). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication concurrently. |
| **Required Medical Information** | INITIAL: (A) ASTHMA: (1) Diagnosis of severe asthma with an eosinophilic phenotype AND (2) Blood eosinophilic level of 150 cells/microliter within the past 12 months AND (3) Patient is currently being treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (beclomethasone, budesonide, mometasone) AND at least ONE other maintenance medication (long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or oral corticosteroid [e.g., prednisone]) AND (4) Patient meets one of the following: (4a) Patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR (4b) Patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months OR (4c) Patient have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week, any activity limitation due to asthma. (B) EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS: INITIAL: (1) Diagnosis of EGPA (also known as Churg-Strauss syndrome). |
| **Age Restrictions** | [Asthma]: 6 years of age or older. [EGPA]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with [Asthma]: an allergist, pulmonologist. [EGPA]: None |
| **Coverage** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
|---|---|
| **Duration** | |
| **Other Criteria** | CONTINUING THERAPY: [EGPA]: Treat as initial. [Asthma]: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an eosinophilic asthma AND (3) Diagnosis confirmed by appropriate specialist AND (4) Fasenra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication AND (5) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid).RENEWAL: (1) Diagnosis of approvable indication AND (2) Fasenra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication AND [ASTHMA]: (3) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid) AND (4) Patient has shown a clinical response as evidenced by ONE of the following: (4a) Reduction in asthma exacerbations from baseline OR (4b) Decreased utilization of rescue medications (e.g., albuterol OR (4c) Increase in percent predicted FEV1 from pre-treatment baseline OR (4d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing). [EGPA]: (3) Patient has a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid (e.g., prednisone) use. PA Automated. |

# FILSPARI

## Products Affected

- FILSPARI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary immunoglobulin A nephropathy (IgAN) |
| **Exclusion Criteria** | Used concurrently with an ACE inhibitor (e.g., benazepril, lisinopril), an ARB (e.g., losartan, valsartan), an endothelin receptor antagonist (e.g., ambrisentan, bosentan), aliskiren. |
| **Required Medical Information** | INITIAL: (A) PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN): (1) Diagnosis of IgAN AND (2) Patient is at risk of disease progression AND (3) Diagnosis is confirmed by a biopsy AND (4) Patient has proteinuria of at least 1 g/day AND (5) Patient has an eGFR of at least 30 mL/min/1.73m 2 AND (6) Patient had a trial of or contraindication to at least 12 weeks of treatment with an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan).<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria AND (3) Filspari will NOT be used concurrently with an ACE inhibitor, an ARB, an endothelin receptor antagonist, aliskiren. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# FILSUVEZ

## Products Affected

- FILSUVEZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.DISEASE: EPIDERMOLYSIS BULLOSA: INITIAL: (1) Prescriber attests patient has dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy |
| **Age Restrictions** | 6 months of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months  Renewal:  12 months |
| **Other Criteria** | PA AUTO |

# FINGOLIMOD

## Products Affected

- *fingolimod hcl*
- GILENYA CAPSULE 0.5 MG ORAL
- TASCENSO ODT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease. |
| **Exclusion Criteria** | A 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, A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker, A baseline QTc interval of at least 500 msec, or Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol). |
| **Required Medical Information** | INITIAL: (A) MULTIPLE SCLEROSIS (MS): (1) Diagnosis of a relapsing form of MS AND (2) [GILENYA]: Tried ONE preferred brand: Avonex, Betaseron, Copaxone 40mg, glatiramer, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Rebif, Vumerity, Zeposia. [TASCENSO]: (2) Patient has a contraindication to or is unable to swallow fingolimod oral capsules AND (3) Patient is 18 years of age or older and has tried or contraindicated to TWO agents: Zeposia, fingolimod, dimethyl fumarate, Vumerity, Mayzent.<br>CONTINUING THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been on therapy for at least 30 days. |
| **Age Restrictions** | 10 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# FINTEPLA

## Products Affected

- FINTEPLA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) DRAVET SYNDROME: (1) Diagnosis of seizures associated with Dravet syndrome AND (2) Tried and contraindicated to valproic acid derivative or clobazam. (B) LENNOX-GASTAUT SYNDROME (LGS): (1) Diagnosis of seizures associated with LGS AND (2) Tried or contraindicated to valproic acid or derivatives AND (3) Tried or contraindicated to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# FIRDAPSE

## Products Affected

- FIRDAPSE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Lambert-Eaton myasthenic syndrome (LEMS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) LAMBERT-EATON MYASTHENIC SYNDROME (LEMS): (1) Diagnosis of LEMS AND (2) Diagnosis of confirmed by both of the following: Electrodiagnostic studies (e.g., reduced compound muscle action potential [CMAP]) and/or voltage-gated calcium channel (VGCC) antibody testing AND (3) Clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced improvement or stabilization in muscle weakness compared to baseline. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or hematologist-oncologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# FLOLIPID

## Products Affected

- *flolipid*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | None. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (1) Patient has a contraindication to or is unable to swallow simvastatin oral tablets AND (2) Patient has dysphagia, difficulty swallowing tablets, or a feeding tube (e.g., G-tube or J-tube).<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# FORTEO

## Products Affected

- BONSITY
- FORTEO
- *teriparatide*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postmenopausal osteoporosis, Primary or hypogonadal osteoporosis in a male patient, Glucocorticoid-induced osteoporosis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO generic teriparatide (2.4 mL) OR TYMLOS PRIOR TO SECONDARY TREATMENT FORTEO/teriparatide (2.48 mL). INITIAL: (A) ALL INDICATIONS: (1) Diagnosis of postmenopausal osteoporosis, primary or hypogonadal osteoporosis in a male patient, or glucocorticoid-induced osteoporosis AND (2) Patient meets one of the following (2a) Patient is at high risk for fractures defined as one of the following: (2a.i) History of osteoporotic (i.e., fragility, low trauma) fracture OR (2a.ii) Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin]) OR (2a.iii) FRAX score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture AND Patient has no prior treatment for osteoporosis OR (2b) Patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems, lower GI problems, trouble remembering to take oral medications or coordinate oral bisphosphonate with other oral medications) OR (2c) Patient had an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva). CONTINUING THERAPY: Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient meets one of the following: (3a) Patient has NOT previously received 24 months cumulative treatment with Forteo (teriparatide) OR (3b) Patient has previously received 24 months cumulative treatment with Forteo (teriparatide) AND remains at, or has returned to having a high risk for fracture. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 24 MONTHS per lifetime |
| **Other Criteria** | PA Automated |

# FORZINITY

## Products Affected

- FORZINITY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Barth syndrome |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) Barth syndrome: (1) Diagnosis of Barth syndrome AND (2) Patient weighs at least 30 kg (66lbs). CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# FULPHILA

## Products Affected

- FULPHILA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy, hematopoietic syndrome of acute radiation syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO ZIEXTENZO. A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME: (1) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# FUROSCIX

## Products Affected

- FUROSCIX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Edema with chronic heart failure or chronic kidney disease (including nephrotic syndrome). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) EDEMA: (1) Diagnosis of edema with chronic heart failure or chronic kidney disease (including nephrotic syndrome) AND (2) Patient weighs at least 43kg (94.6 lbs). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or nephrologist. |
| **Coverage Duration** | Initial: 30 days (all requests will be treated as initial) |
| **Other Criteria** | PA Automated |

# FYLNETRA

## Products Affected

- FYLNETRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy, hematopoietic syndrome of acute radiation syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO ZIEXTENZO. A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME: (1) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# GALAFOLD

## Products Affected

- GALAFOLD

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Fabry Disease. |
| **Exclusion Criteria** | Used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj]). |
| **Required Medical Information** | INITIAL: (A) FABRY DISEASE:(1) Diagnosis of Fabry disease AND (2) Patient has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data as interpreted by a clinical genetics professional as pathogenic or likely pathogenic (i.e., patient does NOT have a benign amenable GLA variant) AND (3) Patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI) AND [FEMALE]: (4) Patient has a galactosidase alpha (GLA) gene mutation via genetic testing. [MALE] (4) One of the following: (4a) An alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay OR (4b) A galactosidase alpha (GLA) gene mutation via genetic testing.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Galafold will NOT be used concurrently with another Fabry disease therapy.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Galafold will NOT be used concurrently with another Fabry disease therapy AND (3) One of the following: (3a) Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss) OR (3b) Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound) OR (3c) Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# GAMASTAN

## Products Affected

- GAMASTAN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Disease Prophylaxis |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: DISEASE PROPHYLAXIS (1) Prescriber attests requested medication is being used for the prophylaxis or passive immunization of hepatitis A, measles, varicella, or rubella.CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | No PA Automation |

# GATTEX

## Products Affected

- GATTEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Short Bowel Syndrome (SBS) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.SHORT BOWEL SYNDROME (SBS): INITIAL: (1) Prescriber attests to a diagnosis of SBS and a dependency on parenteral support, defined as requiring parenteral nutrition at least three times per week. RENEWAL: (1) Prescriber attests to a diagnosis of short bowel syndrome (SBS) AND (2) Prescriber attests parenteral nutrition support has achieved at least a 20 percent reduction in parenteral support compared to baseline AND (3) Prescriber attests the patient has NOT achieved enteral autonomy |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# GIMOTI

## Products Affected

- GIMOTI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute and recurrent diabetic gastroparesis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) DIABETIC GASTROPARESIS: (1) Diagnosis of acute and recurrent diabetic gastroparesis AND (2) Tried or contraindicated to metoclopramide ODT.<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 3 months |
| **Other Criteria** | PA Automated. |

# GLP1 AGONISTS

## Products Affected

- *exenatide*
- *liraglutide*
- MOUNJARO
- OZEMPIC (0.25 OR 0.5 MG/DOSE)
- OZEMPIC (1 MG/DOSE)
- OZEMPIC (2 MG/DOSE)
- RYBELSUS
- TRULICITY
- VICTOZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Type 2 diabetes |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) TYPE 2 DIABETES: (1) Diagnosis of type 2 diabetes provided by one of the following: (1a) medical records OR (1b) chart notes.<br><br>CONTIUING THERAPY: (1) Diagnosis of type 2 diabetes provided by medical records or chart notes. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automated |

# GOMEKLI

## Products Affected

- GOMEKLI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Neurofibromatosis type 1 (NF1) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) NEUROFIBROMATOSIS TYPE 1 (NF1): (1) Diagnosis of NF1 AND (2) Patient has symptomatic plexiform neurofibromas (PN) that cannot be completely resected. CONTINUING THERAPY: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# GRANIX

## Products Affected

- GRANIX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO NIVESTYM. A. FOR NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | 1 month of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# GRASTEK

## Products Affected

- GRASTEK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Grass pollen-induced allergic rhinitis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) GRASS ALLERGY: (1) Diagnosis of grass pollen-induced allergic rhinitis AND (2) Diagnosis is confirmed by a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens AND (3) Patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work) AND (4) Patient has a current claim or prescription for auto-injectable epinephrine.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline. |
| **Age Restrictions** | 5 and 65 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# HAEGARDA

## Products Affected

- HAEGARDA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Haegarda will be used for prophylaxis against HAE attacks AND (3) Patient meets one of the following (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE attacks AND (3) Patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline. |
| **Age Restrictions** | 6 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# HARLIKU

## Products Affected

- HARLIKU

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Alkaptonuria (AKU). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ALKAPTONURIA (AKU): (1) Diagnosis of AKU AND (2) Harliku will be used to reduce the level of urine homogentisic acid (HGA). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# HARVONI

## Products Affected

- HARVONI
- *ledipasvir-sofosbuvir*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6 infection |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to BRAND HARVONI prior to generic. INITIAL: (A) CHRONIC HEPATITIS C GT 1, 4, 5 or 6: (1) Must have a documented diagnosis of Chronic Hepatitis C infection genotype 1, 4, 5, or 6 AND (2) Must provide HCV RNA level dated within last 6 months AND (3) Prescriber must confirm that the patient does not have a limited life expectancy of less than 12 months due to non-liver-related comorbid conditions AND (4) If female of childbearing age, prescriber attests to discussion of risk vs. benefit of treatment due to lack of safety and efficacy data if patient becomes pregnant prior or during treatment. AND (5) Patient must have had hepatitis B testing (HBsAg, anti-HBc, anti-HBs) prior to starting hepatitis C treatment AND (6) Test results are provided to confirm liver fibrosis staging by one or more of the following: liver biopsy, direct serum biomarker, OR transient or shear wave elastography AND (7) Does the patient have suspected cirrhosis (F4), if YES: (7a) Provide status of encephalopathy (none, mild-moderate, severe) AND (7b) Provide level of ascites (none, mild-moderate, severe) AND(7c) Provide the following lab values dated within 12 weeks of initiating therapy: CBC with Platelets, AST / ALT, Total Bilirubin, Serum Albumin, PT / INRThe patient does NOT meet any of the following: (3a) patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions, (3b) Harvoni will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], rosuvastatin, Olysio [simeprevir], Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Aptivus [tipranavir]/ritonavir, St. Johns wort), (3c) Harvoni will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Mavyret, Epclusa, Zepatier, or Vosevi AND SEE OTHER CRITERIA |
| **Age Restrictions** | 3 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 8-24 weeks, See OTHER CRITERIA Field |
| **Other Criteria** | (4) Patient treatment-naive and meets ALL of the following criteria: (4a) The patient has genotype 1 or 4 infection, (4b) patient does not have cirrhosis, (4c) patient has an HCV RNA level of less than 6 million IU/mL OR (5) patient treatment-na?ve and meets ONE of the following criteria: (5a) patient does not have cirrhosis, (5b) patient has compensated cirrhosis (Child-Pugh A), (5c) patient has decompensated cirrhosis (Child-Pugh B or C) AND Harvoni will be used with ribavirin, (5d) patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin, (5e) patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin OR (6) patient have genotype 1 infection and meet ALL of the following criteria: (6a)patient is treatment-experienced (previously failed a peginterferon alfa-based regimen), (6b) patient has compensated cirrhosis (Child-Pugh A) OR (7) Is the patient treatment-experienced (previously failed a peginterferon alfa-based regimen) and meets ONE of the following: (7a) patient does not have cirrhosis, (7b) patient has genotype 4, 5, or 6 infection AND has compensated cirrhosis (Child-Pugh A), (7c) patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin, (7d) patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A) AND Harvoni will be used with ribavirin OR (8) patient treatment-experienced and meets ALL of the following criteria: (8a) patient has decompensated cirrhosis (Child-Pugh B or C), (8b) Harvoni will be used with ribavirin OR (9) patient have decompensated cirrhosis and meet ONE of the following criteria: (9a) patient has a contraindication to ribavirin (ribavirin ineligible), (9b) patient failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa) AND Harvoni will be used with ribavirin (9c) patient is post-liver transplant, treatment-experienced, AND Harvoni will be used with ribavirin OR(10) The patient does meet a condition as specified above but the requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.<br><br>Duration of approval is based on recommendations by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.<br><br>No PA Automation. |

# HEMLIBRA

## Products Affected

- HEMLIBRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hemophilia A (congenital factor VIII deficiency) |
| **Exclusion Criteria** | Used concurrently with another non-factor prophylaxis therapy (e.g., Hympavzi [marstacimab-hncq]) |
| **Required Medical Information** | A. HEMOPHILIA A: INITIAL: (1) Diagnosis of congenital factor VIII deficiency (hemophilia A) AND (2) Hemlibra will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND (3) One the following: (3a) Patient WITH factor VIII inhibitors AND patient has a history of a high titer of factor VIII inhibitor, defined as at least 5 Bethesda units per milliliter OR (3b) Patient WITHOUT factor VIII inhibitors AND Patient has moderate to severe hemophilia A, defined as less than 5 percent factor VIII activity compared to normal OR (3c) Patient has mild hemophilia A, defined as 5 percent - 40 percent factor AND one of the following: (3c.1) Patient has experienced severe, traumatic, or spontaneous bleeding episode(s) (may occur in joint or muscle) OR (3c.2) Patient has experienced a life-threatening bleed (e.g., intracranial hemorrhage [ICH]) OR (3c.3) Patient has venous access difficulties impeding regular clotting factor infusions VIII activity compared to normal. CONTINUATION OF THERAPY: (1) Unchanged from new |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, a hematologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | No PA Automation |

# HETLIOZ

## Products Affected

- HETLIOZ
- HETLIOZ LQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-24 hour sleep-wake disorder (N24HSWD), Nighttime sleep disturbances in Smith-Magenis syndrome (SMS) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL: A. Non-24 hour sleep-wake disorder (N24HSWD): (1) Prescriber attests to a diagnosis of non-24 hour sleep-wake disorder (N24HSWD) AND (2) Prescriber attests patient is light-insensitive or has total blindness AND (3) Prescriber attests patient had a trial and failure of maximally-tolerated melatonin therapy AND (4) The requested medication is for the Hetlioz (tasimelteon) capsules. B. INTIAL: Smith-Magenis syndrome (SMS): (1) Prescriber attests to a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) AND (2) Prescriber attests patient had a trial and failure of maximally-tolerated melatonin therapy AND (3a) The requested medications if for brand Hetlioz capsules AND the patient is 16 years of age or older (3b) The requested medication is for the Hetlioz LQ oral suspension AND the patient is 3 years to 15 years of age.CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days. |
| **Age Restrictions** | N24HSWD: 18 years of age and older SMS: see RMI |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | QUANTITY LIMIT EXISTS. PA Automated |

# HUMAN IMMUNE GLOBULIN

## Products Affected

- ALYGLO
- ASCENIV
- BIVIGAM
- FLEBOGAMMA DIF
- GAMMAGARD S/D LESS IGA
- GAMMAPLEX
- OCTAGAM
- PANZYGA
- PRIVIGEN
- YIMMUGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary Immunodeficiency disease (PID), see RMI |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: [Alyglo, Asceniv, Bivigam, Flebogamma, Gammaplex, Panzyga, Yimmugo]: Tried or contraindicated to TWO agents: Gammagard S-D, Gammagard Liquid, Gamunex-C, Octagam, Privigen. INITIAL: (A) PRIMARY IMMUNODEFICIENCY DISEASE (PID) AND VARIOUS INDICATIONS: (1) Diagnosis of primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83) OR (2) Diagnosis of any of the following: Immune (idiopathic) thrombocytopenic purpura (ITP) (ICD-10 D69.3), Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81), Multifocal motor neuropathy (MMN) (ICD-10 G61.82),Kawasaki syndrome (ICD-10 M30.3), B-cell chronic lymphocytic leukemia (CLL) with hypogammaglobulinemia, Autoimmune hemolytic anemia (AIHA) (ICD-10 Group D59.1), Pure red cell aplasia (PRCA) (ICD-10 D61.01), Guillain-Barre syndrome (GBS) (ICD-10 G61.0), Myasthenia gravis (ICD-10 Group G70.0), Autoimmune Graves ophthalmopathy (ICD-10 E05.00), Cytomegalovirus-induced pneumonitis (ICD-10 B25.0) related to a solid organ transplant, Prevention of bacterial infection in an HIV-infected child, Reduction of secondary infections in pediatric HIV infections, Dermatomyositis or polymyositis (ICD-10 M36.0, Group M33), Autoimmune uveitis (birdshot retinochoroidopathy), Lambert-Eaton myasthenic syndrome (ICD-10 G70.80), IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy, Stiff-man syndrome (ICD-10 G25.82), Neonatal sepsis (ICD-10 Group P36), Rotaviral enterocolitis (ICD-10 A08.0), Toxic shock syndrome (ICD-10 A48.3), Enteroviral meningoencephalitis (ICD-10 A87.0, A85.0), Toxic epidermal necrolysis (ICD-10 L51.2) or Stevens-Johnson syndrome (ICD-10 L51.1, L51.3), Autoimmune mucocutaneous blistering disease (AMBD) |

| PA Criteria | Criteria Details |
|---|---|
| | (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita). |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication. PA Automated. |

# HUMAN IMMUNE GLOBULIN SQ

## Products Affected

- CUTAQUIG
- CUVITRU
- HIZENTRA
- HYQVIA
- XEMBIFY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary Immunodeficiency disease (PID), chronic inflammatory demyelinating polyneuropathy (CIDP). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: [Cutaquig, Cuvitru, Hizentra, Hyqvia]: Tried or contraindicated to TWO agents: Gamunex-C, Gammagard Liquid, Xembify. INITIAL: (A) SUBCUTANEOUS: (1) Diagnosis of (1a) primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83) OR (1b) Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# HUMIRA

## Products Affected

- HUMIRA (2 PEN)
- HUMIRA (2 SYRINGE)
- HUMIRA-CD/UC/HS STARTER
- HUMIRA-PSORIASIS/UVEIT STARTER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Crohn disease (CD), Hidradenitis suppurativa (HS), Polyarticular juvenile idiopathic arthritis (PJIA), Plaque psoriasis (PsO), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC), Intermediate, posterior, or panuveitis. |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE preferred agent: adalimumab-adaz or Simlandi. INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to the clinical standard-of-care agent: an NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (C) HIDRADENITIS SUPPURATIVA (HS): (1) Diagnosis of moderate to severe HS. (D) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRTIS (PJIA): (1) Diagnosis of PJIA. (E) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to Humira AND (3a) Patient has had at least a 3-month trial of one clinical standard-of-care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA for the treatment of PsO OR (3b) Patient has a contraindication or intolerance to both clinical standard-of-care therapies: an immunosuppressants AND PUVA used in the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (F) PSORATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (G) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Tried of or contraindicated to at least 3 months of treatment with ONE clinical standard-of-care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug) such as: methotrexate dose of at least 20mg per week or maximally |

| PA Criteria | Criteria Details |
|---|---|
| | tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine. (H) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. (I) UVEITIS: (1) Diagnosis of non-infectious intermediate, posterior, or panuveitis AND (2) Patient does NOT have isolated anterior uveitis. |
| **Age Restrictions** | [CD]: 6 years of age or older. [PJIA, Uveitis]: 2 years of age or older. [HS]: 12 years of age or older. [AS, PsA, Ps, RA]: 18 years of age or older. [UC]: 5 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, PJIA, PsA, RA]: rheumatologist. [HS, Ps, PsA]: dermatologist. [UC, CD]: gastroenterologist. [UV]: ophthalmologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Requested drug will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Requested drug will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor PDE-4 inhibitor) for an autoimmune indication AND [AS]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. [HS]: (3) Patient has shown improvement while on therapy. [PIJA, PsA, RA]: (3) Patient experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [PsO]: (3) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. [Uveitis]: (3) Patient has NOT experienced treatment failure, defined as ONE of the following: (3a) Development of new inflammatory chorioretinal or retinal vascular lesions OR (3b) A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade OR (3c) A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved. PA Automated |

# HYMPAVZI

## Products Affected

- HYMPAVZI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hemophilia A (congenital factor VIII deficiency), hemophilia B (congenital factor IX deficiency) |
| **Exclusion Criteria** | Hympavzi will be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh]) |
| **Required Medical Information** | A. INITIAL: HEMOPHILIA A (1) Diagnosis of Hemophilia A AND (2) Patients hemophilia is without factor VIII inhibitors AND (3) Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes. B. HEMOPHILIA B (1) Diagnosis of Hemophilia B AND (2) Patients hemophilia is without factor IX inhibitors AND (3) Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes. CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh]) AND (4a) [Hemophilia A] Patients hemophilia is without factor VIII inhibitors OR (4b) [Hemophilia B] Patients hemophilia is without factor IX inhibitorsRENEWAL: (1) Patient has shown a clinical benefit compared to baseline AND (2) Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh]) AND (3a) [Hemophilia A] Patients hemophilia is without factor VIII inhibitors OR (3b) [Hemophilia B] Patients hemophilia is without factor IX inhibitors |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | N/A |

# HYRIMOZ (ADALIMUMAB-ADAZ)

## Products Affected

- *adalimumab-adaz*
- HYRIMOZ
- HYRIMOZ-CROHNS/UC STARTER
- HYRIMOZ-PED<40KG CROHN STARTER
- HYRIMOZ-PED>/=40KG CROHN START
- HYRIMOZ-PLAQ PSOR/UVEIT START

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Crohn disease (CD), Hidradenitis suppurativa (HS), Polyarticular juvenile idiopathic arthritis (PJIA), Plaque psoriasis (PsO), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC), Intermediate, posterior, and panuveitis |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: ALL indications for HYRIMOZ (Brand only): (1) Tried or contraindicated to ONE adalimumab (-adaz, Humira, Simlandi) AND [AS]: (2) TWO agents: Bimzelx, Enbrel, Rinvoq tab, Taltz, Xeljanz (XR) (Tried TNF prior to Rinvoz/Xeljanz) [PJIA]: (2) TWO agents: Enbrel, Rinvoq LQ, Xeljanz (Tried TNF prior to Rinvoq/Xeljanz) [PsA]: (2) TWO agents: Bimzelx, Enbrel, Otezla, Rinvoq tab/LQ, Skyrizi, Taltz, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek), Xeljanz (XR) (Tried TNF prior to Rinvoq/Xeljanz) [RA]: (2) TWO agents: Enbrel, Rinvoq tab, Xeljanz (XR) (Tried TNF prior to Rinvoq/Xeljanz) [HS]: (2) ONE agent: Bimzelx [PsO]: (2) TWO agents: Bimzelx, Enbrel, Otezla, Skyrizi, Sotyktu, Taltz Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) [CD]: (2) TWO agents: Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) (Tried TNF prior to Rinvoq) [UC]: (2) TWO agents: Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) (Tried TNF prior to Rinvoq/Xeljanz). INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to a NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (C) HIDRADENITIS SUPPURATIVA (HS): (1) Diagnosis of moderate to severe HS (D) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (E) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe plaque PsO AND (2a) Patient has psoriasis covering 3 percent or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR |

| PA Criteria | Criteria Details |
|---|---|
| | (2c) Patient was previously stable on another biologic and is switching to Hyrimoz (adalimumab-adaz) AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA for the treatment of PsO OR SEE OTHER CRITERIA |
| **Age Restrictions** | [CD]: 6 years of age or older. [PJIA, Uveitis]: 2 years of age or older. [HS]: 12 years of age or older. [AS, PsA, Ps, RA]: 18 years of age or older. [UC]: 5 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, PJIA, PsA, RA]: rheumatologist. [HS, Ps, PsA]: dermatologist. [UC, CD]: gastroenterologist. [UV]: ophthalmologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (3b) Patient has a contraindication or intolerance to both immunosuppressants AND PUVA used in the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (F) PLAQUE PSORASIS (PsA): (1) Diagnosis of PsA. (G) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Tried or contraindicated to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug) such as: methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine. (H) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. (I) UVEITIS: (1) Diagnosis of non-infectious intermediate, posterior and panuveitis AND (2) Patient does NOT have isolated anterior uveitis. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Requested drug will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Requested drug will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [AS]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. [HS]: (3) Patient has shown improvement while on therapy. [PIJA, PsA, RA]: (3) Patient experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count |

| PA Criteria | Criteria Details |
| --- | --- |
| | while on therapy. [PsO]: (3) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. [Uveitis]: (3) Patient has NOT experienced treatment failure, defined as ONE of the following: (3a) Development of new inflammatory chorioretinal or retinal vascular lesions OR (3b) A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade OR (3c) A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved. PA Auto |

# IBSRELA

## Products Affected

- IBSRELA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Irritable bowel syndrome with constipation (IBS-C) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL: Irritable bowel syndrome with constipation (IBS-C): (1) Patient has a diagnosis of irritable bowel syndrome with constipation AND (2) The patient had a trial of the preferred agents: Trulance AND Linzess.CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ICATIBANT

## Products Affected

- FIRAZYR
- SAJAZIR
- *icatibant acetate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with other agents used for the treatment of acute treatment of HAE attacks (e.g., Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Icatibant will be used for treatment of acute attacks of hereditary angioedema AND (3) Patient meets one of the following (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Requested medication will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a reduction in the severity or duration of HAE attacks AND (3) Requested medication will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ILARIS

## Products Affected

- ILARIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF), systemic juvenile idiopathic arthritis (SJIA), Adult-Onset Still's Disease (AOSD), Gout. |
| **Exclusion Criteria** | Used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication. |
| **Required Medical Information** | STEP ALERT [SJIA]: TRIED OR CONTRAINDICATED TO TYENNE. INITIAL: (A) PERIODIC FEVER SYNDROMES: (1) Diagnosis of one of the following: a. Cryopyrin-Associated Periodic Syndromes (CAPS), b. Familial Cold Autoinflammatory Syndrome (FACS), c. Muckle-Wells Syndrome (MWS) AND (2) Patient has genetic testing for gain-of-function mutations in the NLRP3 gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins) AND (3) Patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities. (B) TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME (TRAPS): (1) Diagnosis of TRAPS. (C) HYPERIMMUNOGLOBULIN D SYNDROME (HIDS)/MEVALONATE KINASE DEFICIENCY (MKD): (1) Diagnosis of HIDS or MKD. (D) FAMILIAL MEDITERRANEAN FEVER (FMF): (1) Patient has a diagnosis of FMF. (E) SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): (1) Diagnosis of SJIA. (F) ADULT-ONSET STILLS DISEASE (AOSD): (1) Diagnosis of AOSD AND (2) Patient had a trial of or contraindication to ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. (G) GOUT: (1) Diagnosis of gout flares AND (2) Tried or contraindicated to all the following: colchicine, NSAID (e.g., ibuprofen, indomethacin, naproxen), and a corticosteroid (e.g., methylprednisolone, prednisolone, prednisone, triamcinolone). SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | [CAPS, FACS, MWS]: 4 years of age or older [TRAPS, HIDS, MKD, FMF, AOSD]: no age restriction [SJIA]: 2 years of age or older, [GOUT]: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [SJIA, AOSD]: rheumatologist, dermatologist, or immunologist. [GOUT]: rheumatologist. [CAPS, FACS, MWS, TRAPS, HIDS, MKD, FMF, PVS]: None. |
| **Coverage Duration** | INTIAL: [PVS]: 56 days [TRAPS, HIDS, MKD, FMF]: 28 days SEE OTHER CRITERIA |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) ILARIS will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication. RENEWAL: [CAPS, FCAS, MWS, TRAPS, HIDS/MKD, FMF]: Refer to Initial. (1) ILARIS will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication AND [AOSD]: (2a) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy OR (2b) Patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis). [SJIA]: (2a) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy OR (2b) Patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis). [GOUT]: (2) Patient has shown improvement of gout flares while on Ilaris AND (3) Diagnosed by appropriate specialist. COVERAGE DURATION: INITIAL, RENEWAL: [AOSD]: 6, 12 months [SJIA, Gout]: 12, 12 months. PA Automated |

# ILUMYA

## Products Affected

- ILUMYA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (PsO) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT [PsO]: Tried or contraindicated to TWO agents: adalimumab (-adaz, Humira, Simlandi),Bimzelyx, Enbrel, Otezla, Skyrizi, Sotyktu, ustekinumab (-aekn, Steqeyma, Yesintek), Taltz, Tremfya. INITIAL: (A) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp AND (3) Patient meets ONE of the following: (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (3b) Contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] for the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Ilumya will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Ilumya will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND (3) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# IMBRUVICA

## Products Affected

- IMBRUVICA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Waldenstrom's macroglobulinemia (WM), chronic graft-versus-host disease (cGVHD) |
| **Exclusion Criteria** | Request for Imbruvica 560 mg tablet |
| **Required Medical Information** | INITIAL: (A) Chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenstrom's macroglobulinemia (WM): (1) Patient has a diagnosis of Chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenstrom's macroglobulinemia (WM). (B) CHRONIC GRAFT-VERSUS-HOST DISEASE (cGVHD): (1) Patient has a diagnosis of cGVHD AND (2) Patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil) AND (3) Imbruvica will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil). CONTINUING THERAPY: (1) Patient has been stable on therapy for 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | [CLL, SLL, WM]: 18 years of age and older. [cGVHD]: 1 year of age and older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# IMCIVREE

## Products Affected

- IMCIVREE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic weight management in those with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency, chronic weight management in those with obesity due to Bardet-Biedl Syndrome (BBS), Medically accepted indication. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TREATMENT OF OBESITY DUE TO PROOPIOMELANOCORTIN (POMC), PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 1 (PCSK1), LEPTIN RECEPTOR (LEPR) DEFICIENCY OR BARDET-BIEDEL SYNDROME (BBS): INITIAL: (1) Prescriber attests that patient has confirmed obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) gene variants interpreted as pathogenic, likely pathogenic, or of uncertain significance confirmed by genetic testing or due to Bardet-Biedl Syndrome (BBS) AND (2a) ADULT ONLY: Prescriber attests patients BMI is in obesity range and is greater than or equal to 30 kg/m2 OR (2b) PEDIATRIC ONLY: Prescriber attests patients BMI is greater than or equal to 95th percentile AND (3) Prescriber attests alternative weight management options have failed to provide at least a 10% weight reduction; such as diet, exercise, bariatric surgery AND (4) Prescriber provides baseline body weight and BMI. RENEWAL: (1a) FIRST RENEWAL Prescriber attests to a reduction in 5% baseline body weight for initial renewal OR (1b) SECONDARY RENEWAL Prescriber attests to sustained weight loss or BMI reduction from baseline while taking IMCIVREE. |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a provider specializing in metabolic disorders and/or genetic obesity |
| **Coverage Duration** | Initial: 4 months Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# IMMUNE GLOBULIN IVSQ

## Products Affected

- GAMMAGARD
- GAMMAGARD ERC
- GAMMAKED
- GAMUNEX-C

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary Immunodeficiency disease (PID), chronic inflammatory demyelinating polyneuropathy (CIDP), see RMI |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: [Gammaked]: Tried or contraindicated to [IV]: TWO agents: Gammagard S-D, Gammagard Liquid, Gammagard Liquid ERC, Gamunex-C, Octagam, Privigen. [SQ]: TWO agents: Gamunex-C, Gammagard Liquid, Gammagard Liquid ERC, Xembify. INITIAL: (A) SUBCUTANEOUS IMMUNOGLOBULIN: (1) Diagnosis of (1a) primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83) OR (1b) Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81). (B) INTRAVENOUS IMMUNOGLOBULIN: (1) Diagnosis of primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83) OR (2) Diagnosis of any of the following: Immune (idiopathic) thrombocytopenic purpura (ITP) (ICD-10 D69.3), Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81), Multifocal motor neuropathy (MMN) (ICD-10 G61.82),Kawasaki syndrome (ICD-10 M30.3), B-cell chronic lymphocytic leukemia (CLL) with hypogammaglobulinemia, Autoimmune hemolytic anemia (AIHA) (ICD-10 Group D59.1), Pure red cell aplasia (PRCA) (ICD-10 D61.01), Guillain-Barre syndrome (GBS) (ICD-10 G61.0), Myasthenia gravis (ICD-10 Group G70.0), Autoimmune Graves ophthalmopathy (ICD-10 E05.00), Cytomegalovirus-induced pneumonitis (ICD-10 B25.0) related to a solid organ transplant, Prevention of bacterial infection in an HIV-infected child, Reduction of secondary infections in pediatric HIV infections, Dermatomyositis or polymyositis (ICD-10 M36.0, Group M33), Autoimmune uveitis (birdshot retinochoroidopathy), Lambert-Eaton myasthenic syndrome (ICD-10 G70.80), IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy, SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | Stiff-man syndrome (ICD-10 G25.82), Neonatal sepsis (ICD-10 Group P36), Rotaviral enterocolitis (ICD-10 A08.0), Toxic shock syndrome (ICD-10 A48.3), Enteroviral meningoencephalitis (ICD-10 A87.0, A85.0), Toxic epidermal necrolysis (ICD-10 L51.2) or Stevens-Johnson syndrome (ICD-10 L51.1, L51.3), Autoimmune mucocutaneous blistering disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita). CONTINUING THERAPY FOR IVIG AND SCIG: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication. PA Automated. |

# INBRIJA

## Products Affected

- INBRIJA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Parkinsons disease (PD) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARKINSONS DISEASE (PD): (1) Diagnosis of PD AND (2) Inbrija is being used for intermittent treatment of OFF episodes associated with PD AND (3) Patient is currently being treated with carbidopa/levodopa AND (4) Patient is NOT currently taking more than 1600mg of levodopa per day AND (5) Prescriber has optimized drug therapy as evidenced by: Change in levodopa/carbidopa dosing strategy or formulation. CONTINUING THERAPY: (1) Patient is stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient had improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair). |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# INCRELEX

## Products Affected

- INCRELEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe IGF-1 deficiency, Growth hormone (GH) gene deletion |
| **Exclusion Criteria** | Used concurrently with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd]). |
| **Required Medical Information** | INITIAL: (A) IGF-1 DEFICIENCY OR GH GENE DELETION: (1a) Diagnosis of IGF-1 deficiency OR (1b) GH gene deletion AND neutralizing antibodies to GH AND (2) Height SD score is less than or equal to -3.0 AND (2) Basal IGF-1 SD score is less than or equal to -3.0 AND (3) Normal or elevated GH (greater than or equal to 10ng/mL to at least 2 stimuli [insulin, arginine, clonidine, or glucagon]) AND (4) Attestation that epiphyses are open. CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Increlex will not be used concurrently with another growth hormone medication AND (3) One of the following: (3a) Patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year OR (3b) Patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year. |
| **Age Restrictions** | 2 to less than 18 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or nephrologist. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# INFERTILITY MEDICATIONS

## Products Affected

- *cetrorelix acetate*
- CETROTIDE
- CLOMID
- *clomiphene citrate oral*
- ENDOMETRIN
- FOLLISTIM AQ
- FYREMADEL
- *ganirelix acetate*
- GONAL-F
- GONAL-F RFF REDIJECT
- MENOPUR
- MILOPHENE
- NOVAREL
- OVIDREL
- PREGNYL
- *progesterone vaginal*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Female infertility (ovulation induction, assisted reproductive technology (ART), etc.), male infertility (including induction of spermatogenesis), hypogonadotropic hypogonadism, cryptorchidism, crinone amenorrhea. Any other FDA approved indications or medically accepted indications. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [Follistim]: Gonal-F. [Pregnyl, chorionic gonadotropin]: Novarel or Ovidrel. [Fyremadel, Cetriotide]: cetrorelix or ganirelix. INITIAL: (A) ALL INDICATIONS: (1) Prescribed in accordance with FDA-approved labeling or a medically accepted indication AND (2) Fertility is NOT restricted from coverage under the patient's benefit. |
| **Age Restrictions** | [Fertility/ART]: 18 years of age or older. [All other indications]: Per package insert. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an [Fertility/ART]: infertility specialist or gynecologist. [All other indications]: None. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated. |

# INGREZZA

## Products Affected

- INGREZZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chorea associated with Huntingtons disease, Tardive dyskinesia. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHOREA ASSOCIATED WITH HUNTINGTONS DISEASE: INITIAL: (1) Documented diagnosis of Huntingtons disease AND (2) Presence of involuntary (choreiform) movements. B. TARDIVE DYSKINESIA (TD): INITIAL: (1) Prescriber attests to a documented diagnosis of moderate to severe tardive dyskinesia AND (2) The patients TD has been present for at least 3 months AND (3) The patient has a history of using antipsychotic medications (e.g., aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if the patient is 60 years of age or older) CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a movement disorder specialist, psychiatrist or neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# INJECTABLE CGRP ANTAGONIST

## Products Affected

- AIMOVIG
- AJOVY
- EMGALITY
- EMGALITY (300 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Preventive treatment of migraine in adults, treatment of episodic cluster headaches [EMGALITY ONLY] |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) PREVENTION OF MIGRAINES: (1a) Request is for preventative treatment of episodic migraines (0 to 14 headache days per month) OR (1b) Request for preventative treatment of chronic migraines (15 or more headache days per month) AND (2) Requested medication will not be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention AND (3a) Tried or contraindicated to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol OR (3b) [patients who meet the chronic migraine definition only] Patient has tried and failed Botox (onabotulinumtoxina). (B) [EMGALITY ONLY]: EPISODIC CLUSTER HEADACHE: (1) Diagnosis of episodic cluster headache. |
| **Age Restrictions** | [Ajovy]: 6 years of age or older. [Aimovig, Emgality]: 18 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND [PREVENTION]: (2) Requested medication will not be used concurrently with other CGRP inhibitors (e.g., Ajovy, Aimovig, Emgality, Vyepti, Qulipta) for migraine prevention AND (3) Patient has experienced a reduction in migraine or headache frequency of at least 2 days per month AND (4) Patient has experienced a reduction in |

| PA Criteria | Criteria Details |
| --- | --- |
| | migraine severity AND (5) patient has experienced a reduction in migraine duration. [CLUSTER]: (2) patient had improvement in episodic cluster headache frequency as compared to baseline. PA Automated |

# INSULIN DEVICES

## Products Affected

- MODD1 PATIENT WELCOME KIT
- MODD1 SUPPLY KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Diabetes mellitus (type 1 or type 2) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: CeQur, Omnipod 5, Omnipod DASH, V-Go, Twiist. INITIAL: (1) Diagnosis of diabetes mellitus (type 1 or type 2) AND (2) Patient has completed a comprehensive diabetes education program within the preceding 24 months AND (3) Patient follows a maintenance program of at least 3 injections of insulin per day and has required frequent self-adjustments of insulin dose for the past 6 months AND (4) Patient has required glucose self-testing of at least 4 times per day on average in the preceding 2 months AND (5) Patient is on a multiple daily insulin injection regimen AND (6) Meets one of the following (6a) Patient has a glycosylated hemoglobin level (HbA1c) that is greater than 7% (6b) Patient has a history of recurring hypoglycemia (6c) Patient has wide fluctuations in blood glucose before mealtime (6d) Patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL (6e) Patient has a history of severe glycemic excursions (sudden spikes in blood sugar levels) AND (7) If the request is more than 10 cartridges a month, Patient is using more than 300 units of insulin per 72 hours.<br><br>CONTINUING THERAPY: (1) Patient is stable on therapy AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# INSULIN PUMPS

## Products Affected

- *ilet insulin pump*
- MINIMED 780G INSULIN PUMP
- T:SLIM X2 BASAL-IQ PUMP
- T:SLIM X2 CONTROL-IQ 7.7 PUMP
- T:SLIM X2 CONTROL-IQ 7.8 PUMP
- T:SLIM X2 INSULIN PMP BASAL6.4
- T:SLIM X2 INSULIN PUMP
- TANDEM MOBI SYSTEM STARTER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Type 1 diabetes mellitus, Type 2 diabetes mellitus. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | NOTE: Prescription coverage of these products may vary and should be verified before review as coverage of this product may be provided through medical benefit, available manufacturer programs, or patient assistance programs for certain members.<br><br>INITIAL: (A) INSULIN PUMP: (1) Patient has completed a comprehensive diabetes education program within the preceding 24 months AND (2) Patient follows a maintenance program of at least 3 injections of insulin per day and requires frequent self-adjustments of insulin dose for the past 6 months AND (3) Patient requires glucose self-testing of at least 4 times per day on average in the preceding 2 months AND (4) Patient has NOT received an insulin pump within the last 4 years (Exception: pump is malfunctioning, not repairable, and not under warranty) AND (5) Patient meets ONE of the following (5a) Patients glycosylated hemoglobin level (HbA1c) is greater than 7% (5b) Patient has a history of recurring hypoglycemia (5c) Patient has wide fluctuations in blood glucose before mealtime (5d) Patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL (5e) Patient has a history of severe glycemic excursions (sudden spikes in blood sugar levels) AND (6) [Tandem Mobi]: (6a) Patient has type 1 diabetes mellitus OR (6b) Patient is 18 years of age or older and has type 2 diabetes mellitus. [MiniMed 670G, MiniMed 770G, MiniMed 780G, MiniMed 630G, iLet Bionic]: (6) Patient has type 1 diabetes mellitus. |
| **Age Restrictions** | [T: Slim X2 with Control-IQ, T: Slim X2, T: Slim X2 with Basal-IQ, iLet Bionic]: 6 years or older. [MiniMed 670G, MiniMed 780G]: 7 years of age or older. [Tandem Mobi, MiniMed 770G]: 2 years of age and older. [MiniMed 630G]: 14 years of age and older. |
| **Prescriber** | Prescribed by or in consultation with an endocrinologist |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | Initial: 1 month |
| **Other Criteria** | PA Automated |

# INZIRQO

## Products Affected

- INZIRQO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypertension, or edema associated with congestive heart failure, hepatic cirrhosis, or renal disease (including nephrotic syndrome) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HYPERTENSION / EDEMA: (1a) Diagnosis of hypertension OR (1b) Diagnosis of edema associated with congestive heart failure, hepatic cirrhosis, or renal disease (including nephrotic syndrome) AND (2) Patient is contraindicated or is unable to swallow hydrochlorothiazide tablets.CONTINUING THERAPY: Treat as Initial.RENEWAL: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# IQIRVO

## Products Affected

- IQIRVO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary Biliary Cholangitis (PBC) |
| **Exclusion Criteria** | Used concurrently with any other second-line PBC treatment (e.g., Livdelzi [seladelpar], Ocaliva [obeticholic acid]). |
| **Required Medical Information** | INITIAL: (A) PRIMARY BILIARY CHOLANGITIS (PBC): (1) Diagnosis of PBC confirmed by at least TWO of the following: (1a) Patient has an elevated alkaline phosphatase (ALP) level OR (1b) Patient has antimitochondrial antibodies (AMA) OR has other PBC-specific autoantibodies (including sp100 or gp210, if AMA is negative) OR (1c) Patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts AND (2) Patient does not have decompensated cirrhosis (Child-Pugh B or C) AND (3a) Iqirvo will be used as monotherapy in a patient who is unable to tolerate ursodiol (UDCA: ursodeoxycholic acid) OR (3b) Iqirvo will be used in combination with ursodiol (UDCA: ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (UDCA: ursodeoxycholic acid) monotherapy.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Iqirvo will NOT be used concurrently with any other second-line PBC treatment (e.g., Livdelzi, Ocaliva).<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has an alkaline phosphatase (ALP) level that is less than 1.67 times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Iqirvo AND (3) Iqirvo will NOT be used concurrently with any other second-line PBC treatment (e.g., Livdelzi, Ocaliva). |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or hepatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated |

# IRON OVERLOAD

## Products Affected

- *deferasirox*
- *deferasirox granules*
- *deferiprone*
- EXJADE
- FERRIPROX
- FERRIPROX TWICE-A-DAY
- JADENU
- JADENU SPRINKLE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic iron overload due to blood transfusions, chronic iron overload with non-transfusion dependent thalassemia syndromes, Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | Do not combine therapies with other iron chelation. DEFERASIROX ONLY: Estimated GFR less than 40 mL/min/1.73 m, patients with poor performance status, patients with high-risk myelodysplastic syndromes (MDS), patients with advanced malignancies, patients with platelet counts less than 50 x 10^9 /L |
| **Required Medical Information** | A.CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: INITIAL: (1) Prescriber attests to a diagnosis of chronic iron overload due to blood transfusions AND (2) Documentation that the patient has had a total transfusion burdenof at least 100 mL/kg of packed red blood cells per year (e.g., at least 20 units of packed red blood cells for a 40 kg person or more in individuals weighing more than 40 kg) OR (3) Documentation of serum ferritin consistently greater than 1000 mcg/L OR (4) Documentation of liver iron (Fe) concentration (LIC) of at least 3 mg per gram of dry weight AND (5) [FERRIPROX ONLY] Documentation of serum ferritin greater than 2,500 mcg/L while treated with other iron chelation therapy (deferoxamine, Exjade or Jadenu or contraindication to taking deferoxamine, Exjade or Jadenu) B. IRON OVERLOAD DUE TO NON-TRANSFUSIONAL-DEPENDENT THALASSEMIA (NTDT) SYNDROMES [EXJADE OR JADENU ONLY]: (1) Prescriber attests to a diagnosis of of iron overload due to non-transfusional-dependent thalassemia syndromes AND (2) Documentation of liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight OR (3) Documentation of serum ferritin greater than 800 mcg/L RENEWAL: Use initial criteria |
| **Age Restrictions** | DEFERASIROX TRANSFUSION IRON OVERLOAD: 2 years of age or older DEFERASIROX NTDT: 10 year of age or older DEFERIPRONE: 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with hematologist, hepatologist or oncologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# JAKAFI

## Products Affected

- JAKAFI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Intermediate or high-risk myelofibrosis (including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis), polycythemia vera, steroid-refractory acute graft-versus-host disease, chronic graft-versus-host disease (cGVHD) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) MYELOFIBROSIS: (1) Diagnosis of intermediate or high-risk myelofibrosis (including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis). (B) POLYCYTHEMIA VERA: (1) Diagnosis of polycythemia vera AND (2) Patient had a trial of or contraindication to hydroxyurea. (C)ACUTE GRAFT-VERSUS-HOST DISEASE: (1) Diagnosis of steroid-refractory acute graft-versus-host disease. (D) CHRONIC GRAFT-VERSUS-HOST DISEASE (cGVHD): (1) Diagnosis of cGVHD AND (2) Patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil) AND (3) Jakafi will NOT be used concurrently with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib). CONTINUING THERAPY: (1) Patient has been stable on therapy for 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (A) MYELOFIBROSIS: (1) Diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis AND (2) Patient shown symptom improvement by meeting ONE of the following criteria: (2a) Patient has had at least a 50 percent reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0) (2b) Patient has had at least a 50 percent reduction in palpable spleen length (2c) Patient has had a spleen volume reduction of at least 35 percent from baseline. |
| **Age Restrictions** | [Myelofibrosis, polycythemia vera]: 18 years of age and older, [acute or chronic graft-versus-host disease]: 12 years of age and older |
| **Prescriber** | None. |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# JASCAYD

## Products Affected

- JASCAYD

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Idiopathic pulmonary fibrosis (IPF), progressive pulmonary fibrosis (PPF). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [IPF]: ONE agent: Ofev, Esbriet. [PPF]: Ofev. INITIAL: (A) IDIOPATHIC PULMONARY FIBROSIS (IPF): (1) Diagnosis of IPF) AND (2) patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT AND (3) patient does NOT have other known causes of interstitial lung disease (ILD) (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, cancer). (B) PROGRESSIVE PULMONARY FIBROSIS (PPF): (1) Diagnosis of PPF AND (2) Patient has interstitial lung disease with a progressive phenotype (PF-ILD) AND (3) Patients lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities [e.g., infection, heart failure]) AND (4) Patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [IPF]: pulmonologist. [PPF]: pulmonologist or rheumatologist. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# JAVADIN

## Products Affected

- JAVADIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypertension. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HYPERTENSION: (1) Diagnosis of hypertension AND (2) Patient has a contraindication to or is unable to swallow clonidine tablets.<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# JOENJA

## Products Affected

- JOENJA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Activated phosphoinositide 3-kinase delta (PI3K?) syndrome (APDS) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACTIVATED PHOSPHOINOSITIDE 3-KINASE DELTA (PI3K?) SYNDROME (APDS): INITIAL: (1) Prescriber attests to a diagnosis of ADPS AND (2) Prescriber attests patient has a APDS/PASLI associated PIK3CD/PIK3R1 mutation AND (3) Prescriber attests patient is not using concurrently with immunosuppressive medication CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a pediatricians, immunologists, hematologists, oncologists, allergists |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automated |

# JOURNAVX

## Products Affected

- JOURNAVX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe acute pain |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ACUTE PAIN: Diagnosis of moderate to severe acute pain AND (2) Patient has NOT previously received treatment with Journavx. CONTINUING THERAPY / RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has previously received treatment with Journavx AND (3) Request for treatment of a new episode of acute pain. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 7 days, Renewal: 7 days |
| **Other Criteria** | PA Automated |

# JUXTAPID

## Products Affected

- JUXTAPID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Homozygous familial hypercholesterolemia (HoFH). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HoFH):(1) Diagnosis of HoFH AND (2) Patient has one of the following (2a) Simon Broome diagnostic criteria (definite) (2b) Dutch Lipid Network criteria with a score of at least 8 (2c) Clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL and either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents AND (3) Patient has an LDL-cholesterol level of at least 70 mg/dL while on maximally tolerated drug treatment AND (4) Tried or contraindicated to Zetia (ezetimibe) AND (5) One of the following: (5a) Patient is currently taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) AND (5a.i) Patient will continue taking statin treatment as described above in combination with Juxtapid (5b) Given that the patient cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), the patient is currently taking a maximally tolerated dose of any statin AND (5b.i) Patient will continue taking statin treatment as described above in combination with Juxtapid (5c) Patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction) (5d) Patient has complete statin intolerance (defined by severe and intolerable adverse effects) (e.g., creatine kinase elevation at least 10 times the upper limit of normal, liver function test elevation at least 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least TWO separate statins AND have improved with the discontinuation of each statin AND (6) Patient meets one of the following (6a) Tried or contraindicated to Repatha OR (6b) Patient lacks functioning LDL receptors |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Meets one of the following: (3a) Patient has continued concurrent therapy with a maximally tolerated dose of ANY statin OR (3b) Patient has an absolute contraindication to statin therapy OR (3c) Patient has complete statin intolerance.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patients low-density lipoprotein-cholesterol (LDL-C) level has decreased while on Juxtapid AND (3) Meets one of the following: (3a) Patient has continued concurrent therapy with a maximally tolerated dose of ANY statin OR (3b) Patient has an absolute contraindication to statin therapy OR (3c) Patient has complete statin intolerance. PA Automated. |

# JYNARQUE

## Products Affected

- JYNARQUE
- *tolvaptan tablet 15 mg oral*
- *tolvaptan tablet 30 mg oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Autosomal dominant polycystic kidney disease (ADPKD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD): (1) Diagnosis of ADPKD AND (2) Patient does NOT have end-stage renal disease (ESRD), including no renal transplantation or dialysis. CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has not progressed to end-stage renal disease (ESRD). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months. |
| **Other Criteria** | PA Automated |

# KALBITOR

## Products Affected

- KALBITOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Firazyr [icatibant]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Kalbitor will be used for treatment of acute attacks of hereditary angioedema AND (3) Patient meets one of the following (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Kalbitor will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a reduction in the severity or duration of HAE attacks AND (3) Kalbitor will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# KALYDECO

## Products Affected

- KALYDECO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis (CF). |
| **Exclusion Criteria** | Used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Required Medical Information** | A. INITIAL: CYSTIC FIBROSIS (CF): (1) Diagnosis of CF AND (2) Patient has a responsive mutation in the CFTR gene AND (3) Patient is NOT homozygous for the F508del mutation in the CFTR gene. CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor).RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in clinical status AND (3) Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Age Restrictions** | 1 month of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cystic fibrosis expert |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# KERENDIA

## Products Affected

- KERENDIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic kidney disease (CKD) associated with type 2 diabetes, heart failure. |
| **Exclusion Criteria** | [CKD]: None. [Heart failure]: Used concurrently with another mineralocorticoid (aldosterone) receptor antagonist (MRA) (e.g., spironolactone, eplerenone). |
| **Required Medical Information** | INITIAL: (A) CHRONIC KIDNEY DISEASE (CKD) ASSOCIATED WITH TYPE 2 DIABETES: (1) Diagnosis of CKD associated type 2 diabetes AND (2) Patient has a history of and will continue on, or has a contraindication to, an angiotensin converting enzyme inhibitor (ACE-I: e.g., benazepril, lisinopril) or an angiotensin receptor blocker (ARB: e.g., losartan, valsartan)AND (3) Patient has trial of or contraindication to a sodium-glucose co-transporter -2 inhibitor (SGLT2i: e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]). (B) HEART FAILURE: (1) Diagnosis of heart failure AND (2) Patient has New York Heart Association (NYHA) Class II-IV AND (3) Patient has a left ventricular ejection fraction (LVEF) of at least 40% that is not due to an underlying cause (e.g., infiltrative cardiomyopathy, hypertrophic cardiomyopathy, valvular disease, pericardial disease, high-output heart failure) AND (4) Patient is NOT diagnosis with type 2 diabetes with CKD, tried or contraindicated to ONE mineralocorticoid (aldosterone) receptor antagonist (MRA) (e.g., spironolactone). CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND [HEART FAILURE]: (3) Patient has a left ventricular ejection fraction (LVEF) of at least 40% AND (4) Kerendia will NOT be used concurrently with another mineralocorticoid (aldosterone) receptor antagonist (MRA). RENEWAL: (1) Diagnosis of approvable indication AND [HEART FAILURE]: (2) Patient has a left ventricular ejection fraction (LVEF) of at least 40% AND (3) Kerendia will NOT be used concurrently with another mineralocorticoid (aldosterone) receptor antagonist (MRA). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [HEART FAILURE]: cardiologist. [CKD]: None. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# KESIMPTA

## Products Affected

- KESIMPTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS), SECONDARY PROGRESSIVE (SPMS), CLINICALLY ISOLATED (CI) INITIAL: (1) Patient has a diagnosis of multiple sclerosis (i.e. RRMS, SPMS,CI) CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# KEVZARA

## Products Affected

- KEVZARA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid arthritis (RA), Polymyalgia rheumatica (PMR), Polyarticular juvenile idiopathic arthritis (PJIA). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT [RA]: TRIED OR CONTRAINDICATED TO TWO AGENTS: ADALIMUMAB (-ADAZ, HUMIRA, SIMLANDI), ENBREL, RINVOQ TAB, OR XELJANZ (XR) (TRIED A TNF PRIOR TO RINVOQ/XELJANZ). [PJIA]: TRIED OR CONTRAINDICATED TO TWO AGENTS: ADALIMUMAB (-ADAZ, HUMIRA, SIMLANDI), ENBREL, RINVOQ LQ, OR XELJANZ (TRIED A TNF PRIOR TO RINVOQ/XELJANZ). INITIAL: (A) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Patient had a trial of or contraindication to at least 3 months of treatment with one conventional synthetic DMARD (disease-modifying antirheumatic drug) such as methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, or sulfasalazine AND (3) Patient meet preferred product requirements in step alert OR (3a) Patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events. (B) POLYMYALGIA RHEUMATICA (PMR): (1) Diagnosis of PMR AND (2) Patient had an inadequate response to corticosteroids (e.g., prednisone) or cannot tolerate a corticosteroid taper. (C) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA AND (2) Patient weighs at least 63 kg (138 lbs.). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Patient will not take another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. SEE OTHER CRITERIA |
| **Age Restrictions** | [RA, PMR]: 18 years of age or older. [PJIA]: None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | RENEWAL: [PMR]: (1) Refer to initial. [RA/PJIA]: (1) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy AND (2) Patient will not take another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. PA Automated |

# KINERET

## Products Affected

- KINERET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cryopyrin-associated periodic syndromes (CAPS) - neonatal-onset multisystem inflammatory disease NOMID, Deficiency of interleukin-1 receptor antagonist (DIRA), Rheumatoid arthritis (RA) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the same indication |
| **Required Medical Information** | STEP ALERT [RA]: TRIED OR CONTRAINDICATED TO TWO AGENTS: ADALIMUMAB (-ADAZ, HUMIRA, SIMLANDI), ENBREL, RINVOQ TAB, OR XELJANZ (XR) (TRIED A TNF PRIOR TO RINVOQ/XELJANZ). A. RHEUMATOID ARTHRITIS (RA): INITIAL : (1) Diagnosis of moderate to severe RA AND (2) Patient trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine AND (3a) Meets step requirements OR (3b) tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events. B. DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA): INITIAL: (1) Diagnosis of DIRA AND (2) Genetic testing for gain-of-function mutations in the IL1RN gene OR has inflammatory markers (i.e., elevated CRP, ESR) AND (3) Patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis) C. NOMID - Cryopyrin-Associated Periodic Syndromes (CAPS): INITIAL: (1) Diagnosis of cryopyrin-associated periodic syndromes (CAPS) including neonatal-onset multisystem inflammatory disease AND (2) Genetic testing for gain-of-function mutations in the NLRP3 gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins) AND (3) Patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities. SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | RA: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | D. COVID-19: Coverage for treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult is ineligible under the prescription benefit. CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of an approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND Kineret will not be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the same indication. RENEWAL: [CAPS-NOMID, DIRA]: Refer to initial. [RA]: (1) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy AND (2) Kineret will not be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the same indication. PA Automated |

# KORLYM

## Products Affected

- KORLYM
- *mifepristone tablet 300 mg oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hyperglycemia secondary to hypercortisolim in adult patients with endogenous Cushings syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Pregnancy, concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses (eg, immunosuppression after organ transplantation), women with a history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma |
| **Required Medical Information** | A. HYPERGLYCEMIA- INITIAL : (1) Patient has a diagnosis of Cushings syndrome AND (2) Patient has secondary type 2 diabetes or glucose intolerance AND(3) Patient has failed surgery or is not a candidate for surgery RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria AND has improvement in glucose tolerance or stabilization of glucose tolerance. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# KOSELUGO

## Products Affected

- KOSELUGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Neurofibromatosis type 1 (NF1). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) NEUROFIBROMATOSIS TYPE 1 (NF1): (1) Diagnosis of NF1 AND (2) Patient has symptomatic, inoperable plexiform neurofibromas (PN). CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | 1 to 17 years of age. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# LANREOTIDE

## Products Affected

- *lanreotide acetate*
- SOMATULINE DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly, gastroenteropancreatic neuroendocrine tumors (GEP-NETs), carcinoid syndrome. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [Acromegaly]: Sandostatin LAR Depot (octreotide acetate ER). INITIAL: (A) ACROMEGALY: (1) Diagnosis of acromegaly AND (2) Patient had an inadequate response to or cannot be treated with surgery or radiation therapy AND (3) Patients serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patients age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load. (B) GASTROENTEROPANCREATIC NEUROENDOCRINE TUMORS (GEP-NETs): (1) Diagnosis of GEP-NETs AND (2) Patient has unresectable, well or moderately differentiated, locally advanced or metastatic GEP-NETs. (C) CARCINOID SYNDROME: (1) Diagnosis of carcinoid syndrome.<br><br>CONTINUING THERAPY: [GEP-NETs]: Treat as Initial. (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND [Acromegaly]: (3) Diagnosis confirmed by appropriate specialist.<br><br>RENEWAL: [GEP-NETs, Carcinoid]: Treat as Initial. [Acromegaly]: (1) Diagnosis of approvable indication AND (2) Patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender AND (3) Patient has shown improvement or has sustained remission of clinical symptoms of acromegaly. |
| **Age Restrictions** | [Acromegaly]: None. [GEP-NETs, Carcinoid]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an [Acromegaly]: endocrinologist. [GEP-NETs, Carcinoid]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# LASIX ONYU

## Products Affected

- LASIX ONYU

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Edema with chronic heart failure |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) EDEMA WITH CHRONIC HEART FAILURE (1) Diagnosis of edema with chronic heart failure. CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or nephrologist. |
| **Coverage Duration** | Initial: 1 month |
| **Other Criteria** | PA Automated. |

# LEMTRADA

## Products Affected

- LEMTRADA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing form of multiple sclerosis (MS), including relapsing-remitting disease or active secondary progressive disease. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to Kesimpta INITIAL: (A) MULTIPLE SCLEROSIS (MS): (1) Diagnosis of a relapsing form of MS to include relapsing-remitting disease or active secondary progressive disease.<br>CONTINUING THERAPY: (1) Patient has been previously treated with Lemtrada AND (2) Diagnosis of approvable indication AND (3) At least 12 months have elapsed since the patient received the most recent course of Lemtrada.<br>RENEWAL: (1) Diagnosis of approvable indication AND [Lemtrada]: (2) At least 12 months have elapsed since the patient received the most recent course of Lemtrada. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# LEQEMBI

## Products Affected

- LEQEMBI IQLIK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Alzheimers disease. |
| **Exclusion Criteria** | Concurrently using any anticoagulant or antiplatelet therapy (e.g., Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less. |
| **Required Medical Information** | INITIAL: (A) ALZHEIMERS DISEASE: (1) Diagnosis of Alzheimers disease AND (2) Patient has mild cognitive impairment or mild dementia AND (3) Presence of amyloid-beta plaques AND (4) Patient has a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE) score of 22-30 AND (5) Patient had a baseline brain MRI within one year prior to treatment AND (6) Patient does NOT have a history of a clotting disorder. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has mild cognitive impairment or mild dementia AND (4) Patient is NOT experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA) AND (5) Patient is NOT concurrently using any anticoagulant or antiplatelet therapy, except for aspirin at 81 mg daily or less. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has mild cognitive impairment or mild dementia AND (3) Patients cognitive decline has slowed or stopped AND (4) Patient is NOT experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA) AND (5) Patient is NOT concurrently using any anticoagulant or antiplatelet therapy, except for aspirin at 81 mg daily or less. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, geriatrician, or psychiatrist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# LEQSELVI

## Products Affected

- LEQSELVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Alopecia areata (AA). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Litfulo (ritlecitinib)], PDE-4 inhibitor) for the treatment of alopecia areata. |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO LITFULO AND OLUMIANT. INITIAL: (A) ALOPECIA AREATA (AA): (1) Diagnosis of severe AA AND (2) Patient has had at least 50% scalp hair loss, as measured by the Severity of Alopecia Tool (SALT), for more than 6 months AND (3) Tried or contraindicated to TWO of the following (from different categories): (3a) Intralesional corticosteroid (e.g., triamcinolone acetonide), (3b) Topical corticosteroid (e.g., fluocinolone acetonide, betamethasone dipropionate, clobetasol propionate), (3c) Minoxidil (e.g., minoxidil 5% solution), (3d) Short contact anthralin, (3e) Topical immunotherapy (e.g., squaric acid dibutyl ester, diphencyprone/diphenylcyclopropenone), (3f) Systemic treatments (e.g., psoralen plus UV-A [PUVA], prednisone, cyclosporine, methotrexate). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Leqselvi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of alopecia areata. RENEWAL: (1) Diagnosis of approvable indication AND (2) Leqselvi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of alopecia areata AND (3) Patient has had improvement while on therapy (e.g., scalp hair coverage). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# LEQVIO

## Products Affected

- LEQVIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C), Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | FORMULARY ALERT: TRIED, FAILED OR INTOLERANT TO PRIMARY TREATMENT REPATHA PRIOR TO PRAULENT, LEQVIOA. HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HEFH) INITIAL: (1) Prescriber attests to a diagnosis of HeFH by ONE of the following: (1a) Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or 1/LDLRAP1 gene OR (1b) History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment) OR (1c) Clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma) OR (1d) Definite or possible familial hypercholesterolemia as defined by the Simon Broome criteria OR (1e) A Dutch Lipid Clinic Network Criteria score of greater than 5 OR (1f) Patient has a treated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 100 mg/dL after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy AND (2) Prescriber attests patient meets ONE of the following: (2a) Currently taking a maximally tolerated statin or at least 8 weeks AND one of the following: (i) LDL-C level after treatment remains greater than or equal to 70 mg/dL OR (ii) Has not achieved a 50% reduction in LDL-C from baseline after treatment OR (iii) If the patient has ASCVD, patient's non-HDL-C level after treatment remains greater than or equal to 100 mg/dL OR (2b) CK >50x ULN related to statin therapy OR (2c) Intolerance, hypersensitivity or contraindication rosuvastatin and atorvastatin AND at least one other statin (approximate dates and doses must be provided) OR (2d) Patient is currently taking maximally tolerated dose of statin (may be low-moderate intensity statin or alternative dosing) for at least 12 weeks |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by, or in conjunction with, a cardiologist, endocrinologist, or lipid specialist |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | B. ESTABLISHED CARDIOVASCULAR DISEASE (CVD): INITIAL: (1) Prescriber attests patient has ONE of the following: (1a) Ischemic heart disease or coronary artery disease (e.g. buildup of plaque in heart or arteries, heart attack, angina, percutaneous coronary intervention (stent placement), coronary artery bypass graft (CABG), etc.) OR (1b) Cerebrovascular disease (e.g. stroke) OR (1c) Peripheral artery disease from an atherosclerotic origin OR (1d) Congenital heart disease OR (1e) Rheumatic heart disease OR (1f) Cardiomyopathies OR (1g) Cardiac arrhythmias AND (2) Prescriber attests patient meets ONE of the following: (2a) Currently taking a maximally tolerated statin 8 weeks AND one of the following: (i) LDL-C level after treatment remains greater than or equal to 70 mg/dL OR (ii) Has not achieved a 50% reduction in LDL-C from baseline after treatment OR (iii) If the patient has ASCVD, patient's non-HDL-C level after treatment remains greater than or equal to 100 mg/dL OR (2b) CK >50x ULN related to statin therapy OR (2c) Intolerance, hypersensitivity or contraindication to rosuvastatin and atorvastatin C. PRIMARY HYPERLIPIDEMIA: INITIAL: (1) Prescriber attests patient has a diagnosis of primary hyperlipidemia AND (2) Prescriber attests patient has ONE of the following: (2a) A coronary artery calcium or calcification (CAC) score greater than or equal to 300 Agatston units OR (2b) A baseline LDL-C level greater than or equal to 220 mg/dL and currently receiving a maximally tolerated statin and ezetimibe AND (3) Precriber attests patient meets ONE of the following: (3a) Currently taking a maximally tolerated statin for 8 weeks AND one of the following: (i) LDL-C level after treatment remains greater than or equal to 70 mg/dL OR (ii) Has not achieved a 50% reduction in LDL-C from baseline after treatment OR (iii) If the patient has ASCVD, patient's non-HDL-C level after treatment remains greater than or equal to 100 mg/dL OR (3b) CK >50x ULN related to statin therapy OR (3c) Intolerance, hypersensitivity or contraindication to rosuvastatin and atorvastatin RENEWAL FOR ALL INDICATIONS: (1) Patient is tolerating the medication AND (2) Prescriber attests that patient will continue to be used in combination with a maximally tolerated statin or is statin intolerant demonstrated. PA Automated |

# LETAIRIS

## Products Affected

- *ambrisentan*
- LETAIRIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) Patient does NOT have idiopathic pulmonary fibrosis (IPF) AND (3) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (4) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (5) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUATION OF THERAPY: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# LEUKINE

## Products Affected

- LEUKINE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute myeloid leukemia (AML), mobilization of hematopoietic progenitor cells, non-Hodgkin?s lymphoma (NHL), acute lymphoblastic leukemia (ALL), Hodgkin?s lymphoma, bone marrow transplantation, hematopoietic syndrome of acute radiation syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | ALERT: IF REQUEST IS FROM A HEMATOLOGIST OR ONCOLOGIST, APPROVE. A. FOR ALL INDICATIONS: (1a) To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND (1b) Patient is 55 years of age or older OR (2a) Mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND (1b) Patient is 18 years of age or older OR (3a) Acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND (3b) Patient is 2 years of age or older OR (4a) Acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND (4b) Patient is 2 years of age or older OR (5a) Treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND (5b) Patient is 2 years of age or older OR (6a) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication RENEWAL: Treat as initial |
| **Age Restrictions** | See RMI |
| **Prescriber Restrictions** | None |
| **Coverage** | 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Duration** | |
| **Other Criteria** | PA Automated |

# LEUPROLIDE ACETATE

## Products Affected

- CAMCEVI
- FENSOLVI (6 MONTH)
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH)
- LUPRON DEPOT-PED (3-MONTH)
- LUPRON DEPOT-PED (6-MONTH)
- LUTRATE DEPOT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Central precocious puberty (Lupron Depot-Ped only), treatment of advanced prostate cancer, breast cancer, endometriosis, uterine leiomyomata (fibroids), gender transition related treatment, female infertility or assisted reproductive technology (ART), medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Pregnancy, lactation, undiagnosed abnormal vaginal bleeding |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [CCP]: ONE agent: Lupron Depot-PED 6, Lupron Depot-PED (3-month) or Lupron Depot-PED (1-month) prior to Fensolvi, Triptodur. [PROSTATE CANCER]: ALL agents: Eligard, leuprolide acetate, AND Lupron Depot prior to Camcevi. INITIAL: (A) CENTRAL PRECOCIOUS PUBERTY (CPP) (1) Diagnosis of CCP AND (2) Patient at the time of onset of CPP was younger than 8 years of age (if female) or younger than 9 years of age (if male) AND (3a) For females: patient has elevated levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis OR (3b) For Males: patient has elevated levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis AND (4a) For females: patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above) OR (4b) For males: patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above). RENEWAL: (1) Diagnosis of approvable indication AND (2) Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year AND (2) Patient has NOT reached the actual age which corresponds to their current pubertal age. (B) UTERINE LEIOMYOMATA (FIBROIDS): (1) Diagnosis of uterine leiomyomata (fibroids) AND (2) Patient has an estimated date of surgery within 3 months AND (3) Patient |

| PA Criteria | Criteria Details |
|---|---|
| | is concurrently taking iron therapy SEE OTHER CRITERIA |
| **Age Restrictions** | Endometriosis/Uterine Leiomyomata/Infertility or ART: females greater than or equal to 18 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, oncologist, or gynecologist, Gender transition related treatment: None, Infertility or ART: infertility specialist or gynecologist |
| **Coverage Duration** | Based on indication. Please see Other Criteria section for Coverage Duration. |
| **Other Criteria** | (C) ENDOMETRIOSIS (1) Diagnosis of endometriosis AND (2a) First treatment course with leuprolide OR (2b) Retreatment with leuprolide AND (i) Patient is taking concomitant norethindrone 5 mg daily AND (ii) Patient has a normal bone mineral density AND (iii) Patient has not exceeded a total of two six month treatment cycles per lifetime of any leuprolide containing medication for the treatment of endometriosis (D) ADVANCED PROSTATE CANCER OR BREAST CANCER: (1) Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1, 2a, 2b only) and Clinical Pharmacology (strong recommendation) AND (2) Documentation of dose and dates of all previous therapies and the resulting outcomes AND (3) Documentation that the proper succession of the therapies have been tried and failed (i.e. intolerance, contraindication, or progression) AND (4) Chart notes detailing the members current clinical status AND (5) Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment AND NOTE: For stage four advanced metastatic cancer, members are not required to step through other treatment options prior to requested therapy. RENEWAL: (1) Diagnosis of approvable indication AND (2) Current chart notes detailing response and adherence to therapy AND (3) Documented clinically significant improvements in the disease state and stability on the medication (E) GENDER TRANSITION RELATED TREATMENT: (1) The request is for use in gender dysphoria and gender dysphoria is not restricted from coverage under the patient's benefit AND (2) Prescriber attests a diagnosis of persistent gender dysphoria has been confirmed by a mental health professional AND (3) Prescriber attests patient does not have any medical contraindications to sex hormone treatment. RENEWAL: (1) Diagnosis of approvable indication AND (2) Prescriber attests hormone replacement therapy is |

| PA Criteria | Criteria Details |
| --- | --- |
| | better aligning the persons gender identity AND (3) Prescriber attests to at least annual monitoring of sex steroid hormone levels AND (4) Patient has not developed any contraindications as a result of hormone replacement (F) INFERTILITY OR ART: (1) Diagnosis of infertility AND (2) Prescriber attests that leuprolide will be used as part of an ART protocol AND (3) No exclusions to therapy (please verify plan design for fertility exclusion) **this prior authorization does not apply to leuprolide acetate 1mg/0.2ml daily injection kits. COVERAGE DURATION: Endometriosis: initial/renewal: 6 months, recommended duration of continuous therapy is limited to a total of 12 months, Uterine leiomyomata (fibroids): up to 6 months total, All other indications: Initial/renewal: 12 months. PA Automated |

# LITFULO

## Products Affected

- LITFULO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Alopecia areata (AA) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Olumiant (baricitinib)], PDE-4 inhibitor) for the treatment of alopecia areata |
| **Required Medical Information** | INITIAL: (A) ALOPECIA AREATA (AA): (1) Diagnosis of severe AA AND (2) Patient has experienced at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for at least 6 months. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Patient will not take another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor for the treatment of alopecia areata. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient will not take another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of alopecia areata AND (3) Patient has shown improvement while on therapy (e.g., scalp hair coverage). |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automated |

# LIVMARLI

## Products Affected

- LIVMARLI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pruritus associated with progressive familial intrahepatic cholestasis (PFIC), Alagille syndrome (ALGS) with cholestatic pruritus |
| **Exclusion Criteria** | Concurrent use with another IBAT inhibitor (such as Bylvay) |
| **Required Medical Information** | A. INITIAL: PROGRESSIVE FAMILIAL INTRAHEPATIC CHOLESTASIS (PFIC) (1) Prescriber attests patient has a diagnosis of PFIC with pruritis AND (2) If the patient is 12 months of age or older, the patient must have had a trial of or contraindication to preferred agent: Bylvay.B.INITIAL: ALAGILLE SYNDROME (ALGS) (1) Prescriber attests patient has a diagnosis of ALGS with cholestatic pruritis AND (2) If the patient is 12 months of age or older, the patient must have had a trial of or contraindication to preferred agent: Bylvay.CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been on therapy for 30 days AND (3) Prescriber attests LIVMARLI will not be used with another IBAT inhibitor (such as Bylvay) RENEWAL: (1) Diagnosis of approvable indication AND (2) Prescriber attests LIVMARLI will not be used with another IBAT inhibitor (such as Bylvay) AND (3) For PFIC prescriber attests the patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline AND patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) OR (4) For ALGS prescriber attests the patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline |
| **Age Restrictions** | PFIC: 12 months of age and older ALGS: 3 months of age and older |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a hepatologist, gastroenterologist, or physician who specializes in PFIC cholestasis or ALGS cholestasis |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# LIVTENCITY

## Products Affected

- LIVTENCITY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Post-transplant cytomegalovirus (CMV) infection. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: CYTOMEGALOVIRUS (CMV): (1) Diagnosis of a post-transplant CMV infection AND (2) The infection is refractory to prior therapy with ganciclovir, valganciclovir, cidofovir, or foscarnet.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a transplant specialist or infectious disease specialist. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# LODOCO

## Products Affected

- LODOCO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | To reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease |
| **Exclusion Criteria** | Pre-existing blood dyscrasias, renal failure and severe hepatic impairment |
| **Required Medical Information** | A. CARDIOVASCULAR DISEASE (CVD): INITIAL: (1) Prescriber attests patient has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) or has at least two risk factors for cardiovascular disease (such as diabetes, hyperlipidemia, hypertension, obesity, smoking) AND (2) Prescriber attests patient meets ONE of the following: (2a) Currently taking a maximally tolerated statin OR (2b) CK >50x ULN related to statin therapy OR (2c) Intolerance, hypersensitivity or contraindication all statins AND (3) Prescriber attests patient is unable to tolerate generic colchicine 0.6 mg CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 90 days AND (3) Patient is currently receiving standard therapy with a lipid lowering agent unless contraindicated or not tolerated |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automated |

# LOPRESSOR

## Products Affected

- LOPRESSOR ORAL SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | None. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) Patient is contraindicated to or is unable to swallow metoprolol tartrate tabletsCONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# LUMRYZ

## Products Affected

- LUMRYZ
- LUMRYZ STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cataplexy with narcolepsy, excessive daytime sleepiness (EDS) with narcolepsy. |
| **Exclusion Criteria** | Used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to generic sodium oxybate. INITIAL: (A) EXCESSIVE DAYTIME SLEEPINESS (EDS) WITH NARCOLEPSY: (1) Diagnosis of EDS with narcolepsy (2) Diagnosis confirmed by one of the following: (2a) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least two early-onset REM sleep periods (SOREMPs) OR (2b) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [Note to Pharmacist: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals] OR (2c) Patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay AND (3) Patient has EDS persisting for at least 3 months AND (4) Patient has an Epworth Sleepiness Scale (ESS) score of greater than 10 AND (5) Tried or contraindicated to a generic typical stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate) AND (6) Patient is 18 years of age or older AND tried or contraindicated to armodafinil (Nuvigil) OR modafinil (Provigil). (B) CATAPLEXY WITH NARCOLEPSY: (1) Diagnosis of cataplexy with narcolepsy AND (2) Tried TWO of the following: venlafaxine, fluoxetine, TCA (tricyclic antidepressant, e.g., amitriptyline, clomipramine, imipramine). |
| **Age Restrictions** | 7 years of age or older. |
| **Prescriber** | Prescribed by or in consultation with a neurologist, psychiatrist, or |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | specialist in sleep medicine. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Lumryz will NOT be used concurrently with a sedative hypnotic agent AND (4) Meets one of the following: [CATAPLEXY]: (4) Demonstrated improvement of cataplexy symptoms compared to baseline. [EDS]: (4a) Maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline OR (4b) Demonstrated improvement in sleep latency compared to baseline. PA Automation |

# LUPKYNIS

## Products Affected

- LUPKYNIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Active lupus nephritis (LN) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A. LUPUS NEPHRITIS: INITIAL: (1) Diagnosis active lupus nephritis AND (2) Requested medication will be used in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil, corticosteroids). CONTINUATION OF THERAPY: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by an appropriate specialist RENEWAL: [LUPUS NEPHRITIS]: Patient has improvement in renal response from baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid use) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist or nephrologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# LYNKUET

## Products Affected

- LYNKUET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Menopausal vasomotor symptoms (VMS). |
| **Exclusion Criteria** | Used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (e.g., Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) agent for VMS. |
| **Required Medical Information** | INITIAL: (A) MENOPAUSAL VASOMOTOR SYMPTOMS (VMS): (1) Diagnosis of moderate to severe VMS AND (2) Patient experiences at least 7 hot flashes per day AND (3) Tried or contraindicated to the clinical standard of care agent: hormonal therapy (e.g., estradiol transdermal patch [e.g., Minivelle, Climara], oral conjugated estrogens [e.g., Premarin], micronized progesterone [e.g., Prometrium]). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Lynkuet will NOT be used concurrently with another hormonal or non-hormonal agent for VMS. RENEWAL: (1) Diagnosis of approvable indication AND (2) Lynkuet will NOT be used concurrently with another hormonal or non-hormonal agent for VMS AND (3) Patient has a continued need for VMS treatment (persistently symptomatic with hot flashes) AND (4) Patient has had a reduction in VMS frequency or severity due to Lynkuet treatment. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# MAVENCLAD

## Products Affected

- *cladribine (10 tabs)*
- *cladribine (4 tabs)*
- *cladribine (5 tabs)*
- *cladribine (6 tabs)*
- *cladribine (7 tabs)*
- *cladribine (8 tabs)*
- *cladribine (9 tabs)*
- MAVENCLAD (10 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)
- MAVENCLAD (7 TABS)
- MAVENCLAD (8 TABS)
- MAVENCLAD (9 TABS)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing forms of Multiple Sclerosis (MS), including Relapsing-remitting disease (RRMS), active secondary progressive disease (SPMS) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TREATMENT FOR ALL INDICATIONS: INTIAL: (1) Patient has a relapsing form of MS. CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has NOT received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses) RENEWAL: (1) Patient has demonstrated a clinical benefit compared to pre-treatment baseline AND (2) Patient does not have lymphopenia AND (3) Has not received a total of two years of treatment with Mavenclad. ONLY 2 COURSE PER LIFETIME MAY BE AUTHORIZED. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial/Renewal: 48 weeks |
| **Other Criteria** | No PA Automation |

# MAVYRET

## Products Affected

- MAVYRET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic hepatitis, genotype (GT) 1, 2,3,4,5, or 6 |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.CHRONIC HEPATITIS C GT 1, 2, 3, 4, 5 or 6: (1) Must have a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5, or 6. AND (2) Must provide HCV RNA level dated within last 6 months AND (3) Patient does not meet the following: (3a) The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions, (3b) The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C), (3c) Mavyret will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. Johns wort), (3d) Mavyret will be used concurrently with Epclusa, Harvoni (ledipasvir/sofosbuvir), Vosevi, or Zepatier AND (4) The patient treatment-na?ve and meets ONE of the following criteria: (5a) patient does not have cirrhosis (5b) patient has compensated cirrhosis (Child-Pugh A) OR (6) patient treatment-naive and meets ONE of the following criteria: (6a) post-liver transplant or post-kidney transplant OR (6b) patient treatment-experienced and meets ALL of the following criteria: (7a) patient is less than 18 years of age, (7b) patient is interferon-experienced OR (8) patient treatment-experienced and meets ALL of the following criteria: (8a) patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age, (8b) patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis, (8c) patient has prior treatment experience with an NS5A inhibitor, Epclusa, (8d) patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio, Zepatier) OR SEE OTHER CRITERIA |
| **Age Restrictions** | 3 years of age or older |
| **Prescriber** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | 8 -16 weeks, SEE OTHER CRITERIA |
| **Other Criteria** | (9) patient treatment-experienced and meets ONE of the following criteria: (9a) patient has failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (e.g., Epclusa, Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir]), (9b) patient has previously failed Mavyret AND Mavyret will be used with Sovaldi and ribavirin, (9c) patient has previously failed Vosevi AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin (9d) Patient is less than 18 years of age, has genotype 3, AND is interferon-experienced OR (10) patient is treatment-experienced and meets ALL of the following criteria: (10a) patient has genotype 1, 2, 4, 5, or 6, (10b) patient does not have cirrhosis (10c) patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (10d) patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio, Zepatier) or an NS5A inhibitor (e.g., Harvoni, Epclusa ) OR (11) Patient treatment-experienced and meets ALL of the following criteria: (11a) patient has genotype 1, 2, 4, 5, or 6, (11b) patient has compensated cirrhosis (Child-Pugh A), (11c) patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi, (11d) The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio, Zepatier) or an NS5A inhibitor (e.g., Harvoni, Epclusa) OR (12) patient treatment-experienced and meets ALL of the following criteria: (12a) patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age, (12b) patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis (12c) patient has prior treatment experience with an NS3/4A protease inhibitor, (12d) The patient has NO prior treatment experience with an NS5A inhibitor (e.g., Harvoni, Epclusa) OR (13) Patient treatment-experienced and meets ALL of the following criteria: (13a) genotype 3, (13b) patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis, (13c) patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi, (13d) patient has NO prior treatment experience with an NS3/4A protease inhibitor or an NS5A inhibitor OR (14) The patient does meet a condition as specified above but the requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.Duration of approval is based on recommendations by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.No PA Automation |

# MAYZENT

## Products Affected

- MAYZENT
- MAYZENT STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing forms of Multiple Sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease. |
| **Exclusion Criteria** | CYP2C9*3/*3 genotype, Within the last 6 months, experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure, A presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, or sick sinus syndrome, unless the patient has a functioning pacemaker. |
| **Required Medical Information** | INITIAL: (A) MULTIPLE SCLEROSIS (MS): (1) Diagnosis of a relapsing form of MS, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease AND (2) Patient has one of the following: (2a) CYP2C9 *1/*1, *1/*2, or *2/*2 genotype OR (2b) CYP2C9 *1/*3 or *2/*3 genotype.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has one of the following: (3a) CYP2C9 *1/*1, *1/*2, or *2/*2 genotype OR (3b) CYP2C9 *1/*3 or *2/*3 genotype. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# MIGLUSTAT

## Products Affected

- *miglustat*
- YARGESA
- ZAVESCA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Type 1 Gaucher disease, Niemann-Pick disease type C |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. TYPE 1 GAUCHERS DISEASE: INITIAL: (1) Diagnosis of mild to moderate type 1 Gauchers disease AND (2) Requested medication will be used as monotherapy AND (3) Enzyme replacement therapy is not a therapeutic option for this patient (e.g., due to allergy, hypersensitivity, poor venous access). B. NIEMANN-PICK DISEASE TYPE C (NPC): INITIAL: (1) Diagnosis of NPC AND Requested medication will be used in combination with Miplyffa (arimoclomol). CONTINUATION OF THERAPY/RENEWAL: Treat as initial |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# MIPLYFFA

## Products Affected

- MIPLYFFA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Niemann-Pick disease type C (NPC) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NITIAL: NIEMANN-PICK DISEASE TYPE C (1) Diagnosis of Niemann-Pick disease type C (NPC) AND (2) Miplyffa will be used in combination with miglustat (Zavesca).CONTINUATION OF THERAPY/RENEWAL: (1) Patient has been on therapy for 90 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Patient has experienced improvement or a slowing of disease progression. |
| **Age Restrictions** | Patient is 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a geneticist or neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal:  12 months |
| **Other Criteria** | None |

# MOTPOLY XR

## Products Affected

- MOTPOLY XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Partial-onset seizures, primary generalized tonic-clonic seizures. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARTIAL-ONSET SEIZURES: (1) Diagnosis of partial-onset seizures AND (2) Patient weighs at least 50 kg (110 lbs) AND (3) Tried or contraindicated to THREE generic antiepileptic medications (e.g., carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate, lamotrigine) AND (4) Patient is unable to tolerate lacosamide IR. (B) TONIC-CLONIC SEIZURES: (1) Diagnosis of primary generalized tonic-clonic seizures AND (2) Patient weighs at least 50 kg (110 lbs) AND (3) Tried or contraindicated to THREE generic antiepileptic medications (e.g., carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate, lamotrigine) AND (4) Patient is unable to tolerate lacosamide IR AND (5) Motpoly XR will be used as adjunctive treatment.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br>RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# MS AGENTS

## Products Affected

- AUBAGIO
- AVONEX PEN
- AVONEX PREFILLED
- BAFIERTAM
- BETASERON
- COPAXONE
- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack*
- *glatiramer acetate*
- GLATOPA
- PLEGRIDY
- PLEGRIDY STARTER PACK
- REBIF
- REBIF REBIDOSE
- REBIF REBIDOSE TITRATION PACK
- REBIF TITRATION PACK
- TECFIDERA
- *teriflunomide*
- VUMERITY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [EXTAVIA (interferon-beta-1B)]: TWO agents: Avonex, Copaxone/Glatiramer/Glatopa, Plegridy, Rebif, teriflunomide [BAFIERTAM]: TWO agents: Zeposia, fingolimod, dimethyl fumarate, Vumerity, Mayzent. [AUBAGIO, COPAXONE 20MG, TECFIDERA]: Avonex, Betaseron, Copaxone 40mg, glatiramer, Glatopa, Kesimpta, Mavenclad, Mayzent, Plegridy, Rebif, Vumerity, Zeposia. INITIAL: (A) MULTIPLE SCLEROSIS (MS): (1) Diagnosis of relapsing form of MS to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# MYALEPT

## Products Affected

- MYALEPT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Congenital or acquired generalized lipodystrophy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) LIPODYSTROPHY: (1) Diagnosis of congenital or acquired generalized lipodystrophy AND (2) Myalept will be used as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency AND (3) Patient has diabetes mellitus, insulin resistance, OR a fasting hypertriglyceridemia of greater than 200mg/dL.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has shown clinical benefit with the use of Myalept (e.g., reduction in glucose levels, reduction of insulin resistance, or reduction of triglycerides. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a an endocrinologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None. |

# MYCAPSSA

## Products Affected

- MYCAPSSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ACROMEGALY: (1) Diagnosis of acromegaly AND (2) Patient has responded to and tolerated treatment with octreotide or lanreotide AND (2) Patients serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patients age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender AND (3) Patient has shown improvement or has sustained remission of clinical symptoms of acromegaly. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation an endocrinologist. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# MYFEMBREE

## Products Affected

- MYFEMBREE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal patients, management of moderate to severe pain associated with endometriosis in premenopausal patients, medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | High risk of arterial, venous thrombotic, or thromboembolic disorder, pregnancy, known osteoporosis, current or history of breast cancer or other hormone-sensitive malignancies, known hepatic impairment or disease, undiagnosed abnormal uterine bleeding. |
| **Required Medical Information** | A. HEAVY MENSTRUAL BLEEDING: INITIAL: (1) Prescriber attests to a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal patient AND (2) Patient does not have pre-existing osteoporosis or other metabolic bone disease AND (3) Prescriber attests that patient has tried and failed or has a contraindication to hormonal therapy (oral contraception, progestin-releasing IUD, Gonadotropin releasing hormone (GnRH) analogs B. MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INTIAL: (1) Prescriber attests patient has a documented diagnosis of endometriosis AND (2) Prescriber attests patient has current symptoms of moderate to severe pain (not mild) AND (3) Prescriber attests that patient has tried and failed (for at least a 3 month trial) or has a contraindication to a hormonal contraceptive (such as: progestin, combined oral contraceptives, medroxyprogesterone acetate, levonorgestrel-releasing intrauterine system) AND (4) Prescriber attests to appropriate measure/assessment of bone health (ie. DXA, FRAX score) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 24 months |
| **Other Criteria** | PA Automated |

# MYHIBBIN

## Products Affected

- MYHIBBIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Prophylaxis of organ rejection |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL: PROPHYLAXIS OF ORGAN REJECTION (1) Prescriber attests Myhibbin will be used for prophylaxis of organ rejection AND (2) Prescriber attests patient has a history of an allogeneic kidney, heart or liver transplant AND (3) Prescriber attests Myhibbin will be used in combination with other immunosuppressants (e.g., cyclosporine) AND (4) Prescriber attests patient had a trial of or contraindication to generic mycophenolate mofetil tablets AND (5) Prescriber attests patient unable to swallow mycophenolate mofetil tabletsCONTINUATION OF THERAPY: 1) Diagnosis of an approvable indication AND (2) Patient has been stable on therapy for 30 days |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | QUANTITY LIMIT APPLIES |

# MYOBLOC

## Products Affected

- MYOBLOC

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles), chronic sialorrhea. |
| **Exclusion Criteria** | Request is for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines). |
| **Required Medical Information** | INITIAL: (A) CERVICAL DYSTONIA: (1) Diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles). (B) SIALORRHEA: (1) Diagnosis of chronic sialorrhea.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# NEMLUVIO

## Products Affected

- NEMLUVIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Prurigo nodularis (PN), Atopic dermatitis (AD) |
| **Exclusion Criteria** | Used concurrently with other systemic biologics (Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO [PN]: DUPIXENT. [AD]: THREE AGENTS: ADBRY, EBGLYSS, DUPIXENT, RINVOQ. INITIAL: (A) PRURIGO NODULARIS (PN): (1) Diagnosis of PN AND (2) Patient has the presence of multiple pruriginous lesions (localized or general) AND (3) Tried or contraindicated to ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (SNRI, SSRI, TCA), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine. (B) ATOPIC DERMATITIS (AD): Diagnosis of moderate to severe AD AND (2) Nemluvio will be used in combination with a topical corticosteroid (e.g., triamcinolone, clobetasol) and/or calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) AND (3a) Patient has atopic dermatitis covering at least 10% of body surface area (BSA) OR (3b) atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas AND (4) Patient has TWO of the following: intractable pruritus, cracking/oozing/bleeding of the affected skin, impaired activities of daily living. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist (4) Nemluvio will NOT be used concurrently with other systemic biologics or targeted small molecules for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Nemluvio will NOT be used concurrently with other systemic biologics or targeted small molecules for an autoimmune indication AND [PN]: (3) Patient has had prurigo nodularis improvement (reduction) of pruritus or pruriginous lesions OR [AD]: (3) Patient has shown improvement while on Nemluvio. |
| **Age Restrictions** | [PN]: 18 years of age or older, [AD]: 12 years of age or older. |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist, immunologist, or allergist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# NEULASTA

## Products Affected

- NEULASTA
- NEULASTA ONPRO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy, hematopoietic syndrome of acute radiation syndrome (no onpro) (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT for NEULASTA: TRIED OR CONTRAINDICATED TO ZIEXTENZO STEP ALERT: for NEULASTA ONPRO]: TRIED OR CONTRAINDICATED TO UDENYCA ONBODY. A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever AND (2) Neulasta Onpro: Patient has a barrier to access (e.g., travel barriers, patient is unable to return to the clinic for Neulasta injections). HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME (NOT Onpro): (1) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# NEUPOGEN

## Products Affected

- NEUPOGEN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy and receiving myelosuppressive chemotherapy, Acute myeloid leukemia, Non-myeloid malignancy and undergoing myeloablative chemotherapy, mobilization of autologous hematopoietic progenitor cells, congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, or Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO NIVESTYM. A. FOR ALL INDICATIONS: (1) Patient has one of the following: (1a) Non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever OR (1b) diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment OR (1c) Non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia) OR (1d) Requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis OR (1e) Diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia OR (1f) requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated |

# NGENLA

## Products Affected

- NGENLA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Growth failure due to an inadequate secretion of endogenous growth hormone |
| **Exclusion Criteria** | Treatment for any of the following: athletic enhancement, anti-aging purposes, idiopathic short stature; Used concurrently with Increlex (mecasermin). |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO ONE AGENT: SKYTROFA OR SOGROYA. INITIAL: (A) ENDOGENOUS GH: (1) Diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) AND (2) Attestation that epiphyses are open AND (3) Patient meets ONE of the following criteria: (3a) Height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender OR (3b) Height velocity less than the 25th percentile for age OR (3c) Low peak GH (less than 10ng/mL) on two GH stimulation tests OR (3d) IGF-1 that is at least 2 SD below the mean for the same age and gender. (B) IDIOPATHIC SHORT STATURE: (1) Request will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition). CONTINUING THERAPY / RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has been on therapy for at least 90 days AND (3) Diagnosed by appropriate specialist AND (4) Exclusion criteria AND (5) Evidence epiphyses still open AND (6) One of the following (6a) Annual growth velocity of at least 2 cm compared with what was observed from the previous year OR (6b) Annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty. SEE OTHER CRITERIA |
| **Age Restrictions** | 3 to 17 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# NITISINONE

## Products Affected

- *nitisinone*
- NITYR
- ORFADIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary tyrosinemia type 1 (HT-1). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to generic nitisinone capsules. INITIAL: (A) HEREDITARY TYROSINEMIA TYPE 1: (1) Diagnosis of hereditary tyrosinemia type 1 AND (2) Patient has elevated urinary or plasma succinylacetone (SA) levels OR a mutation in the fumarylacetoacetate hydrolase (FAH) gene AND (3) Patient has been counseled on maintaining dietary restriction of tyrosine and phenylalanine. CONTINUING THERAPY: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# NIVESTYM

## Products Affected

- NIVESTYM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy and receiving myelosuppressive chemotherapy, Acute myeloid leukemia, Non-myeloid malignancy and undergoing myeloablative chemotherapy, mobilization of autologous hematopoietic progenitor cells, congenital neutropenia, cyclic neutropenia or idiopathic neutropenia, or Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. FOR ALL INDICATIONS: (1) Patient has one of the following: (1a) Non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever OR (1b) diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment OR (1c) Non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia) OR (1d) Requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis OR (1e) Diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia OR (1f) requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# NON-INJECTABLE CGRP ANTAGONISTS

## Products Affected

- NURTEC
- QULIPTA
- UBRELVY
- ZAVZPRET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute migraine treatment [NURTEC ODT, UBRELVY AND ZAVZPRET ONLY]. Migraine prevention [NURTEC ODT, QULIPTA] for episodic or chronic migraines |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ACUTE MIGRAINE TREATMENT: [NURTEC ODT, UBRELVY AND ZAVZPRET ONLY] INITIAL: (1) Request is for acute treatment of migraines AND (2) Requested medication will not be used concurrently with other CGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) AND (3) Patient has tried or contraindicated to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan] AND (4) [FOR ZAVZPRET] Patient is unable to tolerate oral medications B. PREVENTION OF MIGRAINES: [NURTEC ODT, QULIPTA] INITIAL: (1a) Request is for preventative treatment of episodic migraines (0 to 14 headache days per month) OR (1b) Qulipta only: Request for preventative treatment of chronic migraines (15 or more headache days per month) AND (2) Requested medication will not be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention AND (3a) Tried or contraindicated to ONE of the following preventive migraine treatments: divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol OR (3b) [patients who meet the chronic migraine definition only] Patient has tried and failed Botox (onabotulinumtoxina) SEE OTHER CRITERIA |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUATION OF THERAPY: (1) Patient has been on therapy for at |

| PA Criteria | Criteria Details |
| --- | --- |
| | least 90 days AND (2) Diagnosis of approvable indication RENEWAL: [ACUTE]: (1) Requested medication will not be used concurrently with other CGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) AND (2) Patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT]) AND (3) Patient has experienced clinical improvement defined as ONE of the following (3a) Ability to function normally within 2 hours of dose OR (3b) Headache pain disappears within 2 hours of dose OR (3c) Therapy works consistently in majority of migraine attacks. [PREVENTATIVE]: (1) NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy, Aimovig, Emgality, Vyepti, Qulipta) for migraine prevention AND (2) Patient meets ONE of the following: (2a) Patient has experienced a reduction in migraine or headache frequency of at least 2 days per month OR (2b) Patient has experienced a reduction in migraine severity OR (2c) Patient has experienced a reduction in migraine duration PA Automated |

# NORTHERA

## Products Affected

- *droxidopa*
- NORTHERA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Neurogenic orthostatic hypotension, All medically accepted indications |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NEUROGENIC ORTHOSTATIC HYPOTENSION: INITIAL: (1) Prescriber attests to a diagnosis of neurogenic orthostatic hypotension AND (2) Diagnosis of orthostatic hypotension (while on current therapy) confirmed by a drop of 20 mmHg systolic blood pressure or 10 mmHg diastolic blood pressure within two to five minutes of standing up AND (3) Patient scores a minimum of a 5 out of 10 on dizziness scale [On a scale of 0-10, have the patient provide the number that best relates to his or her severity of dizziness, lightheadedness, feeling faint, or feeling like I might black out (0 being none, 10 being worst possible] AND (4) Patient is currently trying or contraindicated to the following non-pharmacologic treatments (not applicable for diagnoses of Parkinsons disease or spinal cord injury): (4a) Increasing dietary salt intake (10 G/day of sodium) AND (4b) Increasing water and fluid intake (2-3 L/day) AND (4c) External pressure to lower body (bandages firmly wrapped around legs, snugly fitted abdominal binders, or waist-high compression garments) AND (5) Patient has tried, failed or intolerant to the following pharmacologic treatments: Midodrine (30 mg/day) AND Fludrocortisone (0.2 mg/day) RENEWAL: (1) Patient has improved at least two points on dizziness scale after at least 3 weeks of treatment. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a cardiologist or neurologist. |
| **Coverage Duration** | Initial: 1 month, Renewal: 3 months |
| **Other Criteria** | No PA Automation |

# NPLATE

## Products Affected

- NPLATE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Immune thrombocytopenia (ITP), Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) IMMUNE THROMBOCYTOPENIA (ITP): (1) Diagnosis of ITP AND (2a) Patient is 18 years of age and older OR (2b) Patient is 1 to 17 years of age AND has had ITP for at least 6 months AND (3) Tried or contraindicated to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy AND (4) Nplate will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Promacta [eltrombopag], Alvaiz [eltrombopag]) AND (5) Patient has a platelet count of less than 30 x 10^9/L OR the patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event. (B) HEMATOPOIETIC SYNDROME OF ACUTE RADIATION SYNDROME (HS-ARS): (1) Diagnosis of HS-ARS. CONTINUING THERAPY / RENEWAL: [HS-ARS]: Refer to initial. (1) Patient has been stable on therapy AND (2) Diagnosis of approvable indication AND (3) Nplate will NOT be used concurrently with other TPO-Ras AND (4) Patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events. |
| **Age Restrictions** | [ITP]: 1 year of age or older. [HS-ARS]: None. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: [ITP]: 4 months, [HSARS]: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# NUCALA

## Products Affected

- NUCALA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe Asthma with eosinophilic phenotype, chronic rhinosinusitis nasal polyps (CRSwNP), eosinophilic granulomatosis with polyangiitis (EGPA), hypereosinophilic syndrome (HES), chronic obstructive pulmonary disease (COPD). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Dupixent [dupliumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication |
| **Required Medical Information** | INITIAL: (A) ASTHMA: (1) Diagnosis of severe asthma with eosinophilic phenotype AND (2) Blood eosinophilic level of 150 cells/microliter within the past 12 months AND (3) Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (beclomethasone, budesonide, mometasone) AND at least ONE other maintenance medication (long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or oral corticosteroid [e.g., prednisone]) AND (4) Patient meets one of the following: (4a) Patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR (4b) Patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months OR (4c) Patient have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week, any activity limitation due to asthma. (B) CRSwNP: (1) Diagnosis of CRSwNP AND (2) Evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan AND (3) Patient has inadeaquately controlled disease AND (4) Patient has tried ONE intranasal corticosteroid (ie. fluticasone) for a 56-day trial AND (5) Nucala will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids). (C) EOSINOPHILIC GRANULOMATOSIS WITH POLYANGITIS (EGPA): (1) Diagnosis of EGPA. SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | [Eosinophilic asthma]: 6 years of age or older. [CRSwNP, EGPA, COPD]: 18 years of age or older. [HES]: 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an [Asthma]: allergist or pulmonologist. [CRSwNP]: allergist, immunologist, or otolaryngologist. [COPD]: pulmonologist. [EGPA, HES]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (D) HYPEREOSINOPHILIC SYNDROME (HES): (1) Diagnosis of HES AND (2) Patient has had HES for at least 6 months without an identifiable non-hematologic secondary cause. (E) CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): (1) Diagnosis of COPD AND (2) Patient has an eosinophilic phenotype of COPD AND (3) Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere). CONTINUING THERAPY: [HES]: Treat as initial. (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Nucala will be used in concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication AND [Asthma]: (5) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid) [COPD]: (5) Patient has an eosinophilic phenotype of COPD AND (6) Used in combo with a LAMA/LABA/ICS. RENEWAL: (1) Diagnosis of approvable indication AND (2) Nucala will be used in concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication AND [ASTHMA]: (3) Patient will continue to use an inhaled ICS (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid) AND (4) Patient has shown a clinical response as evidenced by ONE of the following: (4a) Reduction in asthma exacerbations from baseline OR (4b) Decreased utilization of rescue medications (e.g., albuterol) OR (4c) Increase in percent predicted FEV1 from pre-treatment baseline OR (4d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing). [CRSwNP]: (3) Patient has shown clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps). [EGPA]: (3) Patient has shown a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid use. [COPD]: (3) Patient has an eosinophilic phenotype of COPD AND (4) Used in combination with a |

| PA Criteria | Criteria Details |
| --- | --- |
| | LAMA/LABA/ICS AND (5) Shown a clinical response by a reduction in COPD exacerbations from baseline, reduction in severity or frequency of COPD-related symptoms, or increase in FEV1 of at least 5% from pretreatment baseline. PA Automated |

# NUPLAZID

## Products Affected

- NUPLAZID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Parkinsons disease psychosis |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARKINSONS DISEASE PSYCHOSIS: (1) Diagnosis of Parkinsons disease psychosis. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) During the past 12 months of therapy, patient has experienced an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, geriatrician, or behavioral health physician (such as psychiatrist) |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# NUZYRA

## Products Affected

- NUZYRA ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Community-acquired bacterial pneumonia (CABP), acute bacterial skin or skin structure infection (ABSSSI). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): (1) Diagnosis of CABP AND (2) Patients CABP infection is caused by any of the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, or Chlamydophila pneumoniae AND (3) One of the following: (3a) Request for continuation of care from an inpatient setting OR (3b) Prescribed by or in consultation with an infectious disease (ID) specialist OR (3c) An antimicrobial susceptibility test has been performed and meets all the following: (3c.i) Results from the infection site culture indicate pathogenic organism(s) with resistance to at least TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone) AND (3c.ii) Results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra OR (3d) Meets both of the following: (3d.i) Antimicrobial susceptibility results are unavailable AND (3d.ii) Tried or contraindicated to at least TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone). SEE OTHER CRITERIA |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | See RMI. |
| **Coverage Duration** | Initial: 1 month |
| **Other Criteria** | (B) ACUTE BACTERIAL SKIN OR SKIN STRUCTURE INFECTION (ABSSSI): (1) Diagnosis of ABSSSI AND (2) Patients ABSSSI infection is caused by any of the following susceptible microorganisms: Staphylococcus aureus (methicillin-susceptible and -resistant isolates), |

| PA Criteria | Criteria Details |
| --- | --- |
| | Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, or Klebsiella pneumoniae AND (3) One of the following: (3a) Prescribed by or in consultation with an infectious disease (ID) specialist OR (3b) An antimicrobial susceptibility test has been performed and meets all the following: (3b.i) results from the infection site culture indicate pathogenic organism(s) with resistance to at least TWO standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin) AND (3b.ii) Results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra OR (3c) Meets both of the following: (3c.i) Antimicrobial susceptibility results are unavailable AND (3c.ii) Tried or contraindicated to at least TWO standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin). PA Automated. |

# NYVEPRIA

## Products Affected

- NYVEPRIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy, hematopoietic syndrome of acute radiation syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO ZIEXTENZO. A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME: (1) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# ODACTRA

## Products Affected

- ODACTRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | House dust mite (HDM)-induced allergic rhinitis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HOUSE DUST MITE ALLERGY: (1) Diagnosis of house dust mite (HDM)-induced allergic rhinitis AND (2) Diagnosis is confirmed by in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, OR by skin testing to licensed house dust mite allergen extracts AND (3) Patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks) AND (4) Patient has moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work) AND (5) Patient has a current claim or prescription for an auto-injectable epinephrine within the past 365 days.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline. |
| **Age Restrictions** | 5 and 65 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases. |
| **Coverage** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Duration** | |
| **Other Criteria** | PA Automated. |

# OFEV

## Products Affected

- OFEV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Idiopathic pulmonary fibrosis (IPF), Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype (PF-ILD), Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD). |
| **Exclusion Criteria** | [IPF, PF-ILD]: Used concurrently with Esbriet.<br>[SSc-ILD]: None. |
| **Required Medical Information** | INITIAL: (A) IDIOPATHIC PULMONARY FIBROSIS (IPF): (1) Diagnosis of IPF AND (2) Patient does NOT have other known causes of interstitial lung disease (ILD) (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, cancer) AND (3) Patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT. (B) SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD): (1) Diagnosis of SSc-ILD AND (2) Patient has a diagnosis of Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) AND (3) Patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) AND (4) Patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value AND (5) Patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]. SEE OTHER CRITERIA |
| **Age Restrictions** | [SSc-ILD]: 18 years of age or older. [IPF, PF-ILD]: None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [IPF]: pulmonologist. [SSc-ILD, PF-ILD]: pulmonologist or rheumatologist. |
| **Coverage** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
|---|---|
| **Duration** | |
| **Other Criteria** | (C) CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE: (1) Diagnosis of chronic fibrosis interstitial lung disease with a progressive phenotype (PF-ILD) AND (2) Patients lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities e.g., infection, heart failure) AND (3) Patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND [IPF, PF-ILD]: (4) Ofev will NOT be used concurrently with Esbriet.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline AND [IPF, PF-ILD]: (3) Ofev will NOT be used concurrently with Esbriet. PA Automated. |

# OHTUVAYRE

## Products Affected

- OHTUVAYRE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic obstructive pulmonary disease (COPD) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL: CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) (1) Prescriber attests patient has a diagnosis of COPD AND (2) Prescriber attests Ohtuvayre will be used as maintenance treatment AND (3a) Prescriber attests if patient has a blood eosinophil level of 100 cells/microliter or greater, the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy: LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist)/ICS (inhaled corticosteroid) combination drug (e.g., Trelegy Ellipta, Breztri Aerosphere) OR (3b) Prescriber attests if patient have a blood eosinophil level below 100 cells/microliter, patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy: LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (e.g., Stiolto Respimat, Anoro Ellipta).CONTINUATION OF THERAPY: (1) Diagnosis of an approvable diagnosis AND (2) Patient has been stable on therapy for at least 30 days RENEWAL: (1) Prescriber attests patient has shown a clinical response as evidence by ONE of the following criteria: (2a) patient has a reduction in COPD exacerbations from baseline (2b) patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production, etc.) (2c) patient has an increase in FEV1 by at least 5 percent from pretreatment baseline AND (3) Patient had a history of and will continue on, or has a contraindication or failure to the standard of care therapy appropriate for patients eosinophil levels as noted in the initial approval criteria. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a pulmonologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |

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

# OLUMIANT

## Products Affected

- OLUMIANT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid Arthritis (RA), Alopecia areata (AA) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT [RA]: TRIED OR CONTRAINDICATED TO TWO AGENTS: ADALIMUMAB (-ADAZ, HUMIRA, SIMLANDI), ENBREL, RINVOQ TAB, OR XELJANZ (XR) (TRIED A TNF PRIOR TO RINVOQ/XELJANZ). A. RHEUMATOID ARTHRITIS (RA): INITIAL: (1) Diagnosis of moderate to severe RA AND (2) Patient had a trial of or contraindication to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine. B. ALOPECIA AREATA (AA): INITIAL: (1) Prescriber attests to a diagnosis of severe AA AND (2) Patient has at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months. SEE OTHER CRITERIA |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | RA: Prescribed by or in consultation with a rheumatologis tAA: Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | C. COVID-19: INITIAL: (1) Coverage for treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult is ineligible under the prescription benefit. CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indicationRENEWAL: (1) |

| PA Criteria | Criteria Details |
| --- | --- |
| | Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication AND [RA]: (2) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [AA]: (2) Patient has had improvement while on therapy (e.g., scalp hair coverage). |

# OMEPRAZOLE-BICARBONATE

## Products Affected

- KONVOMEP
- *omeprazole-sodium bicarbonate capsule 20-1100 mg oral (rx)*
- *omeprazole-sodium bicarbonate oral packet*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | None. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (1) Patient has tried or contraindicated to generic esomeprazole packets AND (2) Patient is 12 years of age or older and has a contraindication to OR is unable to swallow the tablet/capsule formulation of omeprazole, pantoprazole, esomeprazole, or lansoprazole.<br><br>CONTINUING THERAPY: (1) Treat as Initial.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has had a clinical benefit AND (3) Patient requires continued therapy of the requested medication. |
| **Age Restrictions** | 1 month of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# OMVOH

## Products Affected

- OMVOH
- OMVOH (300 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ulcerative colitis (UC), Crohns disease (CD) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. (B) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Omvoh will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of an approvable indication AND (2) Omvoh will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ONAPGO

## Products Affected

- ONAPGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Advanced Parkinsons disease (PD) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARKINSONS DISEASE (PD): (1) Diagnosis of advanced PD AND (2) Onapgo will be used for the treatment of motor fluctuations associated with PD AND (3) Patients disease is responsive to treatment with levodopa AND (4) Patients current medication regimen, including levodopa, has been at a stable dose for at least 28 days AND (5) Patient has motor symptoms that are currently uncontrolled (defined as an average ?off? time of at least 3 hours per day, with a minimum 2 hours each day) AND (6) Patient does NOT have any of the following: orthostatic hypotension, history of prolonged QTc (greater than 450 msec for male or greater than 470 msec for female), active or uncontrolled psychosis, active or uncontrolled depression. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced improvement in motor symptoms while on Onapgo. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ONCOLOGY AGENTS

## Products Affected

- *abiraterone acetate*
- ABIRTEGA
- AKEEGA
- ALECENSA
- ALUNBRIG
- AUGTYRO
- AVMAPKI FAKZYNJA CO-PACK
- AYVAKIT
- BALVERSA
- *bexarotene external*
- *bexarotene oral*
- BOMYNTRA
- BRAFTOVI
- BRUKINSA
- CABOMETYX
- CALQUENCE
- *capecitabine*
- CAPRELSA
- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)
- COPIKTRA
- COTELLIC
- *cyclophosphamide injection*
- *cyclophosphamide solution 1 gm/2ml intravenous*
- *cyclophosphamide solution 1 gm/5ml intravenous*
- *cyclophosphamide solution 1000 mg/10ml intravenous*
- *cyclophosphamide solution 2 gm/10ml intravenous*
- *cyclophosphamide solution 2000 mg/20ml intravenous*
- *cyclophosphamide solution 500 mg/2.5ml intravenous*
- *cyclophosphamide solution 500 mg/5ml intravenous*
- *cyclophosphamide solution 500 mg/ml intravenous*
- DANZITEN
- *dasatinib*
- DAURISMO
- ENSACOVE
- ERIVEDGE
- ERLEADA
- *erlotinib hcl*
- *etoposide oral*
- FASLODEX
- FIRMAGON
- FIRMAGON (240 MG DOSE)
- FOTIVDA
- FRINDOVYX SOLUTION 1 GM/2ML INTRAVENOUS
- FRINDOVYX SOLUTION 500 MG/ML INTRAVENOUS
- FRUZAQLA
- *fulvestrant*
- GAVRETO
- *gefitinib*
- GILOTRIF
- GLEEVEC
- GLEOSTINE
- HERCEPTIN HYLECTA
- HERNEXEOS
- HYCAMTIN ORAL
- HYRNUO
- IBTROZI
- ICLUSIG
- IDHIFA
- *imatinib mesylate oral*
- *imkeldi*
- INLURIYO
- INLYTA
- INQOVI
- INREBIC
- IRESSA
- ITOVEBI
- IWILFIN
- JAYPIRCA
- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KOMZIFTI

- KRAZATI
- *lapatinib ditosylate*
- LAZCLUZE
- *lenalidomide*
- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)
- LEUKERAN
- *leuprolide acetate injection*
- *lomustine*
- LONSURF
- LORBRENA
- LUMAKRAS
- LYNPARZA
- LYSODREN
- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)
- MATULANE
- MEKINIST
- MEKTOVI
- MODEYSO
- MYLERAN
- NERLYNX
- NEXAVAR
- *nilotinib d-tartrate*
- *nilotinib hcl*
- *nilutamide*
- NINLARO
- NUBEQA
- ODOMZO
- OGSIVEO
- OJEMDA
- OJJAARA
- ONUREG
- OPDIVO
- ORGOVYX
- ORSERDU
- OSENVELT
- *pazopanib hcl*
- PEMAZYRE
- PHYRAGO
- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)
- POMALYST
- QINLOCK
- RETEVMO
- REVLIMID
- REVUFORJ
- REZLIDHIA
- RITUXAN HYCELA
- ROMVIMZA
- ROZLYTREK
- RUBRACA
- RYDAPT
- *sorafenib tosylate*
- SPRYCEL
- STIVARGA
- *sunitinib malate*
- SUTENT
- TABLOID
- TABRECTA
- TAFINLAR
- TAGRISSO
- TALZENNA
- TARGRETIN EXTERNAL
- TARGRETIN ORAL
- TASIGNA
- TAZVERIK
- *temozolomide*
- TEPMETKO
- THALOMID
- TIBSOVO
- TRELSTAR MIXJECT
- *tretinoin oral*
- TRUQAP
- TUKYSA
- TURALIO
- TYKERB
- UVADEX
- VALCHLOR
- VANFLYTA
- VENCLEXTA
- VENCLEXTA STARTING PACK
- VERZENIO
- VITRAKVI

- VIZIMPRO
- VONJO
- VORANIGO
- VOTRIENT
- WELIREG
- XALKORI
- XOSPATA
- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)
- XTANDI
- YERVOY
- YONSA
- ZEJULA
- ZELBORAF
- ZOLADEX
- ZOLINZA
- ZYDELIG
- ZYKADIA
- ZYTIGA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA-approved indications, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) FOR ALL INDICATIONS: (1) Documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1, 2a, 2b only) and Clinical Pharmacology (strong recommendation). [NOTE]: For stage four advanced metastatic cancer, members are not required to step through other treatment options prior to requested therapy. |
| **Age Restrictions** | As noted in the package insert and approved compendia |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist, hematologist, or other specialist treating cancer. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | No PA Automation |

# OPSUMIT

## Products Affected

- OPSUMIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) PAH diagnosis confirmed by right heart catheterization with ALL of the following: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUATION OF THERAPY: (1) Patient has been stable on therapy for 30 days AND (2) Diagnosis of approvable indication.RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# OPSYNVI

## Products Affected

- OPSYNVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH, WHO Group 1). |
| **Exclusion Criteria** | Used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) ANDUsed concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat]). |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) Patient has WHO functional class II-III symptoms AND (2) PAH diagnosis confirmed by right-heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) greater than 2 Wood units. CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy 30 days AND (3) Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) AND (4) Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat]).RENEWAL: (1) Diagnosis of approvable indication AND (2) Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) AND (3) Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat]). |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# OPZELURA

## Products Affected

- OPZELURA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Mild to moderate atopic dermatitis (AD) and nonsegmental vitiligo (NSV) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ATOPIC DERMATITIS (AD): (1) Patient has a diagnosis of mild to moderate AD AND (2) Patient is NOT immunocompromised AND (3) Tried or contraindicated to (3a) Topical corticosteroid of medium potency or greater (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR (3b) Topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]). (B) NONSEGMENTAL VITILIGO (NSV): (1) Patient has a diagnosis of NSV AND (2) Patient has depigmented areas covering 10% or less of total body surface area AND (3) Patient had a trial of or contraindication to a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]) AND Opzelura will NOT be used concurrently with another non-steroid topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)]), systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm]), JAK inhibitors (e.g., Rinvoq [Upadacitinib], Cibinqo [abrocitinib], or potent immunosuppressants (e.g., azathioprine, cyclosporine). |
| **Age Restrictions** | [NSV]: 12 years of age or older. [AD]: 2 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has started and been prescribed for at least 90 days AND (3) [NSV]: Opzelura will NOT be used concurrently with another non-steroid topicals (e.g., calcineurin inhibitors, PDE-4 inhibitors), systemic therapeutic biologics, JAK inhibitors, or potent immunosuppressants. |

| PA Criteria | Criteria Details |
| --- | --- |
| | RENEWAL: (1) Diagnosis of approvable indication AND [AD]: (2) Patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement. [NSV]: (2) Opzelura will NOT be used concurrently with another non-steroid topicals (e.g., calcineurin inhibitors, PDE-4 inhibitors), systemic therapeutic biologics, JAK inhibitors, or potent immunosuppressants AND (3) Patient has experienced or maintained clinically meaningful repigmentation. PA Automated. |

# ORACEA

## Products Affected

- *doxycycline*
- ORACEA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rosacea. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ROSACEA: (1) Diagnosis of rosacea AND (2) Patient has inflammatory lesions (papules and pustules) associated with rosacea AND (3) Tried or contraindicated to ONE generic oral minocycline or doxycycline monohydrate/hyclate. CONTINUING THERAPY: Treat as initial. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ORALAIR

## Products Affected

- ORALAIR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Grass pollen-induced allergic rhinitis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) GRASS ALLERGY: (1) Diagnosis of grass pollen-induced allergic rhinitis AND (2) Diagnosis is confirmed by a positive skin prick test and/or a positive titer to specific IgE antibodies for any of the five grass (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens) species included in Oralair AND (3) Patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include of one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work) AND (4) Patient has a current claim or prescription for an auto-injectable epinephrine.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline. |
| **Age Restrictions** | 5 and 65 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ORENCIA

## Products Affected

- ORENCIA
- ORENCIA CLICKJECT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid arthritis (RA), Polyarticular juvenile idiopathic arthritis (pJIA), Psoriatic Arthritis (PsA), Prophylaxis for acute graft versus host disease (aGVHD) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [PJIA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Enbrel, Rinvoq LQ, Xeljanz (Tried a TNF prior to Rinvoq/Xeljanz). [PsA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Rinvoq Tab/LQ, Skyrizi, ustekinumab (-aekn, Stegeyma, Yesintek), Taltz, Tremfya, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [RA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Enbrel, Rinvoq tab, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). INITIAL: (A) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of moderate to severe PJIA. (B) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (C) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Tried or contraindicated to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine AND (3a) Patient meets step therapy OR (3b) Patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular event. (D) PROPHYLAXIS OF ACUTE GRAFT VERSUS HOST DISEASE (aGVHD) INTRAVENOUS PRODUCT ONLY: (1) Patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor AND (2) Patient must be taking methotrexate AND (3) Patient must be taking a calcineurin inhibitor (cyclosporine, tacrolimus). SEE OTHER CRITERIA |
| **Age Restrictions** | [RA]: 18 years of age or older, [aGVHD, PJIA, PsA]: 2 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a [PJIA, RA]: rheumatologist, [PsA]: rheumatologist or dermatologist, [aGVHD]: hematologist or oncologist |
| **Coverage Duration** | [PJIA, PsA, RA]: Initial: 12 months, Renewal: 12 months, [aGVHD]: 28 days |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: [aGVHD]: Refer to initial. [PsA, PJIA, RA]: (1) Diagnosis of approvable indication AND (2) Orencia will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. No PA Automation |

# ORENITRAM

## Products Affected

- ORENITRAM
- ORENITRAM MONTH 1
- ORENITRAM MONTH 2
- ORENITRAM MONTH 3

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO GROUP 1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) Patient does NOT have severe hepatic impairment AND (3) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (4) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (5) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# ORIAHNN

## Products Affected

- ORIAHNN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Uterine leiomyomas (fibroids), Medically accepted indication. |
| **Exclusion Criteria** | Women that are at high risk of arterial, venous thrombotic, or thromboembolic disorders, Pregnancy, Osteoporosis, Current or history of breast cancer (or have or are at an increased risk of hormone sensitive malignancies), Hepatic impairment or disease, Undiagnosed abnormal uterine bleeding |
| **Required Medical Information** | A. HEAVY MENSTRUAL BLEEDING DUE TO UTERINE FIBROIDS: INITIAL: (1) Diagnosis of menorrhagia associated with uterine leiomyomas AND (2) Patient does not have pre-existing osteoporosis or other metabolic bone disease AND (3) Patient did not have adequate response to hormonal therapy (oral contraception, progestin-releasing IUD, GnRH analogues) |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | 24 months |
| **Other Criteria** | PA Automated |

# ORILISSA

## Products Affected

- ORILISSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Management of moderate to severe pain associated with endometriosis, medically accepted indications will also be considered by approval |
| **Exclusion Criteria** | Pregnancy, severe hepatic impairment (Child-Pugh class C), diagnosis of osteoporosis, or concomitant use of rifampin |
| **Required Medical Information** | A. MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS: INTIAL: (1). Prescriber attests patient has a documented diagnosis of endometriosis AND (2) Prescriber attests patient has current symptoms of moderate to severe pain (not mild) AND (3) Prescriber attests that patient has tried and failed (for at least a 3 month trial) or has a contraindication to a hormonal contraceptive (such as: progestin, combined oral contraceptives, medroxyprogesterone acetate, levonorgestrel-releasing intrauterine system) AND (4) Prescriber attests to appropriate measure/assessment of bone health (ie. DXA, FRAX score) RENEWAL [FOR ORILISSA 150MG ONLY]: (1) Prescriber attests that patient has a clinically effective decrease in pain OR less analgesic medication is being used AND (2) Prescriber attests to no change in bone density since the start of elagolix therapy. AND (3) Prescriber attests to appropriate measure/assessment of bone health (ie. DXA, FRAX score). AND (4) Prescriber confirms that patient has not exceed greater than 24 months of Orilissa therapy. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 6 months Renewal [ORILISSA 150MG ONLY]: 18 months |
| **Other Criteria** | PA Automated |

# ORKAMBI

## Products Affected

- ORKAMBI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis (CF). |
| **Exclusion Criteria** | Used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Required Medical Information** | A. INITIAL: CYSTIC FIBROSIS (CF): (1) Diagnosis of CF AND (2) Patient is homozygous for the F508del mutation in the CFTR gene. CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor).RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in clinical status AND (3) Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Age Restrictions** | 1 year of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cystic fibrosis expert |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ORLADEYO

## Products Affected

- ORLADEYO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Orladeyo will be used for prophylaxis against HAE attacks AND (3) Patient meets one of the following (3a) Patient has type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE attacks AND (3) Patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline. |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ORLYNVAH

## Products Affected

- ORLYNVAH

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Uncomplicated urinary tract infection (uUTI) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) UNCOMPLICATED URINARY TRACT INFECTION (uUTI): (1) Diagnosis of uUTI AND (2) Patient is female AND (3) Patients infection is caused by Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis AND (4) Patient has limited or no alternative ORAL antibacterial treatment options AND (5) Patient meets one of the following: (5a) Prescribed by or in consultation with an infectious disease (ID) specialist OR (5b) Patient has a documented culture demonstrating uUTI is caused by a bacteria with sensitivity to sulopenem or ertapenem AND resistance or contraindication to all alternatives (e.g. Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g. ciprofloxacin]) OR (5c) Request is for continuation of Orlynvah from an inpatient setting. CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | 18 years of age and older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 5 days |
| **Other Criteria** | PA Automated. |

# OTEZLA

## Products Affected

- OTEZLA
- OTEZLA XR
- OTEZLA/OTEZLA XR INITIATION PK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Psoriasis (PsO), Psoriatic arthritis (PsA), Oral ulcers associated with Behcets Disease. |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) BEHCET: (1) Diagnosis of Behcet with oral ulcers or history of recurrent oral ulcers based on clinical symptoms AND (2) Patient had a trial of or contraindication to ONE or more conservative treatments (e.g., colchincine, topical corticosteroid [e.g., triamcinolone], oral corticosteroid [e.g., prednisolone]) (B1) PLAQUE PSORIASIS (PsO): (1) Diagnosis of mild PsO AND (2) Patient had a trial of or contraindication to one conventional systemic agent (e.g., acitretin, cyclosporine, methotrexate) OR one conventional topical agent (e.g., topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate]) AND (3a) Patient was previously stable on another biologic and is switching to Otezla OR (3b) Patient has a static Physician Global Assessment (sPGA) score of 2 OR (3c) Patient has a Psoriasis Area and Severity Index (PASI) score of 2 to 9. (B2) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3 percent or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to Otezla AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] used in the treatment of PsO OR (3b) Patient has a contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] used in the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira [adalimmab], PDE-4 inhibitor, or JAK inhibitor for same indication. (C) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. SEE OTHER CRITERIA |
| **Age Restrictions** | [Mild PsO, Behcets]: 18 years of age or older. [PsA, Mod-Severe PsO]: 6 years of age or older. |
| **Prescriber** | Prescribed by or in consultation with a [Behcets, PsA]: rheumatologist. |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | [Mod-Severe PsO, PsA]: dermatologist. [Mild PsO]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Otezla will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Otezla will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [Behcet]: (3) Patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers). [Mild PsO]: (3) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more OR a decrease in sPGA (static Physician Global Assessment) by at least a 2-point reduction from baseline. [Mod-severe PsO]: (3) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more. [PsA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. PA Automated |

# OXERVATE

## Products Affected

- OXERVATE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Neurotrophic keratitis (NK). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) NEUROTROPIC KERATITIS (NK):(1) Diagnosis of NK AND (2) Patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage) AND (3) Patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production AND (4) Patient is refractory to conservative management (i.e., artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses). |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist. |
| **Coverage Duration** | Initial: 8 weeks. (1 cycle per eye per lifetime) |
| **Other Criteria** | No PA Automation |

# PALFORZIA

## Products Affected

- PALFORZIA (1 MG DAILY DOSE)
- PALFORZIA (12 MG DAILY DOSE)
- PALFORZIA (120 MG DAILY DOSE)
- PALFORZIA (160 MG DAILY DOSE)
- PALFORZIA (20 MG DAILY DOSE)
- PALFORZIA (200 MG DAILY DOSE)
- PALFORZIA (240 MG DAILY DOSE)
- PALFORZIA (3 MG DAILY DOSE)
- PALFORZIA (300 MG MAINTENANCE)
- PALFORZIA (300 MG TITRATION)
- PALFORZIA (40 MG DAILY DOSE)
- PALFORZIA (6 MG DAILY DOSE)
- PALFORZIA (80 MG DAILY DOSE)
- PALFORZIA INITIAL DOSE 1-3YRS
- PALFORZIA INITIAL DOSE 4-17YRS
- PALFORZIA INITIAL ESCALATION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Peanut allergy. |
| **Exclusion Criteria** | Used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut). |
| **Required Medical Information** | INITIAL: (A) PEANUT ALLERGY: (1) Diagnosis of a peanut allergy AND (2) Patient has a clinical history of an allergic reaction to peanuts AND (3) Palforzia will be used in conjunction with a peanut-avoidance diet AND (4) Meets one of the following: (4a) Patient has completed a purposeful food challenge and one of the following: (4a.i) Patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months OR (4a.ii) Patient has had a peanut-specific immunoglobulin E (IgE) level of at least 0.35 kUA/L within the past 24 months OR (4b) Patient has NOT completed a purposeful food challenge and one of the following: (4b.i) Patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months OR (4b.ii) Patient has had a peanut-specific immunoglobulin E (IgE) level of at least 14 kUA/L within the past 24 months.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Patient will NOT use with a peanut-specific immunotherapy concurrently AND (5) Palforzia will be used together with a peanut-avoidance diet AND (6) Meets one of the following: (6a) Patient has completed a purposeful food challenge and one of the following: (6a.i) Patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months OR (6a.ii) Patient has had a peanut-specific immunoglobulin E (IgE) level of at least 0.35 kUA/L within the past 24 months OR (6b) Patient has NOT completed |

| PA Criteria | Criteria Details |
|---|---|
| | a purposeful food challenge and one of the following: (6b.i) Patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months OR (6b.ii) Patient has had a peanut-specific IgE level of at least 14 kUA/L within the past 24 months. |
| **Age Restrictions** | 1 to 17 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist or immunologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | RENEWAL: (1) Diagnosis of approvable indication AND (2) Diagnosis confirmed by appropriate specialist AND (3) Palforzia will be used in conjunction with a peanut-avoidance diet AND (4) Patient will NOT use with a peanut-specific immunotherapy concurrently AND (5) Meets one of the following: (5a) Patient has completed a purposeful food challenge and one of the following: (5a.i) Patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months OR (5a.ii) Patient has had a peanut-specific immunoglobulin E (IgE) level of at least 0.35 kUA/L within the past 24 months OR (5b) Patient has NOT completed a purposeful food challenge and one of the following: (5b.i) Patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months OR (5b.ii) Patient has had a peanut-specific immunoglobulin E (IgE) level of at least 14 kUA/L within the past 24 months. PA Automated. |

# PALSONIFY

## Products Affected

- PALSONIFY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER). INITIAL: (A) ACROMEGALY: (1) Diagnosis of acromegaly AND (2) Patient had an inadwquate response to surgery OR surgery is not an option for this patient AND (3) Patients serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load. CONTINUING THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: type of hormone) levels based on age and gender. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender AND (3) Patient has shown improvement or has sustained remission of clinical symptoms of acromegaly |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# PALYNZIQ

## Products Affected

- PALYNZIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Phenylketonuria (PKU). |
| **Exclusion Criteria** | Used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g.,Kuvan [sapropterin], Sephience [sepiapterin]). |
| **Required Medical Information** | INITIAL: (A) PHENYLKETOURIA (PKU): (1) Diagnosis of PKU AND (2) Patient has uncontrolled blood phenylalanine (Phe) levels greater than 600 micromoles/L on existing management, as confirmed by a measurement in the last 30 days AND (3) Patient follows a phenylalanine-restricted diet.<br><br>CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Patient has experienced a reduction in phenylalanine (Phe) levels by at least 20% compared to baseline or to a level below 600 micromoles/L AND (4) Used concurrently with another agent indicated for the treatment of phenylketonuria (PKU). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed or in consultation with a metabolic or genetic disease specialist. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# PASIREOTIDE

## Products Affected

- SIGNIFOR
- SIGNIFOR LAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly (LAR only), Cushing's disease. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [Acromegaly]: Sandostatin LAR Depot (octreotide acetate ER). INITIAL: (A) ACROMEGALY: (SIGNIFOR LAR ONLY): (1) Diagnosis of acromegaly AND (2) Patient has had an inadequate response to surgery, or surgery is not an option for this patient AND (3) Patients serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patients age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load). (B) CUSHINGS DISEASE: (1) Diagnosis of Cushings disease AND (2) Patient has undergone non-curative pituitary surgery, or pituitary surgery is not an option for this patient AND (3) Tried or contraindicated to oral ketoconazole.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND [Acromegaly]: (2) Patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender AND (3) Patient has shown improvement or has sustained remission of clinical symptoms of acromegaly. [Cushings]: (2) Patient continues to have improvement of Cushings disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol or improvements in signs and symptoms of disease) AND (3) Patient maintains tolerability to Signifor LAR. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# PER LABEL

## Products Affected

- CAROSPIR
- EGRIFTA SV
- EGRIFTA WR
- NORLIQVA
- POKONZA PACKET 15 MEQ ORAL
- *spironolactone oral suspension*
- TWIIST REFILL KIT/INFUSION SET
- TWIIST STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA approved indications, Medically accepted indications. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A.INITIAL: (1) Prescriber attests that the patient has a diagnosis approved in the FDA prescribing information. CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy |
| **Age Restrictions** | Per FDA label |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA AUTO |

# PHILADELPHIA PST

## Products Affected

- BOSULIF

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA-approved indications, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: [Bosulif]: Tried or contraindicated to imatinib (generic), Tasigna, or Sprycel. INITIAL: (A) FOR ALL INDICATIONS: (1) Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1, 2a, 2b only) and Clinical Pharmacology (strong recommendation). [NOTE]: For stage four advanced metastatic cancer, members are not required to step through other treatment options prior to requested therapy. |
| **Age Restrictions** | As noted in the package insert and approved compendia |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist, hematologist, or other specialist treating cancer. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | No PA Automation |

# POMPE DISEASE

## Products Affected

- LUMIZYME
- NEXVIAZYME
- OPFOLDA
- POMBILITI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pompe disease (GAA deficiency), Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | none |
| **Required Medical Information** | A. POMPE DISEASE (GAA DEFICIENCY), INITIAL: (1) Prescriber attests that diagnosis is documented as Pompe disease (acid alpha-glucosidase deficiency). AND (2) Prescriber attests that diagnosis has been confirmed by an enzymatic assay showing a deficiency in acid alpha glucosidase or genetic testing showing a variant in the GAA gene. RENEWAL: (1) Prescriber attests that patient meets initial criteria AND (2) Prescriber attests to an improvement or stabilization in respiratory function (such as FVC) and/or improvement or stabilization in muscle function/weakness (such as 6 minute walk test). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician who specializes in genetic disorders, neurologist, or a pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# PONVORY

## Products Affected

- PONVORY
- PONVORY STARTER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing form of Multiple sclerosis (MS), including relapsing remitting disease, secondary progressive disease, or clinically isolated syndrome. |
| **Exclusion Criteria** | Within the past 6 months, experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure, OR Presence of Mobitz Type II 2nd degree or 3rd degree AV block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to TWO agents: Zeposia, fingolimod, dimethyl fumarate, Vumerity, Mayzent. INITIAL: MULTIPLE SCLEROSIS (MS):(1) Diagnosis of a relapsing form of MS, to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# PRADAXA

## Products Affected

- PRADAXA ORAL PACKET

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Venous thromboembolic event (VTE). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to rivaroxaban (Xarelto) suspension. INITIAL: VENOUS THROMBOEMBOLIC EVENT (VTE): (1) Request is for one of the following: (1a) Treatment of a venous thromboembolic event (VTE) AND (1a.i) Patient has been treated with a parenteral anticoagulation agent for at least 5 days OR (1b) Reduce the risk of venous thromboembolic event (VTE) recurrence AND (1b.i) Patient has been previously treated AND (2) Patient is 8 to 11 years of age AND unable to swallow dabigatran (Pradaxa) capsule.<br><br>CONTINUING THERAPY: (1) Patient is on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3a) Patient is 3 to 7 years of age OR (3b) Patient is 8 to 11 years of age AND unable to swallow dabigatran (Pradaxa) capsule AND [VTE RECURRENCE]: (4) Patient has been previously treated. |
| **Age Restrictions** | 3 months to 11 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# PREVYMIS

## Products Affected

- PREVYMIS ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Prophylaxis of cytomegalovirus (CMV) infection and disease in an allogenic hematopoietic stem cell transplant (HSCT) recipient, prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) STEM CELL TRANSPLANT: (1) Request is for prophylaxis of cytomegalovirus (CMV) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT) recipient AND (2) Patient is a CMV-seropositive recipient [R+] of an allogenic HSCT AND (3) Patient will start or started Prevymis between Day 0 and Day 28 post-transplant (before or after engraftment) AND (4) One of the following: (4a) Patient will receive Prevymis beyond 100 days post-transplant OR (4b) Patient is at risk for late CMV infection and disease AND will not receive Prevymis beyond 200 days post-transplant. (B) KIDNEY TRANSPLANT: (1) Request is for prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient AND (2) Patient is a kidney transplant recipient at high risk (i.e., donor is CMV seropositive, recipient is CMV seronegative [D+/R-]) AND (3) Patient will start or started Prevymis between Day 0 and Day 7 post-transplant AND (4) Patient will not receive Prevymis beyond 200 days post-transplant.<br><br>CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | [HSCT]: 6 months of age or older, [KIDNEY]: 12 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a transplant specialist or infectious disease specialist. |
| **Coverage Duration** | [100 days post-transplant]: 100 days. [200 days post-transplant, CMV]: 200 days. |
| **Other Criteria** | PA Automated. |

# PROCYSBI

## Products Affected

- PROCYSBI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Nephropathic cystinosis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) NEPHROPATHIC CYSTINOSIS: (1) Diagnosis of nephrotic cystinosis AND (2) Patient has previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon. CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | 1 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# PROLIA

## Products Affected

- CONEXXENCE
- PROLIA
- STOBOCLO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postmenopausal osteoporosis, Osteoporosis in a male patient, Glucocorticoid-induced osteoporosis, Bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer, Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: [PROLIA]: Tried or contraindicated to Stoboclo. INITIAL: (A) POSTMENOPAUSAL OSTEOPOROSIS: (1) Diagnosis of postmenopausal osteoporosis AND (2) Patient meets one of the following (2a) Patient is at high risk for fractures defined as one of the following: (2a.i) History of osteoporotic (i.e., fragility, low trauma) fracture OR (2a.ii) Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin]) OR (2a.iii) FRAX score of at least 20% for any major fracture OR at least 3% for hip fracture AND Patient has no prior treatment for osteoporosis OR (2b) Patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems, lower GI problems, trouble remembering to take oral medications or coordinate oral bisphosphonate with other oral medications) OR (2c) Patient has tried or contraindicated to bisphosphonates (e.g., Fosamax, Actonel, Boniva). (B) OSTEOPOROSIS FOR MALE / GLUCOCORTICOID OSTEOPOROSIS: (1) Diagnosis of osteoporosis in a male patient OR glucocorticoid-induced osteoporosis AND (2) Patient is at high risk for fractures defined as one of the following: (2a) History of osteoporotic (i.e., fragility, low trauma) fracture OR (2b) Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin]) AND (3) Patient has tried or contraindicated to bisphosphonates (e.g., Fosamax, Actonel, Boniva). SEE OTHER CRITERIA |
| **Age Restrictions** | None. |
| **Prescriber** | None. |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (C) BONE LOSS: (1) Diagnosis of bone loss in men receiving androgen deprivation therapy (e.g., Eligard [leuprolide], Zoladex [goserelin]) for non-metastatic prostate cancer OR bone loss in women receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, letrozole) for breast cancer AND (2) Patient is at high risk for fracture (history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin]) AND (3) Tried or contraindicated to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])CONTINUING THERAPY: Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. PA Automated |

# PROMACTA

## Products Affected

- *eltrombopag olamine*
- PROMACTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Persistent or chronic immune thrombocytopenia (ITP), thrombocytopenia due to chronic hepatitis C, severe aplastic anemia. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) IMMUNE THROMBOCYTOPENIA (ITP: (1) Diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia AND (2) Prescriber attests patient had a trial of or contraindication to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy AND (3) Promacta will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag]) AND (4) Patient has a platelet count of less than 30 x 10^9/L OR patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event. (B) CHRONIC HEPATITIS C: (1) Diagnosis of thrombocytopenia due to chronic hepatitis C AND (2) Patients thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. (C) APLASTIC ANEMIA: (1) Diagnosis of severe aplastic anemia AND (2) Patient had an insufficient response to immunosuppressive therapy OR Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment. CONTINUING THERAPY / RENEWAL: (1) Patient has been stable on therapy AND (2) Diagnosis of approvable indication AND (3) [ITP]: Promacta will NOT be used concurrently with other TPO-RAs AND (4) Patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events. |
| **Age Restrictions** | [ITP]: 1 year of age or older, [ANEMIA]: 2 years and older, [HEP C]: none. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | [ITP]: Initial: 2 months Renewal: 12 months. [HEP C, ANEMIA]: 12 months. |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# PULMOZYME

## Products Affected

- PULMOZYME

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic fibrosis, Medically accepted indications will also be considered for coverage |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CYSTIC FIBROSIS, INITIAL: (1) Prescriber attests to a diagnosis of cystic fibrosis and medication is being used to improve pulmonary function and/or reduce the frequency of respiratory infections AND (2) Prescriber attests Pulmozyme will be used in conjunction with standard cystic fibrosis therapies, including but not limited to: chest physiotherapy, bronchodilators, antibiotics, anti-inflammatories. CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | Elixir Quantity Limit Applies. PA Automated |

# PYRUKYND

## Products Affected

- PYRUKYND
- PYRUKYND TAPER PACK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hemolytic anemia due to pyruvate kinase (PK) deficiency. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HEMOLYTIC ANEMIA: (1) Diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency.<br><br>CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has had a clinical benefit while on Pyrukynd. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 6 months Renewal: 12 months |
| **Other Criteria** | PA Automated |

# QBRELIS

## Products Affected

- QBRELIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypertension, heart failure, or acute myocardial infarction. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HYPERTENSION/MYOCARDIAL: (1) Diagnosis of hypertension or acute myocardial infarction AND (2) Patient has a contraindication to is or is unable to swallow lisinopril tablets. (B) HEART FAILURE: (1) Diagnosis of heart failure AND (2) Patient has a contraindication to is or is unable to swallow lisinopril tablets AND (3) Qbrelis will be used as adjunct therapy.<br><br>CONTINUING THERAPY: (1) Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# QFITLIA

## Products Affected

- QFITLIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hemophilia A, Hemophilia B |
| **Exclusion Criteria** | Used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci]). |
| **Required Medical Information** | INITIAL: (A) HEMOPHILIA: (1) Diagnosis of hemophilia A or hemophilia B AND (2) Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Qfitlia will not be used concurrently with another non-factor prophylaxis therapy. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has shown a clinical benefit compared to baseline AND (3) Qfitlia will not be used concurrently with another non-factor prophylaxis therapy. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# RADICAVA

## Products Affected

- *edaravone solution 30 mg/100ml intravenous*
- RADICAVA
- RADICAVA ORS
- RADICAVA ORS STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Amyotrophic lateral sclerosis (ALS). Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. AMYOTROPHIC LATERAL SCLEROSIS (ALS): INITIAL: (1) Prescriber attests that the patient has a diagnosis of probable or definitive ALS AND (2) Prescriber attests that disease duration of 2 years or less AND (3) Prescriber attests to normal respiratory function (defined as percent-predicted forced vital capacity values of {%FVC} greater than or equal to 80%) (4) Prescriber attests that patient is taking, failed or intolerant to riluzole RENEWAL: (1) Prescriber attests that patient has diagnosis of probable or definitive ALS AND (2) Prescriber attests that patient is tolerating treatment AND (3) Prescriber attests that patient has had disease stabilization or improvement in disease (such as stabilization of functional ability & maintenance of activities of daily living). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | Elixir Quantity Limit Applies. PA Automated |

# RAGWITEK

## Products Affected

- RAGWITEK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Short ragweed pollen-induced allergic rhinitis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) RAGWEED ALLERGY: (1) Diagnosis of grass pollen-induced allergic rhinitis AND (2) Diagnosis is confirmed by a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen AND (3) Patient has persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work) AND (4) Patient has a current claim or prescription for auto-injectable epinephrine.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline. |
| **Age Restrictions** | 5 and 65 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated. |

# RALDESY

## Products Affected

- RALDESY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Major depressive disorder (MDD) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) MAJOR DEPRESSIVE DISORDER (MDD): (1) Diagnosis of MDD AND (2) Patient has a contraindication OR is unable to swallow trazodone tablets. CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# RAVICTI

## Products Affected

- *glycerol phenylbutyrate*
- RAVICTI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Urea cycle disorder (UCD). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: sodium phenylbutyrate or Pheburane. INITIAL: (A) UREA CYCLE DISORDER (UCD): (1) Diagnosis of UCD AND (2) Patients disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone AND (3) Patients UCD is confirmed by enzymatic, biochemical, or genetic testing AND (4) Requested medication will be used as adjuctive therapy along with dietary protein AND (5) Patient does NOT have N-acetylglutamate synthetase (NAGS) deficiency or acute hyperammonemia. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient had a clinical benefit compared to baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# REBLOZYL

## Products Affected

- REBLOZYL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Beta thalassemia, very low- to intermediate-risk myelodysplastic syndrome (MDS), anemia associated with very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS), anemia associated with Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) BETA THALASSEMIA: (1) Diagnosis of beta thalassemia AND (2) Patient requires regular red blood cell (RBC) transfusions AND (3) Reblozyl will be used for the treatment of anemia. (B) MYELODYSPLASTIC SYNDROME (MDS): (1) Diagnosis of very low- to intermediate-risk MDS AND (2) Patient is erythropoiesis stimulating agent (ESA)-naive (has not previously used an ESA such as Epogen [epoetin alfa]) AND (3) Reblozyl will be used for the treatment of anemia. (C) OTHER ANEMIA: (1) Diagnosis of (1a) very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS) OR (1b) Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) AND (2) Patient is failing an erythropoiesis stimulating agent (ESA) (e.g., Epogen [epoetin alfa]) AND requires at least 2 red blood cell (RBC) units over 8 weeks AND (3) Reblozyl will be used for the treatment of anemia.<br><br>CONTINUING THERAPY: (1) Patient has received at least one dose of therapy AND (2) Diagnosis of approvable indication AND (3) Reblozyl will be used for the treatment of anemia. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# RECORLEV

## Products Affected

- RECORLEV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cushings Syndrome, Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | Patients with cirrhosis, acute liver disease or poorly controlled chronic liver disease, baseline AST or ALT greater than 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease, Patients taking drugs that cause QT prolongation associated with ventricular arrhythmias, Patients with a prolonged QTcF interval of greater than 470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or prolong QT syndrome. |
| **Required Medical Information** | CUSHINGS SYNDROME: INITIAL: (1) Prescriber attests to a diagnosis of Cushing's syndrome for who surgery is not an option or has not been curative AND (2) Prescriber attests to baseline monitoring of liver function tests (LFTs), urine free cortisol (UFC) and electrocardiogram (ECG). AND(3) Patient has tried and failed ketoconazole. CONTINUATION OF COVERAGE: (1) Diagnosis of approvable indication AND(2) Patient has been stable on therapy for 30 days AND(3) Prescriber continues to monitor LFTs and ECG |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with an endocrinologist |
| **Coverage Duration** | Initial: 6 months Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# REDEMPLO

## Products Affected

- REDEMPLO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Familial chylomicronemia syndrome (FCS). |
| **Exclusion Criteria** | Used concurrently with another agent (e.g., Tryngolza [olezarsen]) for the treatment of FCS. |
| **Required Medical Information** | INITIAL: (A) FAMILIAL CHYLOMICRONEMIA SYNDROME (FCS): (1) Diagnosis of FCS AND (2) Redemplo will be used as an adjunct therapy to diet AND (3) Diagnosis of FCS has been confirmed by genetic testing.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Redemplo will NOT be used concurrently with another agent for the treatment of FCS.<br><br>RENEWAL: Diagnosis of approvable indication AND (2) Patient has experienced a clinical benefit as demonstrated by a reduction in triglyceride levels AND (3) Redemplo will NOT be used concurrently with another agent for the treatment of FCS. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# RELEUKO

## Products Affected

- *releuko*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy and receiving myelosuppressive chemotherapy, Acute myeloid leukemia, Non-myeloid malignancy and undergoing myeloablative chemotherapy, mobilization of autologous hematopoietic progenitor cells, congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, or Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO NIVESTYM. A. FOR ALL INDICATIONS: (1) Patient has one of the following: (1a) Non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever OR (1b) diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment OR (1c) Non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia) OR (1d) Requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis OR (1e) Diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia OR (1f) requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated |

# RELISTOR

## Products Affected

- RELISTOR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Opioid induced constipation |
| **Exclusion Criteria** | None |
| **Required Medical Information** | FORMULARY ALERT: TRIED, FAILED OR INTOLERANT TO MOVANTIK AND SYMPROIC BEFORE RELISTOR (OIC NOT PALLATIVE CARE). A. OPIOID INDUCED CONSTIPATION (OIC): INITIAL: (1) The patient has diagnosis of OIC AND (2) The patient has chronic non-cancer pain (including chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation) AND (3) The patient has been taking opioids for at least 4 weeks. B. OPIOID INDUCED CONSITPATION (OIC) FOR PALLATIVE CARE: INITIAL: (1) The patient has the diagnosis of OIC AND (2) The patient has advanced (terminal) illness or pain caused by active cancer who require opioid dosage escalation for palliative care. CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Patient has a diagnosis of an approvable indication |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# REMICADE

## Products Affected

- AVSOLA
- INFLECTRA
- *infliximab*
- REMICADE
- RENFLEXIS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Crohns disease (CD), Plaque psoriasis (PsO), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [AS]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Rinvoq tab, Taltz, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [PsA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Rinvoq tab/LQ, Skyrizi, ustekinumab (-aekn, Stegeyma, Yesintek), Taltz, Tremfya, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [RA]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Enbrel Rinvoq tab, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [PsO]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Skyrizi, Sotyktu, ustekinumab (-aekn, Stegeyma, Yesintek), Taltz, Tremfya. [CD]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) (Tried a TNF prior to Rinvoq). [UC]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, ustekinumab (-aekn, Stegeyma, Yesintek), Tremfya, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, naproxen, meloxicam). (B) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (C) PLAQUE PSORIASIS (PsO): (1) Diagnosis of severe PsO AND (2a) Patient has psoriasis covering 3% or more of the body surface area (BSA) OR (2b) Patient has psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp AND (3) Patient meets one of the following: (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO OR (3b) Contraindication or intolerance to both immunosuppressant and PUVA (phototherapy) for the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira), PDE-4 inhibitor, or JAK inhibitor for the same indication. |

| PA Criteria | Criteria Details |
|---|---|
| | SEE OTHER CRITERIA |
| **Age Restrictions** | [CD, UC]: 6 years of age or older. [AS, PsO, PsA, RA]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, PsA, RA]: rheumatologist. [PsO, PsA]: a dermatologist. [UC, CD]: a gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (D) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (E) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Patient is currently using or has a contraindication to methotrexate AND (3) Tried or contraindicated to at least 3 months of treatment with conventional synthetic ONE DMARD (disease-modifying anti-rheumatic drug) such as: methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine. (F) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication. RENEWAL: (1) Requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication AND [PsA, RA]: (2) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy AND (3) [RA only]: Patient is currently using or has a contraindication to methotrexate. (2) [AS]: Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy. (2) [PsO]: Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. No PA Automation. |

# REMODULIN

## Products Affected

- REMODULIN
- *treprostinil*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO GROUP 1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU) AND (5) Request for continuation of Remodulin therapy from a hospital discharge OR (6) New start of Remodulin therapy AND meets one of the following: (7) Patient is intermediate or high risk OR (8) Tried or contraindicated to TWO of the following agents from different drug classes: (8a) Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan]), (8b) Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil]), (8c) Oral cGMP stimulator (e.g., Adempas [riociguat]. CONTINUATION OF THERAPY: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication.RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# REVCOVI

## Products Affected

- REVCOVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Adenosine deaminase severe combined immune deficiency, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ADENOSINE DEAMINASE SEVERE COMBINED IMMUNE DEFICIENCY: INITIAL: (1) Prescriber attests that patient has documented genetic testing for adenosine deaminase severe combined immune deficiency or patient has absent or very low adenosine deaminase catalytic activity (less than 1% of normal) at baseline AND (2) Prescriber attests patient is not a candidate for or has failed hematopoietic cell transplantation (HCT) or gene therapy. RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria AND (2) Prescriber attests to disease state stabilization or improvement with the addition of Revcovi AND (3) Prescriber attests that patient continues to receive appropriate monitoring (i.e. ADA activity, erythrocyte dAXP, lymphocytes, etc.). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a physician specializing in metabolic disorders, genetics, or hematologist. |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# REZDIFFRA

## Products Affected

- REZDIFFRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-alcoholic steatohepatitis (NASH), metabolic dysfunction-associated steatohepatitis (MASH). |
| **Exclusion Criteria** | Used concurrently with Wegovy. |
| **Required Medical Information** | INITIAL: (A) STEATOHEPATITIS: (1) Diagnosis of non-alcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH) AND (2) Patient does not have cirrhosis AND (3) Patient is enrolled in or has already completed a lifestyle intervention (e.g., dietary, exercise, psychology) AND (4) Patient has a biopsy or noninvasive testing (e.g., elastography), obtained within the past 12 months, demonstrating ONE of the following: (4a) Patient has liver fibrosis stage 2 or 3 OR (4b) Patient has a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) of at least 4 AND (5) One of the following: (5a) Wegovy is an excluded agent OR (5b) Tried or contraindicated to Wegovy.<br><br>CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Rezdiffra will NOT be used concurrently with Wegovy AND (4) Patient has shown disease stability or an improvement from baseline AND (5) Patient has had a biopsy or non-invasive test (e.g., elastrography) demonstrating ONE of the following: (5a) Patient has liver fibrosis stage 2 or 3 (5b) Pateint has a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) of at least 4. |
| **Age Restrictions** | 18 years of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, hepatologist, or gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# REZUROCK

## Products Affected

- REZUROCK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic graft-versus-host disease (cGVHD) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) CHRONIC GRAFT-VERSUS-HOST DISEASE (cGVHD): (1) Diagnosis of cGVHD AND (2) Patient has tried at least TWO lines of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to Jakafi (ruxolitinib) AND (3) Rezurock will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib). CONTINUING THERAPY: (1) Patient has been stable on therapy for 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated |

# RHAPSIDO

## Products Affected

- RHAPSIDO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: Dupixent, Xolair. INITIAL: CHRONIC SPONTANEOUS URTICARIA (CSU / CIU): (A) Diagnosis of CIU / CSU AND (2) Patient still experiences hives or angioedema on most days of the week for at least 6 weeks AND (3) Patient had a trial of and is maintained on, or contraindication to, 4-times the maximally labeled dose of a second generation H1 antihistamine (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Rhapsido will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication AND (5) Patient is maintained on or contraindication to 4-times the maximally labeled dose of a second generation H1 antihistamine.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Diagnosis confirmed by appropriate specialist AND (3) Rhapsido will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication AND (4) Patient is maintained on or contraindication to 4-times the maximally labeled dose of a second generation H1 antihistamine. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber** | Prescribed by or in consultation with an allergist, dermatologist, or |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | immunologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months. |
| **Other Criteria** | PA Automated. |

# RILUZOLE

## Products Affected

- *riluzole*
- TEGLUTIK
- TIGLUTIK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of patients with amyotrophic lateral sclerosis (ALS), medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. AMYOTROPHIC LATERAL SCEROSIS (ALS): INITIAL: (1) Prescriber attests to a diagnosis of ALS AND (2) [FOR EXSERVAN FILM OR TIGLUTEK SUSPENSION] Prescriber attests that member cannot safely swallow a tablet. RENEWAL: (1) Patient continues to meet initial criteria |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# RINVOQ

## Products Affected

- RINVOQ
- RINVOQ LQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing Spondylitis (AS), Atopic Dermatitis (AD), Crohns disease (CD), Non -radiographic axial spondyloarthritis (nr-axSpA), Psoriatic Arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative Colitis (UC). Polyarticular Juvenile Idiopathic Arthritis (PJIA), Giant cell arteritis (GCA). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [AS, PsA, PJIA, RA]: ONE TNF inhibitor: adalimumab-adaz, Humira, Enbrel, or Simlandi. [CD/UC]: ONE TNF inhibitor: adalimumab-adaz, Humira, or Simlandi OR TNF inhibitor is clinically inappropriate and tried systemic therapy (Skyrizi, Tremfya, Omvoh, ustekinumab [-aekn, Stegeyma, Yesintek]). [nr-axSpA]: ONE TNF inhibitor: CIMZIA. INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) ATOPIC DERMATITIS (AD): (1) Diagnosis of moderate to severe AD AND (2a) Patient has AD involving at least 10% body surface area (BSA) OR (2b) Patient has AD affecting the face, head, neck hands, feet, groin, or intertriginous areas OR (2c) Patient was previously stable on another biologic (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and is switching to Rinvoq AND (3) Tried or contraindicated to one of the following: (3a) topical corticosteroid (e.g., clobetasol propionate, halobetasol propionate, hydrocortisone) OR (3b) topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]) OR (3c) Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole]) OR (3d) Topical JAK inhibitor (e.g., Opzelura [ruxolitinib]) OR (3e) Phototherapy. (C) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (D) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Patient has had at least a 3-month trial of one conventional synthetic DMARD (disease-modifying anti-rheumatic drug) such as: methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine. (E) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. SEE OTHER |

| PA Criteria | Criteria Details |
|---|---|
| | CRITERIA |
| **Age Restrictions** | [AD]: 12 years of age or older. [AS, GCA, nr-axSpA, PsA, RA, CD, UC]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AD]: dermatologist, allergist, immunologist. [AS, nr-axSpA, PJIA RA]: rheumatologist. [PsA]: rheumatologist or dermatologist. [CD, UC]: gastroenterologist. [GCA]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (F) NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA): (1) Diagnosis of nr-axSpA AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, meloxicam, naproxen) AND (3a) Patient has C-reactive protein (CRP) levels above the upper limit of normal OR (3b) Patient has sacroiliitis on magnetic resonance imaging (MRI) OR (3c) Patient was previously stable on another biologic and is switching to Rinvoq. (G) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (H) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (I) GIANT CELL ARTERITIS (GCA): (1) Diagnosis of GCA AND (2) Patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Rinvoq will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Rinvoq will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [AS, nr-axSpA]: (2) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy. [AD]: (2) Patient has shown improvement while on therapy. [PsA, RA, PJIA]: (2) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. PA Automated |

# RITUXAN

## Products Affected

- RIABNI
- RITUXAN SOLUTION 500 MG/50ML INTRAVENOUS
- RUXIENCE
- TRUXIMA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe rheumatoid arthritis (RA), Non-Hodgkins lymphoma (NHL), previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegeners granulomatosis) or microscopic polyangiitis (MPA), moderate to severe pemphigus vulgaris (PV), FDA-approved indication |
| **Exclusion Criteria** | [All indications but FDA-approved indication]: Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: [RA]: TRIED OR CONTRAINDICATED TO TWO AGENTS: ADALIMUMAB (-ADAZ, HUMIRA, SIMLANDI), ENBREL, RINVOQ TAB, OR XELJANZ (TRIED A TNF BEFORE RINVOQ/XELJANZ). INITIAL: (A) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Patient is currently using or has a contraindication to methotrexate AND (3) Tried or contraindicated to at least 3 months of treatment with one conventional synthetic DMARD (disease-modifying antirheumatic drug) (e.g., methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine) AND (4) Patient meet preferred product requirements in step alert OR (4) Patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events. (B) NON-HODGIKINS LYMPHOMA (NHL), PEMPHIGUS VULGARIS (PV): (1) Diagnosis of NHL OR PV. (C) CD20-POSITIVE DIFFULSE LARGE B-CELL LYMPHOMA (DLBCL), BURKITT LYMPHOMA (BL), BURKITT-LIKE LYMPHOMA (BLL), MATURE B-CELL ACUTE LEUKEMIA (B-AL): (1) Diagnosis of DLBCL, BL, BLL, B-AL AND (2) Requested medication will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine- prednisolone]). (D) CHRONIC LYMPHOCYTIC LEUKEMIA (CLL): (1) Diagnosis of |

| PA Criteria | Criteria Details |
|---|---|
| | CLL AND (2) Requested medication will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide). (E) GRANULOMATOSIS WITH POLYANGIITIS (GPA), MICROSCOPIC POLYANGIITIS (MPA): (1) Diagnosis of GPA or MPA AND (2) Requested medication will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone). SEE OTHER CRITERIA |
| **Age Restrictions** | [RA, NHL, CLL. PV]: 18 years of age or older; [DLBCL, BL, BLL, B-AL]: 6 to 17 years of age. [GPA, MPA]: 2 years of age or older. [FDA-indication]: None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with [RA]: a rheumatologist. [NHL, DLBCL, BL, BLL, B-AL, CLL]: an Oncologist. [GPA, MPA, PV, FDA indication]: None |
| **Coverage Duration** | Oncology: Initial/Renew: 12 months, RA: Initial/Renew: 90 days, PV, GPA, MPA Initial/Renew: 6 months |
| **Other Criteria** | (F) FDA-APPROVED INDICATION: (1) Diagnosis of a FDA-Approved indication AND (2) Requested medication will be used in combination with another chemotherapy agent. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by an appropriate specialist AND (4) Requested medication will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: [NHL, DLBCL, BL, BLL, B-AL, CLL, GPA, MPA, PV]: Refer to initial. [RA]: (1) Diagnosis of RA AND (2) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy AND Requested medication will not be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. PA Automated |

# RIVFLOZA

## Products Affected

- RIVFLOZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | To lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ? 30 mL/min/1.73 m2, Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.PRIMARY HYPEROXALURIA TYPE 1 (PH1) INITIAL: (1) Prescriber attest to a diagnosis of primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR greater than or equal to 30 mL/min/1.73 m2. CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days |
| **Age Restrictions** | 9 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA AUTO |

# ROLVEDON

## Products Affected

- ROLVEDON

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO ZIEXTENZO. A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **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** | PA Automated |

# RUCONEST

## Products Affected

- RUCONEST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Ruconest is being used for acute attacks of hereditary angioedema AND (3) Patient meets one of the following: (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Ruconest will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a reduction in the severity or duration of HAE attacks AND (3) Ruconest will NOT be used concurrently with other agents used for the treatment of acute HAE attacks. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None |

# RUKOBIA

## Products Affected

- RUKOBIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Human immunodeficiency virus type 1 (HIV-1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HUMMAN IMMUNODEFICIENCY VIRUS (HIV-1): (1) Diagnosis of HIV-1 AND (2) Requested medication will be used in combination with other antiretroviral(s) AND (3) Patient is treatment experienced AND (4) Patient has multidrug-resistant HIV-1 infection AND (5) Patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. CONTINUING THERAPY: (1) Patient has been on therapy for any length of time AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# SABRIL

## Products Affected

- SABRIL
- VIGADRONE
- *vigabatrin*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Refractory Complex Partial Seizures, Infantile Spasms. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) REFRACTORY COMPLEX PARTIAL SEIZURES: (1) Diagnosed with refractory complex partial seizures AND (2) Tried or contraindicated to at least THREE antiepileptic medications, at least TWO of which must be generic (e.g., carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam IR/ER, gabapentin, zonisamide, topiramate, lamotrigine) AND (3) The potential benefits outweigh the potential risk of vision loss AND (4) Requested medication will be used as adjunctive therapy. (B) INFANTILE SPASMS: (1) Diagnosis of infantile spasms AND (2) Requested medication will be used as monotherapy AND (3) The potential benefits outweigh the risk of vision loss. CONTINUING THERAPY: (1) Patient has been on therapy any amount of time AND (2) Diagnosis of approvable indication AND (3) [Infantile spasms]: Patient is 1 month to 2 years of age. RENEWAL: (1) Diagnosis of approvable indication AND (2) [Infantile spasms]: Patient is 1 month to 2 years of age. |
| **Age Restrictions** | [Complex partial seizures]: 2 years of age or older. [Infantile spasms]: 1 month to 2 years of age. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# SANDOSTATIN

## Products Affected

- *octreotide acetate intramuscular*
- *octreotide acetate subcutaneous*
- SANDOSTATIN LAR DEPOT
- SOMAVERT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acromegaly, metastatic carcinoid tumors, vasoactive intestinal peptide-secreting tumors (VIPomas). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) ACROMEGALY: (1) Diagnosis of acromegaly AND (2) Patient had an inadequate response to surgery or radiotherapy, OR surgery or radiotherapy is not an option for this patient AND (3) Patients serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patients age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load AND [Sandostatin LAR (octreotide ER)]: (4) Patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks. (B) CARCINOID TUMORS: (1) Diagnosis of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors AND [Sandostatin LAR (octreotide ER)]: (2) Patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks. (C) VASOACTIVE INTESTINAL PEPTIDE-SECRETING TUMORS (VIPomas): Diagnosis of profuse watery diarrhea associated with VIPomas AND (2) [Sandostatin LAR (octreotide ER)]: Patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND [Acromegaly]: (3) Diagnosis confirmed by appropriate specialist.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND [Acromegaly]: (2) Patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender AND (3) Patient has shown improvement or has sustained remission of clinical symptoms of acromegaly. [Carcinoid, VIPomas]: (2) Patient has shown improvement or has sustained remission of clinical symptoms. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with an [Acromegaly]: endocrinologist. [Carcinoid, VIPomas]: None. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# SAPHNELO

## Products Affected

- SAPHNELO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe systemic lupus erythematosus (SLE) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE |
| **Required Medical Information** | A. MODERATE TO SEVERE SYSTEMIC LUPUS ERYTHEMATOSUS: INITIAL: (1) Diagnosis of moderate to severe systemic lupus erythematosus AND (2) Patient is receiving standard SLE therapy (e.g., oral corticosteroids, antimalarials, or immunosuppressants). CONTINUING THERAPY: (1) Patient has been on therapy for any amount of time AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by an appropriate specialist AND (4) Saphnelo will not be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE RENEWAL: (1) Saphnelo will not be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE AND (2) Patient has shown clinical improvement while on Saphnelo |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a rheumatologist |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automation |

# SCEMBLIX

## Products Affected

- SCEMBLIX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). Ph+ CML in CP with the T315I mutation. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+CML) in chronic phase (CP): INITIAL: (1) Diagnosis of Ph+CML) AND (2) Patient had a mutational analysis prior to initiation of therapy AND (3) Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile (Please see header CML-5 of the current NCCN guidelines) AND (4) One of the following (4a) Patients cancer has the T315I mutation OR (4b) Patient has been previously treated with at least TWO tyrosine kinase inhibitors (TKIs: e.g., Bosulif [bosutinib], Sprycel [dasatinib], Gleevec [imatinib], Tasigna [nilotinib]) CONTINUING THERAPY/RENEWAL: Unchanged from New. No PA Automation |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, renewal: 12 months |
| **Other Criteria** | B.PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA IN CHRONIC PHASE WITH T3151 MUTATION: INITIAL: (1) Confirmed T3151 mutation AND (2) Must have a documented diagnosis for a medically accepted indication including: Use of a drug which is FDA-approved. Use of which is supported by one or more citations included or approved for inclusion in any of the compendia: American Hospital Formulary Service Drug Information, DRUGDEX Information System, National Comprehensive Cancer Network (categories 1, 2a, 2b only) and Clinical Pharmacology (strong recommendation) AND (3) Documentation of dose and dates of all previous therapies and the resulting outcomes AND (4) Documentation that the proper succession of |

| PA Criteria | Criteria Details |
| --- | --- |
| | the therapies have been tried and failed (i.e. intolerance, contraindication, or progression) AND (5) Chart notes detailing the members current clinical status AND (5) Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment AND NOTE: For stage four advanced metastatic cancer, members are not required to step through other treatment options prior to requested therapy RENEWAL: (1) Current chart notes detailing response and adherence to therapy AND (2) Documented clinically significant improvements in the disease state and stability on the medication. No PA Automation |

# SEPHIENCE

## Products Affected

- SEPHIENCE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Sepiapterin-responsive phenylketonuria (PKU) with hyperphenylalaninemia (HPA). |
| **Exclusion Criteria** | Used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g., Kuvan [sapropterin], Palynziq [pegvaliase-pqpz]). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to Kuvan (sapropterin). INITIAL: (A) SEPIAPTERIN RESPONSIVE PHENYLKETONURIA (PKU) WITH HYPERPHENYLALANINEMIA (HPA): (1) Diagnosis of sepiapterin responsive PKU with HPA AND (2) Patient follows a phenylalanine-restricted diet.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Sephience will not be used concurrently with another agent indicated for the treatment of PKU.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a reduction in phenylalanine (Phe) levels by at least 30% compared to baseline or to a level below 360 micromoles/L AND (3) Sephience will not be used concurrently with another agent indicated for the treatment of PKU. |
| **Age Restrictions** | 1 month of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a metabolic or genetic disease specialist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# SEROSTIM

## Products Affected

- SEROSTIM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | HIV wasting or cachexia |
| **Exclusion Criteria** | Treatment for any of the following: athletic enhancement, anti-aging purposes, idiopathic short stature. |
| **Required Medical Information** | INITIAL: (A) HIV WASTING/CACHEXIA: (1) Diagnosis of HIV wasting/cachexia AND (2) Patient is on HIV anti-retroviral therapy (e.g., Descovy [emtricitabine-tenofovir], Triumeq [abacavir-dolutegravir-lamivudine]) AND (3) Patient has inadequate response to previous therapy (exercise training, nutritional supplements, appetite stimulants, or anabolic steroids) AND (4) Patient has an inadequate response to one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate) AND (5) Alternative causes of wasting have been ruled out (e.g., altered metabolism [metabolic and hormonal abnormalities] including testosterone deficiency or peripheral growth hormone resistance, diarrhea, inadequate energy/caloric intake, malignancies, opportunistic infections) AND (6) Patient meets ONE of the following for weight loss: (6a) 10% unintentional weight loss over 12 months OR (6b) 7.5% unintentional weight loss over 6 months OR (6c) 5% body cell mass (BCM) loss within 6 months OR (6d) BCM less than 35% (men) AND a BMI less than 27 kg/m2 OR (6e) BCM less than 23% (women) of total body weight AND a BMI less than 27 kg/m2 OR (6f) BMI less than 18.5 kg/m2 AND (7) Patient has NOT received a total of 48 weeks of cumulative treatment with any somatropin (e.g., Genotropin, Humatrope, Norditropin) AND (8) Patient is hypogonadal as defined by ONE of the following: (8a) Total serum testosterone level of less than 300ng/dL (10.4 nmol/L) OR (8b) Low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days OR (8c) Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L) AND (9) For patients that are hypogonadal, they have tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto). SEE OTHER CRITERIA |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, nutritional support specialist, or infectious disease specialist. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 weeks, Renewal: 36 weeks. LIFETIME: 48 weeks. |
| **Other Criteria** | CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 12 weeks AND (2) Diagnosis of approvable indication AND (3) Patient has NOT received a total of 48 weeks of cumulative treatment with any somatropin (e.g., Genotropin, Humatrope, Norditropin) AND (3) Exclusion criteria AND (4) Patient is on HIV anti-retroviral therapy AND (5) Patient has shown clinical benefit in muscle mass and weight as indicated by a 10% or greater increase in weight or BCM from baseline (Note: Current and baseline weight must be documented including dates of measurement). No PA Automation |

# SILDENAFIL

## Products Affected

- REVATIO ORAL
- *sildenafil citrate oral suspension*
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate tablet 20 mg oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). |
| **Exclusion Criteria** | Used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) AND Used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat]). |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND ADULTS [Revatio IV, suspension, tablets, Liqrev]: (2) PAH diagnosis confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU) AND (5a) [Revatio suspension]: Patient is unable to swallow pills AND has tried crushed sildenafil tablets OR (5b) [Liqrev]: patient is unable to swallow Revatio (sildenafil) tablets AND has tried generic sildenafil powder for suspension. PEDIATRICS [Revatio suspension, tablets]: (2) PAH diagnosis confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU) AND (5) [Revatio suspension]: Patient is unable to swallow pills AND has tried crushed sildenafil tablets.CONTINUATION OF THERAPY: (1) Patient is stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Not used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis, Viagra) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) AND (4) Not used concurrently with guanylate cyclase stimulators (e.g., Adempas). RENEWAL: (1) Diagnosis of approvable indication AND (2) Not used concurrently or intermittently with oral erectile dysfunction agents or any organic nitrates in any form AND (3) Not used concurrently with guanylate cyclase stimulators (e.g., Adempas) AND (4a) [Revatio suspension]: Patient is 1 to 17 years of age OR (4b) [Other formulations]: 18 years of age or older. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | Revatio IV, Liqrev: 18 years of age or older; Revatio (sildenafil) suspension, tablets: 1 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# SILIQ

## Products Affected

- SILIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (PsO) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to THREE agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Skyrizi, Sotyktu, Taltz, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek). INITIAL: (A) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patients has psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp AND (3) Patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior AND (4a) Patient has had at least a 3-months trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (4b) Contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] used in the treatment of PsO OR (4c) Patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Siliq will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more AND (3) Patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors AND (4) Siliq will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. |
| **Age Restrictions** | 18 years of age or older |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | PsO: prescribed by or in consultation with dermatologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# SIMLANDI

## Products Affected

- *adalimumab-ryvk (1 pen)*
- *adalimumab-ryvk (2 pen)*
- *adalimumab-ryvk (2 syringe)*
- SIMLANDI (1 PEN)
- SIMLANDI (2 PEN)
- SIMLANDI (2 SYRINGE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Crohn disease (CD), Hidradenitis suppurativa (HS), Polyarticular juvenile idiopathic arthritis (PJIA), Plaque psoriasis (PsO), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC), Intermediate, posterior, and panuveitis |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to a NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (C) HIDRADENITIS SUPPURATIVA (HS): (1) Diagnosis of moderate to severe HS. (D) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (E) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3 percent or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to Simlandi AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA for the treatment of PsO OR (3b) Patient has a contraindication or intolerance to both immunosuppressants AND PUVA used in the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (F) PSORATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (G) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Tried or contraindicated to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug) such as: methotrexate dose of at least 20mg per week or maximally tolerated dose, hydroxychloroquine, leflunomide, sulfasalazine. (H) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. (I) UVEITIS: (1) Diagnosis of non-infectious intermediate, posterior and |

| PA Criteria | Criteria Details |
|---|---|
| | panuveitis AND (2) Patient does NOT have isolated anterior uveitis. SEE OTHER CRITERIA |
| **Age Restrictions** | [CD]: 6 years of age or older. [PJIA, Uveitis]: 2 years of age or older. [HS]: 12 years of age or older. [AS, PsA, PsO, RA]: 18 years of age or older. [UC]: 5 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, PJIA, PsA, RA]: rheumatologist. [HS, Ps, PsA]: dermatologist. [UC, CD]: gastroenterologist. [UV]: ophthalmologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Simlandi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Simlandi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor PDE-4 inhibitor) for an autoimmune indication AND [AS]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. [HS]: (3) Patient has shown improvement while on therapy. [PIJA, PsA, RA]: (3) Patient experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [PsO]: (3) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. [Uveitis]: (3) Patient has NOT experienced treatment failure, defined as ONE of the following: (3a) Development of new inflammatory chorioretinal or retinal vascular lesions OR (3b) A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade OR (3c) A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved. PA Automated |

# SIMPONI

## Products Affected

- SIMPONI
- SIMPONI ARIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing spondylitis (AS), Active polyarticular Juvenile Idiopathic Arthritis (PJIA), Psoriatic arthritis (PsA), Rheumatoid arthritis (RA), Ulcerative colitis (UC) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [AS] SIMPONI 50mg/ARIA: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Rinvoq tab, Taltz, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [PJIA] SIMPONI ARIA: TWO agents: adalimumab (-adaz, Humira, Simlandi), Enbrel, Rinvoq LQ, or Xeljanz (Tried a TNF prior to Rinvoq/Xeljanz). [PsA] SIMPONI 50mg/ARIA: TWO agents: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Rinvoq LQ/tab, Skyrizi, Taltz, ustekinumab (-aekn, Stegeyma, Yesintek), Tremfya, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [RA] SIMPONI 50mg/ARIA: TWO agents: adalimumab (-adaz, Humira, Simlandi), Enbrel, Rinvoq tab, or Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [UC] SIMPONI: ONE agent: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, ustekinumab (-aekn, Stegeyma, Yesintek), Tremfya, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, meloxicam, naproxen). (B) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (C) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (D) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Patient is concurrently using or has a contraindication to methotrexate AND (3) Tried or contraindicated to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine AND (4a) Patient meets step therapy OR (4b) Patient has tried a TNF inhibitor AND physician has indicated patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and |

| PA Criteria | Criteria Details |
|---|---|
| | serious cardiovascular events. SEE OTHER CRITERIA |
| **Age Restrictions** | [AS, RA]: 18 years of age or older. [UC]: 5 years of age or older. [PsA, PJIA]: 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, PJIA, RA]: rheumatologist. [PsA]: rheumatologist or dermatologist. [UC]: gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (E) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC AND (2) Patient weighs at least 15 kg (33lbs).CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Simponi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Simponi will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication AND [PJIA, PsA, RA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [AS]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy. PA Automated |

# SIRTURO

## Products Affected

- SIRTURO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary tuberculosis (TB). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) PULMONARY TUBERCULOSIS (TB): Diagnosis of pulmonary TB AND (2a) Patient has an isolate of Mycobacterium tuberculosis that is resistant to rifampin and isoniazid AND (3a) Patient is 5 years of age or older AND (3a.i) Sirturo will be used in combination with at least 3 other antibiotics OR (3b) Patient is 18 years of age AND (3b.i) Sirturo will be used in combination with pretomanid and linezolid OR (2b) Patient has an isolate of Mycobacterium tuberculosis that is resistant to isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside AND (3) Patient is 18 years of age or older AND (4) Sirturo will be used in combination with pretomanid and linezolid. CONTINUING THERAPY: Treat as initial. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 26 weeks, Renewal: None. |
| **Other Criteria** | PA Automation |

# SIVEXTRO

## Products Affected

- SIVEXTRO ORAL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute bacterial skin or skin structure infection (ABSSSI) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: A. ACUTE BACTERIAL SKIN OR SKIN STRUCTURE INFECTION (ABSSSI): (1) The patient has ABSSSI AND (2) Patient meets one of the following: (2a) Request is for continuation of therapy (oral or intravenous) OR (2b) Patient is being transitioned from intravenous Sivextro to oral Sivextro OR (2c) Patient had a trial of, contraindication to, or resistance to generic linezolid tablets AND (3) Patient weighs at least 35 kilograms (77 pounds). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 30 days |
| **Other Criteria** | PA Automated |

# SKYCLARYS

## Products Affected

- SKYCLARYS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Friedreichs ataxia. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) FRIEDREICHS ATAXIA: (1) Diagnosis of Friedreichs ataxia AND (2) Diagnosis is confirmed by genetic testing (homozygous for GAA repeat expansion in intron-1 of FXN gene). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | 16 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# SKYRIZI

## Products Affected

- SKYRIZI INTRAVENOUS
- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE
- SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate-to-severe plaque psoriasis (PsO), Psoriatic Arthritis (PsA), moderate-severe Crohns disease (CD), Ulcerative colitis (UC) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patient has psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to Skyrizi AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (3b) Contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] for the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (B). PsA: (1) Diagnosis of PsA. (C) CROHNS DISEASE (CD): (1) Diagnosis of moderate-severe CD. (D) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Skyrizi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Skyrizi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [PsO]: (3) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more. [PsA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [PsO, PsA]: dermatologist or rheumatologist. [CD, UC]: gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# SKYTROFA

## Products Affected

- SKYTROFA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Growth failure due to an inadequate secretion of endogenous GH, growth hormone deficiency (GHD). |
| **Exclusion Criteria** | Treatment for any of the following: athletic enhancement, anti-aging purposes, idiopathic short stature; Used concurrently with Increlex (mecasermin). |
| **Required Medical Information** | INITIAL: (A) ENDOGENOUS GH: (1) Diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) AND (2) Attestation that epiphyses are open AND (3) Patient meets ONE of the following criteria: (3a) Height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender OR (3b) Height velocity less than the 25th percentile for age OR (3c) Low peak GH (less than 10ng/mL) on two GH stimulation tests OR (3d) IGF-1 that is at least 2 SD below the mean for the same age and gender. (B) ADULT GROWTH HORMONE DEFICIENCY (GHD): (1) Diagnosis of GHD AND (2a) Patients GHD caused by a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation) OR (2b) Patients GHD is confirmed by ONE of the following GH stimulation tests: (2b.i) Insulin tolerance test (peak growth hormone of 5 ng/mL or less) OR (2b.ii) Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patients BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patients BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patients BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patients BMI is greater than 30 kg/m2) OR (2b.iii) Macimorelin test (peak growth hormone of 2.8 ng/mL or less). (C) IDIOPATHIC SHORT STATURE: (1) Request will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition). |
| **Age Restrictions** | [ENDOGENOUS]: 1 to 17 years of age. [GHD]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Approved by appropriate specialist AND [ENDOGENOUS]: (4) Evidence epiphyses still open AND (5) Patient weighs at least 11.5 kg AND Skytrofa will not be used concurrently with Increlex AND (6) One of the following: (6a) Annual growth velocity of at least 2 cm compared with what was observed from the previous year OR (6b) Annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty. [GHD]: (4) Patient has achieved and/or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health, etc.). PA Automation |

# SODIUM PHENYLBUTYRATE

## Products Affected

- BUPHENYL
- OLPRUVA (2 GM DOSE)
- OLPRUVA (3 GM DOSE)
- OLPRUVA (4 GM DOSE)
- OLPRUVA (5 GM DOSE)
- OLPRUVA (6 GM DOSE)
- OLPRUVA (6.67 GM DOSE)
- PHEBURANE
- *sodium phenylbutyrate oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Urea cycle disorder (UCD). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to ONE agent: sodium phenylbutyrate or Pheburane prior to Buphenyl, Olpruva. INITIAL: (A) UREA CYCLE DISORDER (UCD): (1) Diagnosis of UCD AND (2) Patients UCD is confirmed by enzymatic, biochemical or genetic testing AND (3) Requested medication will be used as adjunctive therapy along with dietary protein restriction AND (4) Patients disorder cannot be managed by dietary protein restriction or amino acid supplementation alone. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# SOFDRA

## Products Affected

- SOFDRA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary axillary hyperhidrosis |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL: PRIMARY AXILLARY HYPERHIDROSIS (1) Prescriber attests to a diagnosis of primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least 6 months duration with all secondary causes ruled out AND (2) Prescriber attests the patient had a trial of the preferred topical anticholinergic agent: Qbrexza (glycopyrronium tosylate) AND (3) Sofdra will NOT be used concurrently with other topical anticholinergics indicated for primary axillary hyperhidrosis (e.g., Qbrexza [glycopyrronium tosylate]) AND (4) Prescriber attests to two of the following: (4a) symptoms occur bilaterally, (4b) symptoms impair daily activities, (4c) patient has at least one episode per week, (4d) primary axillary hyperhidrosis onset occurred prior to the patient turning 25 years of age, (4e) patient has a family history of primary axillary hyperhidrosis, (4f) patient is not symptomatic during sleep. CONTINUATION OF THERAPY: (1) Diagnosis of an approvable indication AND (2) Patient has been stable on therapy for at least 90 days |
| **Age Restrictions** | 9 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None |

# SOGROYA

## Products Affected

- SOGROYA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Growth failure due to an inadequate secretion of endogenous GH, Adult Growth hormone deficiency (GHD). |
| **Exclusion Criteria** | Treatment for any of the following: athletic enhancement, anti-aging purposes, idiopathic short stature; Used concurrently with Increlex (mecasermin). |
| **Required Medical Information** | INITIAL: (A) ENDOGENOUS GH: (1) Diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) AND (2) Attestation that epiphyses are open AND (3) Patient meets ONE of the following criteria: (3a) Height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender OR (3b) Height velocity less than the 25th percentile for age OR (3c) Low peak GH (less than 10ng/mL) on two GH stimulation tests OR (3d) IGF-1 that is at least 2 SD below the mean for the same age and gender. (B) ADULT GROWTH HORMONE DEFICIENCY (GHD): (1) Diagnosis of GHD AND (2a) Patients GHD caused by a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation) OR (2b) Patients GHD is confirmed by ONE of the following GH stimulation tests: (2b.i) Insulin tolerance test (peak growth hormone of 5 ng/mL or less) OR (2b.ii) Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patients BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patients BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patients BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patients BMI is greater than 30 kg/m2) OR (2b.iii) Macimorelin test (peak growth hormone of 2.8 ng/mL or less). (C) IDIOPATHIC SHORT STATURE: (1) Request will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition). SEE OTHER CRITERIA |
| **Age Restrictions** | [Endogenous]: 2.5 to 17 years of age. [Adult GHD]: 18 years of age or older. |
| **Prescriber** | Prescribed by or in consultation with an endocrinologist |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Diagnosed by appropriate specialist AND (4) Exclusion criteria AND [ENDOGENOUS]: (5) Evidence epiphyses still open AND (6) One of the following (6a) Annual growth velocity of at least 2 cm compared with what was observed from the previous year OR (6b) Annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty. [ADULTS]: (5) Patient has achieved or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health). PA Automation |

# SOMATROPIN

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- ZOMACTON

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Growth failure due to an inadequate secretion of endogenous growth hormone (GH), short stature associated with Noonan syndrome, short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency, short stature associated with Turner syndrome, short stature born small for gestational age, growth failure secondary to chronic kidney disease, growth hormone deficiency (GHD), Prader-Willi syndrome (PWS). |
| **Exclusion Criteria** | Treatment for any of the following: athletic enhancement, anti-aging purposes, idiopathic short stature; Used concurrently with Increlex (mecasermin). |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO NORDITRIOPIN AND GENOTROPIN. INITIAL: [ENDOGENOUS GH]: (1) Diagnosis of growth failure due to an inadequate secretion of endogenous growth hormone (GH) AND (2) Attestation that epiphyses are open AND (3) Patient meets ONE of the following criteria: (3a) Height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender OR (3b) Height velocity less than the 25th percentile for age OR (3c) Low peak GH (less than 10ng/mL) on two GH stimulation tests OR (3d) IGF-1 that is at least 2 SD below the mean for the same age and gender. (B) NOONAN SYNDROME / SHORT STATURE HOMEOBOX-CONTAINING GENE (SHOX) DEFICIENCY: (1) Diagnosis of short stature associated with Noonan syndrome or short stature or growth failure with SHOX deficiency AND (2) Attestation that epiphyses are open AND (3) Height 2 or more standard deviations (SD) below the mean height for normal children of the same age or gender. (C) TURNER SYNDROME: Diagnosis of short stature associated with Turner syndrome AND (2) Diagnosis confirmed by chromosomal analysis (karyotyping) AND (3) Attestation that epiphyses are open AND (4) Height 2 or more standard deviations (SD) below the mean height for normal children of the same age or gender. (D) SMALL FOR GESTATIONAL AGE (SGA): (1) Diagnosis of short stature born SGA AND (2) Attestation that epiphyses are open AND (3) Height or weight 2 |

| PA Criteria | Criteria Details |
|---|---|
| | or more SD below the mean height for normal children of the same age and gender AND (4) Failure to show catch-up growth by age 2 to 4 years. (E) CHRONIC KIDNEY DISEASE (CKD): Diagnosis of growth failure secondary to CKD AND (2) Patient has not had a renal transplant, or it has been at least one year since renal transplant AND (3) Persistent growth failure (height below the 10th percentile) AND persistent low height velocity (below the 25th percentile). SEE OTHER CRITERIA |
| **Age Restrictions** | Initial/Renewal: [Endogenous, CKD]: under 18 years of age. [GHD]: 18 years of age or older. [SGA]: 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist. [CKD]: endocrinologist or nephrologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (F) ADULT GROWTH HORMONE DEFICIENCY (GHD): (1) Diagnosis of GHD AND (2a) Patients GHD caused by a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation) OR (2b) Patients GHD is confirmed by ONE of the following GH stimulation tests: (2b.i) Insulin tolerance test (peak growth hormone of 5 ng/mL or less) OR (2b.ii) Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patients BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patients BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patients BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patients BMI is greater than 30 kg/m2) OR (2b.iii) Macimorelin test (peak growth hormone of 2.8 ng/mL or less). (G) PRADER-WILLI SYNDROME (PWS): (1) Confirmed genetic diagnosis of PWS. (G) IDIOPATHIC SHORT STATURE: (1) Request will NOT be approved for athletic enhancement, anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition). CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Exclusion criteria AND [ENDOGENOUS, NOONAN, SHOX, TURNER, SGA, CKD]: (5) Evidence epiphyses still open AND (6) ONE of the following: (6a) Growth velocity of 2 cm or more compared with what was observed from the previous year OR (6b) Growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty AND [CKD]: (7) Patient has not undergone a renal transplantation within the past year. [PWS]: (5) Patient has shown improvement in body |

| PA Criteria | Criteria Details |
| --- | --- |
| | composition. PA Automation |

# SOTYKTU

## Products Affected

- SOTYKTU

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (PsO) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2) Meets one of the following: (2a) Patient has psoriasis covering 3 percent or more of body surface area (BSA) OR (2b) Patients with psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to Sotyktu AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] used in the treatment of PsO OR (3b) Patient has a contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] used in the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira [adalimumab], PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Sotyktu will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Sotyktu will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND (3) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist |
| **Coverage** | Initial: 12 months Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Duration** | |
| **Other Criteria** | PA Automated |

# SOVALDI

## Products Affected

- SOVALDI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic hepatitis C- GT 1, 2, 3, or 4. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.CHRONIC HEPATITIS C GT 1, 2, 3 or 4: (1) Must have a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3 or 4 AND (2) Must provide HCV RNA level within last 6 months AND (3) Prescriber attests that the patient does NOT meet any of the following: (3a) patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions, (3b) Sovaldi will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin [rifapentine], St. Johns wort, Aptivus [tipranavir]/ritonavir), (3c) Solvadi will be used concurrently with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir) AND (4a) Patient has a genotype 2 infection and will use Sovaldi with ribavirin AND (4b) patient has compensated cirrhosis (Child-Pugh A) or patient does not have cirrhosis OR (5) Patient is 3 to 17 years of age OR (6a) Patient has a genotype 3 infection and will use Sovaldi with ribavirin AND (6b) patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis OR (7) Patient has a genotype 1 or 4 infection and meets ALL of the following: (7a) patient is 18 years of age or older, (7b) patient is treatment-naive, (7c) The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis, AND (7d) Sovaldi will be used with peginterferon alfa and ribavirin OR (8) Patient have genotype 1 infection and meet ALL of the following criteria: (8a) patient is 18 years of age or older, (8b) patient is treatment-na?ve, (8c) patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis AND (8d) Sovaldi will be used with ribavirin, AND (8e) The patient has a contraindication to interferon (interferon ineligible) OR SEE OTHER CRITERIA |
| **Age Restrictions** | GT 2, 3: 3 years or older GT 1, 4: 18 years or older |
| **Prescriber** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | 12-48 weeks, See OTHER CRITERIA Field |
| **Other Criteria** | (9) request to prevent post-transplant HCV reinfection and the patient meets ALL of the following criteria: (9a) patient has hepatocellular carcinoma, (9b) patient is awaiting liver transplantation (9c) Sovaldi will be used with ribavirin as pre-transplant treatment OR (10) The patient previously failed treatment with Mavyret OR Vosevi and meets ALL of the following criteria: (11a) patient has compensated cirrhosis OR does not have cirrhosis, (11b) Sovaldi will be used with Mavyret AND ribavirin OR(12) The patient does meet a condition as specified above but the requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.Duration of approval is based on recommendations by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.No PA Automation |

# SPEVIGO

## Products Affected

- SPEVIGO SUBCUTANEOUS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Generalized pustular psoriasis (GPP) |
| **Exclusion Criteria** | Spevigo used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of generalize pustular psoriasis |
| **Required Medical Information** | A. INITIAL: GENERALIZED PUSTULAR PSORIASIS (GPP) (1) Patient has a diagnosis of GPP AND (2) Prescriber attests patient weighs at least 40 kg (88 lbs) AND (3) Patient has a history of GPP as defined by the presence of sterile, macroscopically visible pustules on non-acral skin (per ERASPEN diagnostic criteria).CONTINUATION OF THERAPY/RENEWAL: (1) Patient has an approvable indication AND (2) Patient has shown a clinical response to therapy AND (3) Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of generalize pustular psoriasis |
| **Age Restrictions** | 12 years of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist |
| **Coverage Duration** | Initial: 3 months Renewal: 12 months |
| **Other Criteria** | PA AUTO |

# SPRAVATO

## Products Affected

- SPRAVATO (56 MG DOSE)
- SPRAVATO (84 MG DOSE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment-resistant depression (TRD), Major depressive disorder (MDD). |
| **Exclusion Criteria** | Patient has active substance abuse. |
| **Required Medical Information** | INITIAL: (A) TREATMENT-RESISTANT DEPRESSION (TRD): (1) Diagnosis of TRD AND (2) Patient has non-psychotic, unipolar depression. (B) MAJOR DEPRESSIVE DISORDER (MDD):: (1) Diagnosis of MDD AND (2) Spravato will be used in combination with an oral antidepressant (e.g., Zoloft, Cymbalta) AND (3) Patient has acute suicidal ideation or behavior AND (4) Patient has non-psychotic, unipolar depression.<br>CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has demonstrated clinical benefit (improvement in depression) compared to baseline. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a psychiatrist, or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider. |
| **Coverage Duration** | [TRD]: Initial: 6 months Renewal: 12 months; [MDD]: 2 month, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# STELARA

## Products Affected

- IMULDOSA
- OTULFI
- PYZCHIVA
- SELARSDI INTRAVENOUS
- SELARSDI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- STELARA
- STEQEYMA
- *ustekinumab*
- *ustekinumab-aauz*
- *ustekinumab-aekn*
- *ustekinumab-ttwe intravenous*
- *ustekinumab-ttwe subcutaneous solution prefilled syringe*
- YESINTEK

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (PsO), Psoriatic arthritis (PsA), Crohns disease (CD), ulcerative colitis (UC) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: [STELARA]: Tried or contraindicated to ustekinumab (-aekn, Stegeyma, Yesintek) AND TWO agents: [PsA]: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Rinvoq, Skyrizi, Taltz, Tremfya, Xeljanz (Tried TNF prior to Rinvoq/Xeljanz). [PsO]: adalimumab (-adaz, Humira, Simlandi), Bimzelx, Enbrel, Otezla, Skyrizi, Sotyktu, Taltz, Tremfya. [CD]: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq, Skyrizi, Tremfya (Tried TNF prior to Rinvoq). [UC]: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq, Skyrizi, Tremfya, Xeljanz (XR) (Tried TNF prior to Rinvoq/Xeljanz). INITIAL: (A) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (B) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patient has psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp OR (2c) [Not Stelara]: Patient was previously stable on another biologic and is switching to ustekinumab AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (3b) Contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] for the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (C) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (D) ULCERATIVE COLITIS (UC): (1) Diagnosis of |

| PA Criteria | Criteria Details |
|---|---|
| | moderate to severe active UC. |
| **Age Restrictions** | [PsO, PsA]: 6 years of age or older, [CD, UC]: 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [PsA]: rheumatologist or dermatologist. [PsO]: dermatologist. [CD, UC]: gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Ustekinumab will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND (5) Meets step alert.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Ustekinumab will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND (3) Meets step alert AND [PsO] (4) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more. [PsA] (4) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. PA Automated. |

# STIMUFEND

## Products Affected

- STIMUFEND

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy, hematopoietic syndrome of acute radiation syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO ZIEXTENZO. A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME: (1) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# STRENSIQ

## Products Affected

- STRENSIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Perinatal/Infantile-Onset Hypophosphatasia (HPP), Juvenile-Onset Hypophosphatasia (HPP), Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. FOR ALL INDICATIONS: INITIAL: (1) Prescriber attests that patient has a documented diagnosis of perinatal/infantile or Juvenile-onset HPP AND (2) Prescriber attest to confirmed tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation(s) AND (3) Prescriber attests to serum alkaline phosphatase (ALP) levels below the age-adjusted normal range AND (4) Prescriber attests to plasma pyridoxal-5-phsphate (PLP) above the upper limit of normal at baseline AND (5) Prescriber attests that patient must have been less than or equal to 18 years of age at the onset of signs or symptoms AND (6) Prescriber provides patients most recent weight AND (7) Prescriber attests to baseline renal ultrasound and periodically throughout treatment AND (8) Prescriber attests to documentation of ophthalmologic exam at baseline and periodically throughout treatment RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria AND (2) Prescriber attests that patient is responding to and tolerating treatment (improvement in growth, respiratory status, or radiographic findings) |
| **Age Restrictions** | Perinatal/Infantile-Onset HPP: diagnosis during pregnancy and up to 2 years of age. Juvenile-Onset HPP: diagnosis before the age of 18 years |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or a specialist in the treatment of metabolic bone disorders |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# SUBLOCADE

## Products Affected

- SUBLOCADE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Opioid use disorder. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) OPIOID USE DISORDER: (1) Diagnosis of moderate to severe opioid use disorder AND (2a) Patient initiated treatment with a single dose of a transmucosal buprenorphine product (e.g., Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]) OR (2b) Patient is already being treated with buprenorphine. CONTINUING THERAPY / RENEWAL: Treat as initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# SUBVENITE

## Products Affected

- SUBVENITE ORAL SUSPENSION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Partial-onset seizures, primary generalized tonic-clonic (PGTC) seizures or generalized seizures of Lennox-Gastaut syndrome, bipolar I disorder. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A): PARTIAL-ONSET SEIZURES: (1) Diagnosis of partial-onset seizures AND (2) Patient has a contraindication or is unable to swallow lamotrigine tablets AND (3) ONE of the following: (3a) Subvenite will be used as adjunctive therapy OR (3b) Subvenite will be used as monotherapy AND (3b.i) Patient is 16 years of age or older AND (3b.ii) Patient is receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug (AED) but will be switched to Subvenite. (B) GENERALIZED SEIZURES: (1) Diagnosis of primary generalized tonic-clonic (PGTC) seizures or generalized seizures of Lennox-Gastaut syndrome AND (2) Patient has a contraindication or is unable to swallow lamotrigine tablets AND (3) Subvenite will be used as adjunctive therapy. (C) BIPOLAR DISORDER: (1) Diagnosis of bipolar I disorder AND (2) Patient has a contraindication or is unable to swallow lamotrigine tablets AND (3) Subvenite will be used for maintenance treatment AND (4) Patient is receiving treatment with standard therapy (e.g., olanzapine, valproate, lithium) for acute mood episodes (depression, mania, hypomania, mixed episodes). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has a contraindication or is unable to swallow lamotrigine tablets. |
| **Age Restrictions** | [Seizures]: 2 years of age or older. [Bipolar]: None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# SUCRAID

## Products Affected

- SUCRAID

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) CONGENITAL SUCRASE-ISOMALTASE DEFICIENCY (CSID): (1) Diagnosis of genetically determined sucrase deficiency, which is a part of CSID AND (2) Diagnosis is confirmed by one of the following (2a) Small bowel biopsy OR (2b) Sucrose breath test OR (2c) Genetic test.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced or maintained improvement on treatment. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or medical geneticist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# SUNLENCA

## Products Affected

- SUNLENCA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Human immunodeficiency virus type 1 (HIV-1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1): (1) Diagnosis of HIV-1 AND (2) Patient is treatment-experienced AND (3) Patients HIV-1 is multidrug resistant and has failed current antiretroviral regimen due to resistance, tolerance, or safety considerations. CONTINUING THERAPY: (1) Patient has been on therapy for any length of time AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# SUNOSI

## Products Affected

- SUNOSI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Excessive daytime sleepiness (EDS) with narcolepsy, excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) NARCOLEPSY: (1) Diagnosis of excessive daytime sleepiness (EDS) with narcolepsy AND (2) Diagnosis confirmed by one of the following: (2a) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least two early-onset REM sleep periods (SOREMPs) OR (2b) Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [Note to Pharmacist: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals] OR (2c) Patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay AND (3) Patient has EDS persisting for at least 3 months AND (4) Patient has an Epworth Sleepiness Scale (ESS) score of greater than 10 AND (5) Tried or contraindicated to ONE of the following generics: amphetamine derivative (such as amphetamine sulfate, methylphenidate), modafinil/armodafinil. (B) OBSTRUCTIVE SLEEP APNEA (OSA): (1) Diagnosis of excessive daytime sleepiness (EDS) with OSA AND (2) OSA is confirmed by ONE of the following (2a) Polysomnograhy OR (2b) Home sleep apnea testing devices OR (2c) Hospital-based bedside monitoring AND (3) Patient has EDS persisting for at least 3 months AND (4) Patient has an Epworth Sleepiness Scale (ESS) score of greater than 10 AND (5) Patient is in ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and has been counseled on weight-loss intervention (if BMI > 30) AND (6) Tried or contraindicated to armodafinil OR modafinil. |
| **Age Restrictions** | None. |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Prescribed by or in consultation with a [Narcolepsy]: neurologist, psychiatrist, or specialist in sleep medicine. [OSA]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: Treat as initial. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has demonstrated at least 25% improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline. PA Automation |

# SUPPRELIN LA

## Products Affected

- SUPPRELIN LA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of children with central precocious puberty, medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Females who are or may become pregnant |
| **Required Medical Information** | A. CENTRAL PRECOCIOUS PUBERTY (CPP) INITIAL: (1) Patient is currently less than 11 years of age AND (2) ONE of the following: (2a) Luteinizing hormone (LH) morning values greater than 0.3 IU/L OR (2b) Peak LH after GnRH stimulation greater than 5 IU/L AND (3) ONE of the following: (3a) Patient had pubertal development prior to 8 years of age (girls) or 9 years of age (boys) OR (3b) Sexual maturation progresses to next stage (Tanner scale) within 3-6 months OR (3c) Growth velocity greater than 6 cm/year OR (3d) Bone age advanced by 1 year or more OR (3e) Predicted adult height below target range or declining on serial determinations RENEWAL: (1) Patient is not more than 11 years of age |
| **Age Restrictions** | Patient is not more than 11 years of age |
| **Prescriber Restrictions** | Prescribed by or in conjunction with endocrinologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# SYMDEKO

## Products Affected

- SYMDEKO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis (CF). |
| **Exclusion Criteria** | Used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Required Medical Information** | A. INITIAL: CYSTIC FIBROSIS (CF): (1) Diagnosis of CF AND (2) Patient is homozygous for the F508del mutation OR has a responsive mutation in the CFTR gene. CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in clinical status AND (3) Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **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: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# SYNAREL

## Products Affected

- SYNAREL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Central precocious puberty (CPP), endometriosis, gender dysphoria (GD) |
| **Exclusion Criteria** | [Endometriosis] Used concurrently with another gonadotropin-releasing hormone (GnRH)-modulating agent (e.g., Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone acetate], Lupron Depot [leuprolide]).[CPP, GD]: None. |
| **Required Medical Information** | INITIAL: (A) CENTRAL PRECOCIOUS PUBERTY (CPP): (1) Diagnosis of CCP AND (2) Patient at the time of onset of CPP was younger than 8 years of age (if female) or younger than 9 years of age (if male) AND (3a) For females: patient has elevated levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis OR (3b) For Males: patient has elevated levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis AND (4a) For females: patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above) OR (4b) For males: patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above). (B) ENDOMETRIOSIS: (1) Diagnosis of endometriosis AND (2) Diagnosis confirmed by surgical or direct visualization (e.g., pelvic ultrasound or histopathological confirmation [e.g., laparoscopy]) in the last 10 years AND (3) Patient has not received more than 6 months of treatment with Synarel per lifetime AND (4) Tried or contraindicated to both of the following: (4a) Nonsteroidal anti-inflammatory drug (NSAID) AND (4b) Progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation). (C) GENDER DYSPHORIA (GD): (1) Diagnosis of GD AND (2) Gender dysphoria is NOT restricted from coverage under the patient's benefit. CONTINUING THERAPY / RENEWAL: [ENDOMETRIOSIS]: Treat as Initial. [CPP]: (1) Diagnosis of approvable indication AND (2) Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year AND (2) Patient has NOT reached the actual age which corresponds to their current pubertal age. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | [ENDOMETRIOSIS]: 18 years of age or older. [CPP]: 2 years of age or older. [GD]: None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an [CPP]: pediatric endocrinologist. [Endometriosis]: obstetrician/gynecologist. |
| **Coverage Duration** | [CPP, GD]: Initial: 12 months, Renewal: 12 months, [Endometriosis]: 6 months |
| **Other Criteria** | PA Automated. |

# TADALAFIL

## Products Affected

- ADCIRCA
- ALYQ
- *tadalafil (pah)*
- TADLIQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). |
| **Exclusion Criteria** | Used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) AND Used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat]). |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Pulmonary arterial hypertension (WHO Group 1) AND (2) PAH diagnosis is confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) greater than 2 Wood units AND TADLIQ (3) Patient is unable to swallow tadalafil tablets. CONTINUATION OF THERAPY: Patient has been stable on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Not used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) AND (4) Not used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat]).RENEWAL: (1) Diagnosis of approvable indication AND (2) Not used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate) AND (3) Not used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat]). |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# TAKHZYRO

## Products Affected

- TAKHZYRO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary angioedema (HAE) |
| **Exclusion Criteria** | Used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY ANGIOEDEMA (HAE): (1) Diagnosis of HAE AND (2) Takhyzro will be used for prophylaxis against HAE attacks AND (3) Patient meets one of the following: (3a) Patient has Type I or II HAE, as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q OR (3b) Patient has Type III HAE. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE attacks. RENEWAL: (1) Diagnosis of approvable indication AND (2) Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE attacks AND (3) Patient has experienced an improvement in HAE attacks (i.e., reductions in attack frequency or attack severity) compared to baseline. |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# TALTZ

## Products Affected

- TALTZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing Spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), Plaque psoriasis (PsO), Psoriatic arthritis (PsA) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, meloxicam. naproxen) (B) NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA): (1) Diagnosis of nr-axSpA AND (2) Patient had a trial of or contraindication to an NSAID (e.g., ibuprofen, meloxicam. naproxen) AND (3a) Patient has C-reactive protein (CRP) levels above the upper limit of normal OR (3b) Patient has sacroiliitis on magnetic resonance imaging (MRI) OR (3c) Patient was previously stable on another biologic and is switching to Taltz. (C) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patient has psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp OR (2c) Patient was previously stable on another biologic and is switching to Taltz AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA [phototherapy] for the treatment of PsO OR (3b) Contraindication or intolerance to both immunosuppressants AND PUVA for the treatment of PsO OR (3c) Patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for same indication. (D) PSORATIC ARTHRITIS (PSA): (1) Diagnosis of PsA. |
| **Age Restrictions** | [PsO]: 6 years of age or older. [AS, nr-axSpA, PsA] :18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, nr-axSpA, PsA]: rheumatologist. [PsO, PsA]: dermatologist. |
| **Coverage** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
|---|---|
| **Duration** | |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Taltz will NOT be used concurrently with another systemic biologic or targeted small molecules, PDE-4 inhibitor for an autoimmune indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Taltz will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [PsO] (3) Patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more. [PsA] (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [AS, nr-axSpA] (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy. PA Automated. |

# TARGETED

## Products Affected

- *adzynma*
- APHEXDA
- CYSTADROPS
- CYSTAGON
- CYSTARAN
- *dichlorphenamide*
- DOJOLVI
- HYFTOR
- IMPAVIDO
- KEVEYIS
- KLARITY-C DROPS
- MOZOBIL
- NUEDEXTA
- NULIBRY
- ORMALVI
- PEGASYS
- *plerixafor*
- RYPLAZIM
- SOHONOS CAPSULE 1 MG ORAL
- SOHONOS CAPSULE 1.5 MG ORAL
- SOHONOS CAPSULE 10 MG ORAL
- SOHONOS CAPSULE 2.5 MG ORAL
- *tasimelteon*
- TASMAR
- *tolcapone*
- TPOXX ORAL
- XPHOZAH
- XURIDEN
- ZOKINVY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | FDA approved indications, Medically accepted indications. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (1) Prescriber attests that the patient has a diagnosis approved in the FDA prescribing information.<br>CONTINUING THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy. |
| **Age Restrictions** | Per FDA label |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# TARPEYO

## Products Affected

- TARPEYO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary immunoglobulin A nephropathy (IgAN) |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN): INITIAL: (1) Diagnosis of IgAN AND (2) Diagnosis confirmed by renal biopsy AND (3) Progressively declining glomerular filtration rate (GFR) and/or worsening proteinuria (e.g., greater than 1 gram protein/24-hour urine collection or UPCR [urine protein to creatinine ratio] of at least 1 g/g) AND (4) Patient has an eGFR of at least 35 mL/min/1.73m2 AND (5) Patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes AND (4) Patient has tried an SGLT2 inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]) and will continue use, OR has a contraindication to an SGLT2 inhibitor. CONTINUATION OF THERAPY/RENEWAL: (1) Patient has an approvable indication AND (2) Patient is stable on medication for 30 days AND (3) Patient has improved, or stable kidney function compared to baseline OR a reduction in proteinuria. |
| **Age Restrictions** | 18 years or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a nephrologist |
| **Coverage Duration** | Initial: 9 months Renewal: 9 months |
| **Other Criteria** | PA Automation |

# TAVABOROLE

## Products Affected

- *tavaborole*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Onychomycosis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ONYCHOMYCOSIS: (1) Diagnosis of onychomycosis AND (2) Tried or contraindicated to oral terbinafine OR oral itraconazole, AND (3) Tried or contraindicated to ciclopirox topical solution AND (4) One of the following: (4a) Diagnosis of diabetes, peripheral vascular disease (PVD), or immunosuppression OR (4b) Patient has pain surrounding the nail or soft tissue involvement.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has not completed 48 weeks of treatment. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 48 weeks |
| **Other Criteria** | PA Automated. |

# TAVALISSE

## Products Affected

- TAVALISSE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic immune thrombocytopenia (cITP) |
| **Exclusion Criteria** | Used concurrently with a Brutons tyrosine kinase (BTK) inhibitor (e.g., Wayrilz [rilzabrutinib]) for the treatment of cITP. |
| **Required Medical Information** | INITIAL: (A) CHRONIC IMMUNE THROMBOCYTOPENIA (cITP): (1) Diagnosis of cITP AND (2) Tried or contraindicated to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy AND (3) Patient meets one of the following: (3a) Platelet count of less than 30 x 10^9/L OR (3b) Platelet count of less than 50 x 10^9/L AND a prior bleeding event. CONTINUING THERAPY / RENEWAL: (1) Patient has been stable on therapy AND (2) Diagnosis of approvable indication AND (3) Patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events AND (4) Tavalisse will NOT be used concurrently with a Brutons tyrosine kinase (BTK) inhibitor for the treatment of cITP. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 3 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# TAVNEOS

## Products Affected

- TAVNEOS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Adjunctive treatment of severe active antineutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis (GPS) and microscopic polyangiitis (MPA)) in combination with standard therapy, including glucocorticoids, in adults, Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. ANTINEUTROPHIL CYTOPLASMIC AUTOANTIBODY(ANCA)-ASSOCIATED VASCULITIS: INITIAL: (1) Clinical diagnosis of SEVERE ACTIVE GPA or MPA variant to ANCA-associated vasculitis AND (2) Diagnosis confirmed by prescriber attestation of BOTH of the following:(2a) Positive test for either anti-PR3 or anti-MPO AND (2b) Patients EGFR greater than or equal to 15mL/min/1.73m2 AND (3) Patient does not currently require dialysis or have a kidney transplant AND (4) Patient has not received plasma exchange in the past 12 weeks AND (5) Patient is currently receiving standard therapy with cyclophosphamide or rituximab RENEWAL: (1) Prescriber attests that patient has had clinically significant improvements or stabilization of disease with the addition of this medication AND (2) Confirm patient continues to be on standard of therapy cyclophosphamide or rituximab |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a rheumatologist or nephrologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# TESTOSTERONE

## Products Affected

- ANDROGEL PUMP
- DEPO-TESTOSTERONE
- NATESTO
- TESTIM
- TESTOPEL
- *testosterone cypionate intramuscular*
- *testosterone gel 1.62 % transdermal*
- *testosterone gel 12.5 mg/act (1%) transdermal*
- *testosterone gel 20.25 mg/act (1.62%) transdermal*
- *testosterone gel 25 mg/2.5gm (1%) transdermal*
- *testosterone gel 40.5 mg/2.5gm (1.62%) transdermal*
- *testosterone gel 50 mg/5gm (1%) transdermal*
- *testosterone transdermal solution*
- VOGELXO
- VOGELXO PUMP

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary or secondary male hypogonadism (hypotestosteronism or low testosterone), gender dysphoria (GD) [Androderm, Androgel, and generic formulations]. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT [HYPOGONADISM]: Tried or contraindicated to [NATESTO]: ONE agent: testosterone cypionate, testosterone enanthate, testosterone gel pump, testosterone topical solution. [ANDRODERM, FORTESTA, STRIANT]: TO BOTH agents: testosterone cypionate, testosterone enanthate. INITIAL: (A) HYPOGONADISM: (1) Diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) for a male patient AND (2) Patient meets one of the following: (2a) Patient has a previously approved prior authorization for testosterone OR patient has been receiving any form of testosterone replacement therapy OR (2b) Patient has one of the following criteria confirming low testosterone levels: (2b.i) At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L taken on separate occasions OR (2b.ii) A free serum testosterone level of less than 5ng/dL (0.17 nmol/L) AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. (B) GENDER DYSPHORIA (GD) [Androderm, Androgel, generic formulations]: (1) Diagnosis of GD AND (2) Diagnosis is supported by the compendia (e.g., |

| PA Criteria | Criteria Details |
|---|---|
| | DrugDex strength of recommendation Class I, IIa, or IIb). AND (3) GD is not restricted from coverage under the patients benefit. |
| **Age Restrictions** | [GD]: 16 years of age or older. [Hypogonadism]: None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND [HYPOGONADISM]: (3) Patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. [GD]: (2) GD is not restricted from coverage.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND [HYPOGONADISM] (2) Patient has had improved symptoms compared to baseline and has tolerated treatment AND (3) Patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. [GD]: (2) Diagnosis is supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) AND (3) GD is not restricted from coverage. PA Automated. |

# TESTOSTERONE ENANTHATE

## Products Affected

- XYOSTED

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary or secondary male hypogonadism (hypotestosteronism or low testosterone), gender dysphoria (GD), delayed puberty not due to a pathological disorder in a male, metastatic breast cancer in a female. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT [HYPOGONADISM]: [XYOSTED]: Tried or contraindicated to ONE AGENT: testosterone cypionate, testosterone enanthate, testosterone gel pump, testosterone topical solution. INITIAL: (A) HYPOGONADISM: (1) Diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) for a male patient AND (2) Patient meets one of the following: (2a) Patient has a previously approved prior authorization for testosterone OR patient has been receiving any form of testosterone replacement therapy OR (2b) Patient has one of the following criteria confirming low testosterone levels: (2b.i) At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L taken on separate occasions OR (2b.ii) A free serum testosterone level of less than 5ng/dL (0.17 nmol/L) AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. (B) GENDER DYSPHORIA (GD): (1) Diagnosis of GD AND (2) Diagnosis is supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or Iib) AND (3) GD is not restricted from coverage under the patients benefit. (C) DELAYED PUBERTY: (1) Diagnosis of delayed puberty not secondary to a pathological disorder for a male patient AND (2) Request is for generic intramuscular testosterone enanthate 200 mg/mL AND (3) Patient has not received more than two 6-month courses of testosterone replacement therapy. |
| **Age Restrictions** | [XYOSTED]: 18 years of age or older. [GD]: 16 years of age or older. [Hypogonadism, breast cancer, delayed puberty]: None. |
| **Prescriber** | None. |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (D) BREAST CANCER: (1) Diagnosis of metastatic breast cancer for a female patient AND (2) Request is for generic intramuscular testosterone enanthate 200 mg/mL AND (3) Patient meets one of the following: (3a) Patient is postmenopausal OR (3b) Patient is premenopausal who benefitted from an oophorectomy AND is considered to have a hormone-responsive tumor. CONTINUING THERAPY: [DELAYED PUBERTY]: Treat as initial. (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND [HYPOGONADISM]: (3) Patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. [BREAST CANCER]: (3) Request is for generic intramuscular testosterone enanthate 200 mg/Ml AND [GD]: (3) GD is not restricted from coverage.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND [HYPOGONADISM] (2) Patient has had improved symptoms compared to baseline and has tolerated treatment AND (3) Patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. [GD]: (2) Diagnosis is supported by the compendia AND (3) GD is not restricted from coverage. [DELAYED PUBERTY] (2) Patient has not received more than two 6-month courses of testosterone replacement therapy AND (3) Request is for generic intramuscular testosterone enanthate 200 mg/mL. [BREAST CANCER]: (2) Request is for generic intramuscular testosterone enanthate 200 mg/mL AND (3) Patient meets one of the following: (3a) Patient is postmenopausal OR (3b) Patient is premenopausal who benefitted from an oophorectomy AND is considered to have a hormone-responsive tumor. PA Automated |

# TESTOSTERONE UNDECANOATE

## Products Affected

- AVEED
- JATENZO
- KYZATREX
- TLANDO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary or secondary male hypogonadism (hypotestosteronism or low testosterone), gender dysphoria (GD) [Aveed only]. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated [AVEED]: TO BOTH agents: testosterone cypionate, testosterone enanthate. [JATENZO; KYZATREX]: TWO agents: Tlando AND testosterone cypionate, testosterone enanthate. INITIAL: (A) HYPOGONADISM: (1) Diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) for a male patient AND (2) Patient meets one of the following: (2a) Patient has a previously approved prior authorization for testosterone OR patient has been receiving any form of testosterone replacement therapy OR (2b) Patient has one of the following criteria confirming low testosterone levels: (2b.i) At least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L taken on separate occasions OR (2b.ii) A free serum testosterone level of less than 5ng/dL (0.17 nmol/L) AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. (B) GENDER DYSPHORIA (GD) [Aveed only]: (1) Diagnosis is supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) AND (2) GD is not restricted from coverage under the patients benefit. |
| **Age Restrictions** | [Hypogonadism]: 18 years of age or older, [GD]: 16 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND |

| PA Criteria | Criteria Details |
| --- | --- |
| | [HYPOGONADISM]: (3) Patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. [GD]: (2) GD is not restricted from coverage. [GD]: (3) GD is not restricted from coverage.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND [HYPOGONADISM] (2) Patient has had improved symptoms compared to baseline and has tolerated treatment AND (3) Patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range AND (4) If patient is 40 years of age or older, patients prostate specific antigen (PSA) has been evaluated for prostate cancer screening within the past 12 months AND (4a) PSA level is less than or equal to 4 OR (4b) PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA. [GD]: (2) Diagnosis is supported by the compendia AND (3) GD is not restricted from coverage. PA Automated. |

# TEZRULY

## Products Affected

- TEZRULY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Benign prostatic hyperplasia (BPH), Hypertension. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) BENIGN PROSTATIC HYERPLASIA (BPH), HYPERTENSION: (1) Diagnosis of (1a) BPH or (1b) hypertension AND (2) Patient has a contraindication or is unable to swallow terazosin capsules. CONTINUING THERAPY: Treat as Initial |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# TEZSPIRE

## Products Affected

- TEZSPIRE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe asthma, Chronic rhinosinusitis nasal polyps (CRSwNP). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Dupixent [dupliumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication. |
| **Required Medical Information** | INITIAL: (A) ASTHMA: (1) Diagnosis of severe asthma AND (2) Tezspire will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (beclomethasone, budesonide, mometasone) AND at least ONE other maintenance medication (long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline) AND (3) Patient meets one of the following: (3a) Patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR (3b) Patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months OR (3c) Patient have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week, any activity limitation due to asthma. (B) CRSwNP: (1) Diagnosis of CRSwNP AND (2) Evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan AND (3) Patient has inadequately controlled disease AND (4) Patient has tried ONE intranasal corticosteroid (ie. fluticasone) for a 56-day trial AND (5) Tezspire will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids). |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an [Asthma]: allergist or pulmonologist. [CRSwNP]: allergist, immunologist, or otolaryngologist. |
| **Coverage** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
|---|---|
| **Duration** | |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosed by an appropriate specialist AND (4) Patient must not be taking with another systemic biologic or targeted small molecules for the same indication AND [Asthma]: (5) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline). RENEWAL (1) Diagnosis of approvable indication AND (2) Patient must not be taking with another systemic biologic or targeted small molecules for the same indication AND [Asthma]: (3) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline) AND (4) Patient has shown clinical response as evidenced by ONE of the following: Reduction in asthma exacerbations from baseline, decreased utilization of rescue medications (e.g., albuterol), increase in percent predicted FEV1 from pretreatment baseline, reduction in severity or frequency of asthma-related symptoms. [CRSwNP]: (3) Patient has shown clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps). PA Automated. |

# THIOLA

## Products Affected

- THIOLA
- THIOLA EC
- *tiopronin*
- VENXXIVA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Severe homozygous cystinuria . Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Patients with a prior history of developing agranulocytosis, aplastic anemia or thrombocytopenia while on this medication. Females that are breastfeeding. Member weighs less than 20 kg. |
| **Required Medical Information** | A. SEVERE HOMOZYGOUS CYSTINURIA, INITIAL: (1) Prescriber attests to a documented diagnosis of severe homozygous cystinuria AND (2) Confirmation of urinary cysteine levels greater than 500mg/day by at least one 24 hour urine collection AND (3) Prescriber attests to trial and failure of high fluid intake, restriction of dietary sodium and protein intake and urinary alkalization. RENEWAL: (1) Prescriber attests that patient continues to meet all initial therapy criteria requirements AND (2) Prescriber attests that medication is effective defined as urinary cysteine concentration is below its solubility limit ( generally less than 300mg/L) and that is it being measure every 6 months. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist or urologist |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# TOBRAMYCIN INHALED

## Products Affected

- BETHKIS
- KITABIS PAK (W/ NEBULIZER)
- TOBI
- TOBI PODHALER
- *tobramycin inhalation*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic Fibrosis, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | FEV1 less than 25% predicted (KITABIS,TOBI); FEV1 less than 40% (BETHKIS ONLY), Patients colonized with Burkholderia cepacia |
| **Required Medical Information** | FORMULARY ALERT: TRIED, FAILED OR INTOLERANT TO PRIMARY TREATMENT TOBI PODHALER AND tobramycin nebulization PRIOR TO SECONDARY TREATMENT BETHKIS, KITABIS AND TOBI NEBULIZATION A. CYSTIC FIBROSIS: INITIAL: (1) Prescriber attests to a diagnosis of Cystic Fibrosis AND (2) Prescriber attests to colonization of Pseudomonas aeruginosa in the lungs CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication |
| **Age Restrictions** | 6 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | Must have 28 days off tobramycin therapy. Elixir Quantity Limit Applies PA Automated |

# TRACLEER

## Products Affected

- *bosentan*
- TRACLEER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). |
| **Exclusion Criteria** | Used concurrently with cyclosporine A or glyburide. |
| **Required Medical Information** | A. INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) Patient does NOT have idiopathic pulmonary fibrosis (IPF) AND (3) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (4) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (5) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUATION OF THERAPY: (1) Patient has been stable on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Tracleer will NOT be used concurrently with cyclosporine A or glyburide.RENEWAL: (1) Diagnosis of approvable indication AND (2) Tracleer will NOT be used concurrently with cyclosporine A or glyburide |
| **Age Restrictions** | 3 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# TRAMADOL SOL

## Products Affected

- *tramadol hcl oral solution*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pain management. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PAIN MANAGEMENT: (1) Request is for management of pain AND (2) Patients pain is severe enough to require an opioid analgesic AND (3) Alternative treatments for the patients pain are inadequate AND (4) Tried or contraindicated to generic tramadol IR tablet or generic tramadol with acetaminophen product AND (5) Patient is unable to take oral solid formulations of tramadol or tramadol with acetaminophen (e.g., difficulty swallowing).<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient is unable to take oral solid formulations of tramadol or tramadol with acetaminophen (e.g., difficulty swallowing). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | PA Automated. |

# TREMFYA

## Products Affected

- TREMFYA
- TREMFYA ONE-PRESS
- TREMFYA PEN
- TREMFYA-CD/UC INDUCTION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque psoriasis (PsO), Psoriatic Arthritis (PsA), Ulcerative Colitis (UC), Crohns disease (CD). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | INITIAL: (A) PLAQUE PSORIASIS (PsO): (1) Diagnosis of moderate to severe PsO AND (2a) Patient has psoriasis covering 3% or more of body surface area (BSA) OR (2b) Patients has psoriatic lesions (rashes) affecting the face, hands, feet, genital area, or scalp OR (2c) Patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication AND (3a) Patient has had at least a 3-month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA for the treatment of PsO OR (3b) Contraindication or intolerance to both immunosuppressants AND PUVA [phototherapy] for the treatment of PsO OR (3c) patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication. (B) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PsA. (C) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. (D) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Tremfya will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Tremfya will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [PsO] (3) Patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more. [PsA] (3) Patient has experienced or maintained a 20 percent or greater improvement in tender or swollen joint count while on therapy. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | [CD, UC]: 18 years of age or older. [PsA, PsO]: 6 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [PsO]: dermatologist. [PsA]: rheumatologist or dermatologist. [CD, UC]: gastroenterologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# TRIENTINE

## Products Affected

- CUVRIOR
- SYPRINE
- *trientine hcl capsule 250 mg oral*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Wilsons disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. WILSONS DISEASE: INITIAL: (1) Prescriber attests to a documented diagnosis of Wilsons disease confirmed by: genetic testing OR the presence of the following diagnostic features: a) If presence of Kayser-Fleisher rings, serum ceruloplasmin (CPN) less than 20 mg/dL AND 24-hour urine copper greater than 40 mcg b) If no presence of Kayser-Fleisher rings, serum ceruloplasmin (CPN) less than 20 mg/dL AND 24-hour urine copper greater than 100 mcg OR liver biopsy with copper dry weight greater than 250 mcg/g AND (2) Prescriber attests to a trial and failure, intolerance, or contraindication to Depen Titratabs (penicillamine) AND (3) [CUVRIOR ONLY] Confirmation that patient will not continue to take pencillamine AND prescriber attests patient has been taking and is tolerant to pencillamine for at least 4 months AND (4) Prescriber attests that patient must adhere to a low copper diet. RENEWAL: (1)Prescriber attests that patient is tolerating and responding to therapy AND (2) Prescriber attests that patient remains adherent to a low copper diet. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant prescriber |
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# TRIKAFTA

## Products Affected

- TRIKAFTA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cystic fibrosis (CF). |
| **Exclusion Criteria** | Used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Required Medical Information** | A. INITIAL: CYSTIC FIBROSIS (CF): (1) Diagnosis of CF AND (2) Patient has at least ONE F508del mutation or a responsive mutation in the CFTR gene. CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor).RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced an improvement in clinical status AND (3) Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor). |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or cystic fibrosis expert |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# TRIPTODUR

## Products Affected

- TRIPTODUR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Central precocious puberty,  Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Pregnancy |
| **Required Medical Information** | FORMULARY ALERT: TRIED, FAILED OR INTOLERANT TO PRIMARY TREATMENT LUPRON DEPOT-PED (3-MONTH) OR LUPRON DEPOT-PED (1-MONTH) A. CENTRAL PRECOCIOUS PUBERTY (CPP) INITIAL: (1) Patient is currently less than 11 years of age AND (2) ONE of the following: (2a) Luteinizing hormone (LH) morning values greater than 0.3 IU/L OR (2b) Peak LH after GnRH stimulation greater than 5 IU/L AND (3) ONE of the following (3a) Patient had pubertal development prior to 8 years of age (girls) or 9 years of age (boys) OR (3b) Sexual maturation progresses to next stage (Tanner scale) within 3-6 months OR (3c) Growth velocity greater than 6 cm/year OR (3d) Bone age advanced by 1 year or more OR (3e) Predicted adult height below target range or declining on serial determinations RENEWAL: (1) Patient is not more than 11 years of age |
| **Age Restrictions** | Less than 11 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultations with pediatric endocrinologist. |
| **Coverage Duration** | Initial:  12 months, Renewal:  12 months |
| **Other Criteria** | Elixir Quantity Limit Applies. PA Automated |

# TRYNGOLZA

## Products Affected

- TRYNGOLZA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Familial chylomicronemia syndrome (FCS). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) FAMILIAL CHYLOMICRONEMIA SYNDROME (FCS): (1) Diagnosis of FCS AND (2) Tryngolza will be used as an adjunct therapy to diet AND (3) Patients diagnosis of FCS has been confirmed by genetic testing.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Tryngolza will be used as an adjunct therapy to diet AND (4) Tryngolza will not be used concurrently with another agent the treatment of FCS.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced a clinical benefit as demonstrated by a reduction in triglyceride levels AND (3) Tryngolza will not be used concurrently with another agent the treatment of FCS. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# TRYPTYR

## Products Affected

- TRYPTYR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dry eye disease (DED). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO TWO AGENTS: RESTASIS, XIIDRA, MIEBO. INITIAL: (A) DRY EYE DISEASE (DED) (1) Diagnosis of DED AND (2) Patient has ONE positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test) AND (3) Tried or contraindicated to ONE ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, TheraTears], polyvinyl alcohol [LiquiTears, Refresh Classic], or wetting agent [Systane, Lacri-Lube]). CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has demonstrated improvement of dry eye disease. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# TRYVIO

## Products Affected

- TRYVIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypertension |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: A. HYPERTENSION (1) Patient has a diagnosis of hypertension AND (2) Patients blood pressure is NOT controlled on at least three anti-hypertensive agents of different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine], a diuretic [e.g., hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks AND (3) Patient does NOT have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except sleep apnea) AND (4) Patient had a trial of or contraindication to (4a) A potent diuretic (i.e., chlorthalidone or indapamide) AND (4b) a mineralocorticoid receptor antagonist (i.e., spironolactone or eplerenone) AND (5) Tryvio will be used concurrently treatment with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses.CONTINUATION OF THERAPY/RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days AND (3) Tryvio will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses.RENEWAL:(1) Patient continues to benefit from the medication AND (2) Tryvio will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist |
| **Coverage Duration** | Initial: 2 months,  Renewal:  12 months |
| **Other Criteria** | PA Automated |

# TYENNE

## Products Affected

- TYENNE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Rheumatoid arthritis (RA), giant cell arteritis (GCA), systemic sclerosis-associated interstitial lung disease (SSc-ILD), polyarticular juvenile idiopathic arthritis (PJIA), systemic juvenile idiopathic arthritis (SJIA) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO [RA]: ONE AGENT: ADALIMUMAB-ADAZ, ENBREL, HUMIRA, RINVOQ TAB, SIMLANDI, OR XELJANZ (XR) (TRIED A TNF PRIOR TO RINVOQ/XELJANZ) [PJIA]: ONE AGENT: ADALIMUMAB-ADAZ, ENBREL, HUMIRA, RINVOQ LQ, SIMLANDI, OR XELJANZ (TRIED A TNF PRIOR TO RINVOQ/XELJANZ). [GCA]: ONE AGENT: RINVOQ. INITIAL: (A) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Patient had a trial of or contraindication to 3-months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine (B) GIANT CELL ARTERITIS (GCA): (1) Diagnosis of GCA AND (2) Patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone). (C) SYSTEMIC SCLEROSIS ASSOCIATED INTERSTITIAL LUNC (SSc-ILD): (1) Diagnosis of SSc according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) AND (2) Patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease [MCTD]) (D) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (F) SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SIJA): (1) Diagnosis of SJIA. SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | [GCA, RA, SSc-ILD]: 18 years of age and older. [PJIA, SJIA]: 2 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [RA, PJIA]: rheumatologist. [SSc-ILD]: pulmonologist or rheumatologist. [SJIA]: rheumatologist, dermatologist, or immunologist. [GCA]: None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [RA, PJIA]: (3) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. [SJIA]: (3a) Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy OR (3b) Patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis) [SSc-ILD]: (3) Patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline. PA Automated |

# TYMLOS

## Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postmenopausal osteoporosis, osteoporosis in a male patient |
| **Exclusion Criteria** | Received 24 cumulative months of treatment with any parathyroid hormone therapy (e.g., Tymlos [abaloparatide], Forteo [teriparatide]). |
| **Required Medical Information** | INITIAL: (A) POSTMENOPAUSAL OSTEOPOROSIS: (1) Diagnosis of postmenopausal osteoporosis AND (2) Patient meets one of the following (2a) Patient is at high risk for fractures defined as one of the following: (2a.i) History of osteoporotic (i.e., fragility, low trauma) fracture OR (2a.ii) Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin) OR (2a.iii) FRAX score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture AND Patient has no prior treatment for osteoporosis OR (2b) Patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems, lower GI problems, trouble remembering to take oral medications or coordinate oral bisphosphonate with other oral medications) OR (2c) Patient had an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva).(B) OSTEOPOROSIS FOR MALE: (1) Diagnosis of osteoporosis in a male patient AND (2) Patient is at high risk for fractures defined as one of the following: (2a) History of osteoporotic (i.e., fragility, low trauma) fracture OR (2b) Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin]) AND (3) Patient has failed or is intolerant to other available osteoporosis therapy (e.g., Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate]). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has NOT received 24 cumulative months of treatment with any parathyroid hormone therapy (e.g., Tymlos, Forteo). |
| **Age Restrictions** | None. |
| **Prescriber** | None. |

| PA Criteria | Criteria Details |
|---|---|
| **Restrictions** | |
| **Coverage Duration** | 24 MONTHS per lifetime |
| **Other Criteria** | PA Automated |

# TYRVAYA

## Products Affected

- TYRVAYA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dry eye disease (DED). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) DRY EYE DISEASE (DED): (1) Patient has a diagnosis of dry eye disease AND (2) Patient has at least ONE positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has demonstrated the improvement of dry eye disease. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# TYSABRI

## Products Affected

- TYRUKO
- TYSABRI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Crohns disease, Multiple sclerosis (MS) (relapsing remitting MS, active secondary progressive MS (SPMS), clinically isolated (CI) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication. |
| **Required Medical Information** | STEP ALERT: [CD]: Tried or contraindicated to TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq, Skyrizi, Tremfya, Ustekinumab (Selarsdi, Stelara, Yesintek) (Tried a TNF prior to Rinvoq). INITIAL: (A) CROHNS DISEASE (CD): (1) Diagnosis of moderate to severe CD. (B) MULTIPLE SCLEROSIS (MS): (1) Diagnosis of MS AND (2) Requested medication will be used as monotherapy. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Tysabri will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Requested medicaiton will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [CD]: (3) One of the following: (3a) Received only 6 months of requested medication and not currently on corticosteroids (i.e., the patient has tapered off corticosteroids during the first 6 months of Tyruko therapy) OR (3b) Received at least 12 months of requested medication and not received more than 3 months of corticosteroids within the past 12 months. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | [CD]: Prescribed by or in consultation with a gastroenterologist, [MS]: None |
| **Coverage Duration** | [MS]: Initial: 12 months, Renewal: 12 months. [CD]: Initial: 6 months. Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# TYVASO

## Products Affected

- TYVASO
- TYVASO DPI MAINTENANCE KIT
- TYVASO DPI TITRATION KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO GROUP 1), Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). (B) PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (PH-ILD): (1) Diagnosis of PH-ILD (WHO Group 3) AND (2) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# UDENYCA

## Products Affected

- UDENYCA
- UDENYCA ONBODY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy, hematopoietic syndrome of acute radiation syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT for Udenyca: TRIED OR CONTRAINDICATED TO ZIEXTENZO. A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever AND (2) Udenyca Onbody: Patient has a barrier to access (e.g., travel barriers, patient is unable to return to the clinic for Udenyca injections). HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME: (1) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# UPNEEQ

## Products Affected

- UPNEEQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Blepharoptosis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: BLEPHAROPTOSIS: (1) Diagnosis of blepharoptosis AND (2) Patient has been evaluated for surgical intervention AND (3) Patient has experienced visual impairment due to blepharoptosis AND (4) Patient has tried TWO ophthalmic alpha-adrenergic agonists (e.g., apraclonidine, naphazoline, tetrahydrozoline).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient continues to benefit from Upneeq. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or optometrist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# UPTRAVI

## Products Affected

- UPTRAVI ORAL
- UPTRAVI TITRATION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO Group 1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VAFESO

## Products Affected

- VAFSEO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Anemia due to chronic kidney disease (CKD) |
| **Exclusion Criteria** | Used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Jesduvroq [daprodustat]) OR erythropoiesis-stimulating agents (ESAs) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]). |
| **Required Medical Information** | INITIAL: (A) ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD): (1) Diagnosis of anemia due to CKD AND (2) Patient has been receiving dialysis for at least 3 months AND (3) Patient has an eGFR of less than 60 mL/min/1.73m(2) corresponding to stage 3, 4, or 5 chronic kidney disease (CKD) AND (4) Patient has a hemoglobin level of less than 12 g/dL while treated with an erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa]), and will discontinue ESA therapy prior to starting Vafseo. CONTINUING THERAPY / RENEWAL: (1) Patient has been stable on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Vafseo will NOT be used concurrently with other HIF-PHIs OR ESAs AND (4) One of the following: (4a) Patient has a hemoglobin level of at least 10 g/dL OR (4b) Patients hemoglobin level has increased by at least 2 g/dL from their baseline level. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a nephrologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# VANRAFIA

## Products Affected

- VANRAFIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Primary immunoglobulin A nephropathy (IgAN) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) IMMUNOGLOBULIN A NEPHROPATHY (IgAN): Diagnosis of primary IgAN AND (2) Patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] of at least 1.5 g/g) AND (3) Diagnosis confirmed by a biopsy AND (4) Patient has a proteinuria of at least 1 g/day AND (5) Patient has an eGFR of at least 30 mL/min/1.73 m(2) AND (6) Patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria AND (3) Patient has had a reduction in proteinuria. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VECAMYL

## Products Affected

- VECAMYL

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderately severe to severe essential (primary) hypertension or uncomplicated malignant hypertension. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ESSENTIAL HYPERTENSION: (1) Diagnosis of moderately severe to severe essential (primary) hypertension or uncomplicated malignant hypertension AND (2) Patients blood pressure is NOT controlled on at least three anti-hypertensive agents from different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine], a diuretic [e.g., hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks AND (3) Vecamyl will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses AND (4) Patient does NOT have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except sleep apnea) AND (5) Tried or contraindicated to a potent diuretic (i.e., clorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (i.e., spironolactone or eplerenone). CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Vecamyl will be used concurrently with at least three other anti-hypertensive agents at maximally tolerated doses. RENEWAL: (1) Diagnosis of approvable indication AND (2) Vecamyl will be used concurrently with at least three other anti-hypertensive agents at maximally tolerated doses AND (3) Patient continues to benefit from Vecamyl. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation. |

# VELSIPITY

## Products Affected

- VELSIPITY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ulcerative colitis (UC) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, ustekinumab (-aekn, Stegemya, Yesintek), Tremfya, Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). INITIAL: (A) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Velsipity will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Velsipity will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VELTASSA

## Products Affected

- VELTASSA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hyperkalemia |
| **Exclusion Criteria** | Used concurrently with another potassium binder (e.g., Lokelma [sodium zirconium cyclosilicate], sodium polystyrene sulfonate). |
| **Required Medical Information** | INITIAL: (A) HYPERKALEMIA: (1) Diagnosis of hyperkalemia AND (2) Veltassa is NOT being used as an emergency treatment for life-threatening hyperkalemia AND (3) Patient is NOT currently receiving dialysis AND (4) Tried one of the following approaches to reduce the modifiable risks for hyperkalemia (4a) Patient is not taking both an angiotensin converting enzyme inhibitor (ACE-I; e.g., lisinopril, benazepril) and an angiotensin receptor blocker (ARB; e.g., valsartan, losartan) at the same time OR (4b) Patient is not taking both an angiotensin converting enzyme inhibitor (ACE-I; e.g., lisinopril, benazepril) and an angiotensin receptor blocker (ARB; e.g., valsartan, losartan) at the same time AND (5) If the patient has an estimated glomerular filtration rate (eGFR) of at least 30mL/min/1.73m2, patient meets one of the following criteria (5a) Tried a loop diuretic (e.g., bumetanide, furosemide, torsemide) or (5b) Tried a thiazide diuretic (e.g., chlorthalidone, hydrochlorothiazide, metolazone) OR (6) If the patient has an estimated glomerular filtration rate (eGFR) of less than 30mL/min/1.73m2 AND has tried a loop diuretic (e.g., bumetanide, furosemide, torsemide) AND (6) If the patient is 18 years of age or older, they have had a trial of Lokelma (sodium zirconium cyclosilicate). CONTINUING THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days AND (3) Veltassa will not be used concurrently with another potassium binder. |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist or cardiologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VERQUVO

## Products Affected

- VERQUVO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic heart failure (HF). |
| **Exclusion Criteria** | Used concurrently with Adempas (riociguat), or PDE-5 inhibitors (e.g, vardenafil, tadalafil). |
| **Required Medical Information** | INITIAL: (A) HEART FAILURE (HF): (1) Diagnosis of chronic HF AND (2) Patient has an ejection fraction less than 45% AND Patient is high-risk with worsening heart failure, as evidenced by a hospitalization for heart failure or requirement for intravenous (IV) diuretics AND (4) Patient has a history of and will continue on, or has a contraindication to ONE agent from EACH of the following Guideline-Directed Medical Therapy (GDMT) medication classes: (4a) ACE inhibitor (e.g., enalapril, lisinopril), ARB (e.g., valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto [sacubitril/valsartan]) AND (4b) Beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate) AND (4c) Aldosterone antagonists (spironolactone or eplerenone) AND (4d) SGLT2 inhibitor indicated for heart failure (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin], Inpefa [sotagliflozin]). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Verquvo will NOT be used concurrently with Adempas or PDE-5 inhibitors. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has an ejection fraction of less than 45 % AND (3) Prescribed by or in consultation with a cardiologist AND (4) Verquvo will NOT be used concurrently with Adempas or PDE-5 inhibitors AND (5) Patient has a history of and will continue on, or has a contraindication to ONE agent from EACH of the following Guideline-Directed Medical Therapy (GDMT) medication classes: (5a) ACE inhibitor, ARB, or angiotensin ARNI AND (5b) Beta-blocker AND (5c) Aldosterone antagonists (spironolactone or eplerenone) AND (5d) SGLT2 inhibitor indicated for heart failure. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation. |

# VEVYE

## Products Affected

- VEVYE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dry eye disease (DED). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to TWO preferred agents: Miebo, Restasis, Xiidra, Tryvaya. INITIAL: (A) DRY EYE DISEASE (DED): (1) Diagnosis of DED AND (2) Patient has at least ONE positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test) AND (2) Tried or contraindicated to ONE ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, TheraTears], polyvinyl alcohol [LiquiTears, Refresh Classic], wetting agent [Systane, Lacri-Lube]).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has demonstrated improvement of dry eye disease. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation by an ophthalmologist or optometrist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# VIGAFYDE

## Products Affected

- VIGAFYDE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Infantile Spasms |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) Infantile Spasms: (1) Diagnosis of infantile spasms AND (2) Vigafyde will be used as monotherapy AND (3) Potential benefits outweigh the potential risk of vision loss AND (4) Tried or contraindicated to generic vigabatrin powder for solution. CONTINUING THERAPY: (1) Patient has been on therapy any amount of time AND (2) Diagnosis of approvable indication AND (3) Patient is 1 month to 2 years of age. RENEWAL: (1) Diagnosis of approvable indication AND (2) [Infantile spasms]: Patient is 1 month to 2 years of age. |
| **Age Restrictions** | 1 month to 2 years of age |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VIJOICE

## Products Affected

- VIJOICE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | PIK3CA Related Overgrowth Spectrum. Medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. PIK3CA RELATED OVERGROWTH SPECTRUM (PROS) INITIAL: (1) Prescriber attests to diagnosis of PROS AND (2) Patient has at least one target lesion identified on imaging AND (3) Documented evidence of a mutation in the PIK3CA gene AND (4) The condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician RENEWAL: (1) Prescriber attests to lesion stabilization or improvement defined by one of the following: (1a) Reductions in lesion volume OR (1b) No new lesions |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in conjunction with a geneticist, pediatrician, surgeon. |
| **Coverage Duration** | Initial: 6 months Renewal: 12 months |
| **Other Criteria** | No PA Automation |

# VISCOSUPPLEMENTS

## Products Affected

- DUROLANE
- EUFLEXXA
- GEL-ONE
- GELSYN-3
- GENVISC 850
- HYALGAN
- HYMOVIS
- HYMOVIS ONE
- MONOVISC
- ORTHOVISC
- SUPARTZ FX
- SYNOJOYNT
- SYNVISC
- SYNVISC ONE
- TRILURON
- TRIVISC
- VISCO-3

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Osteoarthritis of the knee(s). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to: Euflexxa AND Synvisc or Synvisc-One. INITIAL: (A) OSTEOARTHRITIS OF THE KNEE: (1) Diagnosis of osteoarthritis of the knee(s) AND (2) Patient has failed a 6-week trial of non-pharmacologic therapy (e.g., education, exercise, use of insoles or braces, weight reduction, physical therapy) AND (3) Tried or contraindicated to one of the following: Intra-articular steroid (e.g., methylprednisolone acetate, triamcinolone acetonide), topical NSAID (e.g., diclofenac), oral NSAID (e.g., meloxicam, diclofenac) OR acetaminophen.<br>CONTINUING THERAPY / RENEWAL: (1) Patient has received previous treatment on the same knee with requested drug AND (2) At least 6 months has lapsed since last treatment with requested drug. |
| **Age Restrictions** | 21 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | PA Automated |

# VOQUENZA

## Products Affected

- VOQUEZNA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Erosive esophagitis, non-erosive gastroesophagitis disease, H. Pylori when used with specified antibiotics |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) EROSIVE ESOPHAGITIS (EE): (1) Diagnosis of EE AND (2) Diagnosis is confirmed by endoscopy (e.g., Los Angeles Classification of Reflux Esophagitis Grade A-D) AND (3) Patient has tried, failed, or is contraindicated to TWO proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole) at a maximum dose for 8 weeks each. (B) H. PYLORI: (1) Diagnosis of H. pylori. (C) NON-EROSIVE GASTROESOPHAGEAL DISEASE: (1) Diagnosis of non-erosive gastroesophageal disease AND (2) Request is for Voquezna 10 mg AND (3) Patients diagnosis is confirmed by endoscopy AND does not have the presence of visible erosion (e.g., does not have Los Angeles Classification of Reflux Esophagitis Grade A-D) AND (4) Patient had no previous treatment failure with Voquezna in the last 12 months AND (5) Patient has tried, failed, or is contraindicated to TWO proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole) at a maximum dose for 8 weeks each. CONTINUING THERAPY / RENEWAL: [EE]: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has maintained a clinical response on Voquezna. [H. PYLORI, Non-erosive]: Treat as New. |
| **Age Restrictions** | Prescribed by or in consultation with a gastroenterologist |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | EE: Initial: 8 weeks, Renewal: 24 weeks, H. PYLORI: Initial: 30 days, Non-erosive: Initial 28 days |
| **Other Criteria** | PA Automated |

# VOSEVI

## Products Affected

- VOSEVI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic hepatitis genotype (GT) 1, 2, 3, 4, 5, or 6. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. CHRONIC HEPATITIS C GT: 1, 2, 3, 4, 5 or 6: (1) Must have a diagnosis of Chronic Hepatitis C infection genotype 1, 2, 3, 4, 5, or 6. AND (2) Must provide HCV RNA level dated within last 6 months AND (3) Patient does NOT meet ANY of the following criteria (3a) patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions , (3b) patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C), (3c) Vosevi will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, rifabutin, Priftin [rifapentine], rosuvastatin, pitavastatin, pravastatin at doses greater than 40mg, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, St. Johns wort, HIV regimens containing atazanavir, lopinavir, Aptivus [tipranavir]/ritonavir, or efavirenz), (3d) Vosevi will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir) AND (4) the patient treatment-na?ve and meets ALL of the following criteria (4a) patient has genotype 3 infection, (4b) patient has compensated cirrhosis, (4c) patient has NS5A RAS Y93H polymorphism OR (5) patient treatment-experienced and meets ALL of the following criteria: (5a) patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis, (5b) The patient has failed prior treatment with a full course of an HCV regimen containing an NS5A inhibitor (e.g., Harvoni, Mavyret, or a DAA (e.g., Olysio [simeprevir]/peginterferon/ribavirin, Epclusa) if post-liver or kidney transplant OR SEE OTHER CRITERIA |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12-24 weeks, See OTHER CRITERIA Field |
| **Other Criteria** | (6) patient treatment-experienced and meets ALL of the following criteria: (6a) patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis, (6b) patient has failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa, sofosbuvir with ribavirin, sofosbuvir with Olysio) OR (7) patient treatment-experienced and meets ALL of the following criteria: (7a) patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis, (7b) patient failed prior treatment with Vosevi, (7c) Vosevi will be used with ribavirin OR (8) The patient does meet a condition as specified above but the requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.Duration of approval is based on recommendations by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.No PA Automation |

# VOWST

## Products Affected

- VOWST

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Recurrent Clostridioides difficile infection prevention |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) CLOSTRIDIOIDES DIFFICILE INFECTION (CDI): (1) Request is for the prevention of recurrent Clostridioides difficile infection (2) Patient has completed antibiotic treatment (e.g., vancomycin [Vancocin], fidaxomicin [Dificid]) for the treatment of recurrent CDI (defined as at least 3 CDI episodes).<br>CONTINUING THERAPY: (1) Diagnosis of approvable indication AND (2) Diagnosis confirmed by appropriate specialist AND (3) Patient has previously received Vowst AND (4) Patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for C. difficile AND (5) Patient has not previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or infectious disease specialist. |
| **Coverage Duration** | Initial: 1 month (One treatment course per 12 months) |
| **Other Criteria** | PA Automated |

# VOXZOGO

## Products Affected

- VOXZOGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Achondroplasia. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ACHONDROPLASIA: (1) Diagnosis of achondroplasia AND (2) Patient has open epiphyses.<br><br>CONTINUING THERAPY: Treat as initial.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has open epiphyses AND (3) Patient has experienced an improvement in annual growth velocity since baseline. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, orthopedist, or medical geneticist. |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# VOYDEYA

## Products Affected

- VOYDEYA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Paroxysmal nocturnal hemoglobinuria (PNH) |
| **Exclusion Criteria** | Voydeya used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan]) |
| **Required Medical Information** | STEP ALERT: PNH: PATIENT HAD A TRIAL OF OR CONTRAINDICATION TO FABHALTA. A. INITIAL: (1) Prescriber attests that the patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND (2) Prescriber attests Voydeya will be used for the treatment of extravascular hemolysis (EVH) AND (3) Prescriber attests the patient has anemia (Hgb level less than or equal to 9.5 g/dL) with an absolute reticulocyte count of at least 120 x 109/L AND (4) Prescriber attests the patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent AND (5) Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been on therapy for 30 days AND (3) Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab]) AND (4) Voydeya will NOT be used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan]) AND (5) Prescriber attests the patient has experienced a clinical benefit (e.g., improvement in hemoglobin levels) compared to baseline |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VTAMA

## Products Affected

- VTAMA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Atopic dermatitis (AD), Plaque psoriasis (PsO). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) ATOPIC DERMATITIS (AD): (1) Diagnosis of AD AND (2) Tried or contraindicated to a (2a) Topical corticosteroid (e.g., triamcinolone, mometasone furoate, fluocinonide, halobetasol propionate) OR (2b) Topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]). (B) PLAQUE PSORIASIS (PsO): (1) Diagnosis of PsO AND (2) Tried or contraindicated to one of the following: (2a) High or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate) OR (2b) Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment) OR (2c) Topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]) OR (2d) Topical retinoid (e.g., tazarotene cream/gel) OR (2e) Anthralin.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND [AD]: (2) Patient has achieved or maintained clear or minimal disease. [PsO]: (3) Patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement. |
| **Age Restrictions** | [AD]: 2 years of age or older; [PsO]: 18 years of age or older |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VYALEV

## Products Affected

- VYALEV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Parkinsons disease (PD) |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PARKINSONS DISEASE (PD): (1) Diagnosis of advanced PD AND (2) Vyalev is being used for the treatment of motor fluctuations associated with PD AND (3) Patients disease is responsive to treatment with levodopa AND (4) Patient is currently being treated with at least 400 mg of levodopa per day AND (5) Patient has motor symptoms that are currently uncontrolled (defined as an average [off] time of at least 2.5 hours per day over 3 consecutive days, with a minimum 2 hours each day) AND (6) Patient meets one of the following: (6a) Patient is unable to swallow extended-release tablets or administer extended-release capsules via a feeding tube OR (6b) Patient has failed to adhere to an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen via a feeding tube. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient has experienced improvement in motor symptoms while on Vyalev. |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or given in consultation with a neurologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation |

# VYKAT

## Products Affected

- VYKAT XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hyperphagia |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) HYPERPHAGIA: (1) Diagnosis of hyperphagia AND (2) Patient has a genetically confirmed Prader-Willi syndrome (PWS). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has a genetically confirmed Prader-Willi syndrome (PWS). RENEWAL: (1) Diagnosis of approvable indication AND (2) Patients hyperphagia is associated with Prader-Willi syndrome (PWS) AND (3) Patient has had clinical improvement. |
| **Age Restrictions** | 4 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, geneticist, or neurologist |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VYNDAQEL AND VYNDAMAX

## Products Affected

- VYNDAMAX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cardiomyopathy is associated with wild type transthyretin-mediated amyloidosis or hereditary transthyretin-mediated amyloidosis (ATTR-CM) |
| **Exclusion Criteria** | Use another ATTR-CM TTR (transthyretin) stabilizers (e.g., acoramidis) concurrently. |
| **Required Medical Information** | INITIAL: (A) TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTR): (1) Diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis AND (2) Patient has New York Heart Association (NYHA) class I, II, or III heart failure AND (3) Diagnosis is confirmed by ONE of the following (3a) A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP(Note: Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system) OR (3b) A biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient will not use another ATTR-CM TTR (transthyretin) stabilizers (e.g., acoramidis) concurrently. RENEWAL: (1) Diagnosis of approvable indication AND (2) Patient will not use another ATTR-CM TTR (transthyretin) stabilizers (e.g., acoramidis) concurrently. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# VYVGART HYTRULO

## Products Affected

- VYVGART HYTRULO PREFILLED SYRINGE SUBCUTANEOUS SOLUTION

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Generalized myasthenia gravis (gMG), chronic inflammatory demyelinating polyneuropathy (CIDP) |
| **Exclusion Criteria** | Request is for Vyvgart vials; Used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Imaavy [nipocalimab-aahu]) or complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG. |
| **Required Medical Information** | INITIAL: (A) GENERALIZED MYASTHENIA GRAVIS (gMG): (1) Diagnosis of gMG AND (2) Diagnosis confirmed by a positive serologic test for anti-acetylcholine receptor antibody (AChR-Ab+) AND (3) Patient is Myasthenia Gravis Foundation of America class II, III, or IV AND (4) Patient has tried or contraindicated to ONE corticosteroid (e.g., prednisone) AND (5) Patient meets ONE of the following (5a) Tried or contraindicated to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate) OR (5b) Tried or contraindicated to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange. (B) CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP): (1) Diagnosis of CIDP AND (2) Request is for Vyvgart Hytrulo.<br><br>CONTINUING THERAPY: Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Request is for Vyvgart Hytrulo PFS AND (4) Vyvgart will not be used concurrently with another neonatal Fc receptor blocker, complement inhibitor, or CD-19 antibody for the treatment of gMG.<br><br>RENEWAL: [CIDP]: Treat as initial. [gMG]: (1) Diagnosis of gMG AND (2) Patient has had clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool) AND (3) Vyvgart will not be used concurrently with another neonatal Fc receptor blocker, complement inhibitor, or CD-19 antibody for the treatment of gMG. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [gMG]: neurologist. [CIDP]: None. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# WAINUA

## Products Affected

- WAINUA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN). |
| **Exclusion Criteria** | Used concurrently with other hATTR-PN agents (e.g., Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran]). |
| **Required Medical Information** | INITIAL: (A) HEREDITARY TRANSTHYRETIN-MEDIATED AMYLODOSIS-POLYNEUROPATHY (hATTR-PN): (1) Diagnosis of hATTR-PN AND (2) Patient is ambulatory (i.e. Familial Amyloid Polyneuropathy [FAP] stage 1  2 OR Polyneuropathy Disability [PND] stage I  IIIb polyneuropathy) AND (3) Diagnosis is confirmed by one of the following: (3a) Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR (transthyretin) protein OR (3b) DNA genetic sequencing to confirm hATTR mutation. CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient has not progressed to FAP stage 3 or PND Stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden) AND (4) Wainua will NOT be used concurrently with other hATTR-PN agents. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist. |
| **Coverage Duration** | Initial: 6 months  Renewal: 12 months |
| **Other Criteria** | PA Automation |

# WAKIX

## Products Affected

- WAKIX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Excessive daytime sleepiness (EDS) with narcolepsy or cataplexy with narcolepsy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL (A) EXCESSIVE DAYTIME SLEEPINESS (EDS) WITH NARCOLEPSY: (1) Diagnosis of EDS with narcolepsy AND (2) Diagnosis confirmed by one of the following: (2a) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least two early-onset REM sleep periods (SOREMPs) OR (2b) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [Note to Pharmacist: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals] OR (2c) Patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay AND (3) Patient has EDS persisting for at least 3 months AND (4) Patient has an Epworth Sleepiness Scale (ESS) score of greater than 10 AND (5) Tried or contraindicated to generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND (6) Tried or contraindicated to solriamfetol, armodafinil, or modafinil. (B) CATAPLEXY WITH NARCOLEPSY: (1) Diagnosis of cataplexy with narcolepsy AND (2) TWO of the following: venlafaxine, fluoxetine, or a tricyclic antidepressant (TCA) (e.g., clomipramine, imipramine). CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication (3) Confirmed by appropriate specialist. RENEWAL: (1) Diagnosis of approvable indication AND (2a) Demonstrated improvement of cataplexy symptoms compared to baseline OR (2b) Maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline OR (2c) Demonstrated improvement in sleep latency compared to baseline. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automation. |

# WAYRILZ

## Products Affected

- WAYRILZ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Persistent or chronic immune thrombocytopenia (ITP). |
| **Exclusion Criteria** | Used concurrently with a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib]). |
| **Required Medical Information** | INITIAL: (A) IMMUNE THROMBOCYTOPENIA (ITP) (1) Diagnosis of persistent or chronic ITP AND (2) Tried or contraindicated to a corticosteroid or IV immunoglobulin, OR had an insufficient response to a splenectomy AND (3) Patient has a platelet count of less than 30 x 10 9/L, OR has a platelet count of less than 50 x 10 9/L and had a prior bleeding event AND (4) Tried or contraindicated to a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib]) OR a thrombopoietin receptor agonist (e.g., Doptelet [avatrombopag], Promacta [eltrombopag]). CONTINUING THERAPY / RENEWAL: (1) Patient has been stable on therapy AND (2) Diagnosis of approvable indication AND (3) Wayrilz will NOT be used concurrently with a spleen tyrosine kinase (SYK) inhibitor AND (4) Patient has shown a clinical response to therapy, defined as having an improvement in platelet counts from baseline OR a reduction in bleeding events. |
| **Age Restrictions** | 18 years of age and older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 3 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# WINREVAIR

## Products Affected

- WINREVAIR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events , Medically accepted indications. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | A. INITIAL: (1) Prescriber attests that the patient has a diagnosis of treatment of PAH (WHO group 1) AND (2) Documented confirmatory diagnosis based on right-heart catheterization with the following parameters: (2a) Mean pulmonary artery pressure (PAP) greater than 20 mmHg AND (2b) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg AND (2c) Pulmonary vascular resistance (PVR) greater than 2 Wood units AND (3) One of the following: (3a) Patient is on background PAH therapy for at least 3 months with TWO or more of the following agents from different drug classes: oral ERA (e.g., ambrisentan, bosentan, or macitentan) OR oral PDE5 (e.g., sildenafil or tadalafil), OR oral CGMP stimulator (e.g., riociguat) OR IV/SQ prostacyclin (e.g., epoprostenol, treprostinil) OR (3b) Patient is on ONE of the above drug classes AND has a contraindication OR is unable to tolerate all other drug classes CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy 90 days |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or given in consultation with cardiologist or pulmonologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | None. |

# XDEMVY

## Products Affected

- XDEMVY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Demodex blepharitis. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) DEMODEX BLEPHARITIS: (1) Diagnosis of Demodex blepharitis. |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 6 weeks |
| **Other Criteria** | PA Automated. |

# XELJANZ

## Products Affected

- XELJANZ
- XELJANZ XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Ankylosing Spondylitis (AS), Polyarticular course juvenile idiopathic arthritis (PJIA), psoriatic arthritis (PsA), Rheumatoid arthritis (RA), ulcerative colitis (UC) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [AS, PJIA, PsA, RA]: ONE TNF inhibitor: adalimumab-adaz, Humira, Enbrel, or Simlandi. [UC]: ONE TNF inhibitor: adalimumab-adaz, Simlandi. INITIAL: (A) ANKYLOSING SPONDYLITIS (AS): (1) Diagnosis of AS AND (2) Tried or contraindicated to an NSAID (e.g., ibuprofen, meloxicam, naproxen, diclofenac). (B) POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): (1) Diagnosis of PJIA. (C) PSORIATIC ARTHRITIS (PsA): (1) Diagnosis of PSA. (D) RHEUMATOID ARTHRITIS (RA): (1) Diagnosis of moderate to severe RA AND (2) Tried or contraindicated to at least 3 months of treatment with ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine. (E) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Xeljanz will NOT be used concurrently with another systemic biologic or targeted small molecules (JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. RENEWAL: (1) Diagnosis of approvable indication AND (2) Xeljanz will NOT be used concurrently with another systemic biologic or targeted small molecules (JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication AND [AS]: (3) Patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy. (3) [PJIA, PsA, RA]: Patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | [AS, RA, UC]: 18 years of age or older. [PJIA, PsA]: 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [AS, PJIA, RA]: rheumatologist. [UC]: gastroenterologist. [PsA]: rheumatologist or dermatologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# XENAZINE

## Products Affected

- *tetrabenazine*
- XENAZINE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chorea associated with Huntington disease, Medically accepted indications will also be considered for approval |
| **Exclusion Criteria** | Hepatic function impairment, patients who are actively suicidal or who have untreated or inadequately treated depression |
| **Required Medical Information** | A. CHOREA ASSOCIATED WITH HUNTINGTONS DISEASE: INITIAL: (1) Documented diagnosis of Huntingtons disease AND (2) Presence of involuntary (choreiform) movements not due to any other causes CONTINUATION OF THERAPY: (1) Patient has been on therapy for 30 days AND (2) Diagnosis of approvable indication AND (3) Prescribed?by?an appropriate specialist AND (4) Meets formulary requirements |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# XEOMIN

## Products Affected

- XEOMIN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles), chronic sialorrhea, blepharospasm, upper limb spasticity. |
| **Exclusion Criteria** | Request is for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines). |
| **Required Medical Information** | INITIAL: (A) CERVICAL DYSTONIA: (1) Diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) AND (2) Patient is 18 years of age or older. (B) SIALORRHEA: (1) Diagnosis of chronic sialorrhea AND (2) Patient is 2 years of age or older. (C) BLEPHAROSPASM: (1) Diagnosis of blepharospasm AND (2) Patient is 18 years of age or older. (D) SPASTICITY: (1) Diagnosis of upper limb spasticity AND (2) One of the following: (2a) Patient is 18 years of age or older OR (2b) Patient is 2 to 17 years of age AND (2b.i) Patient does NOT have spasticity caused by cerebral palsy.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | See RMI. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# XERMELO

## Products Affected

- XERMELO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Carcinoid syndrome diarrhea. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) CARCINOID SYNDROME DIARRHEA: (1) Diagnosis of carcinoid syndrome diarrhea AND (2) Patient has been receiving a stable dose of long-acting somatostatin analog (SSA) therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for at least 3 months AND (3) Xermelo will be used in combination with a somatostatin analog (SSA) (e.g., octreotide) AND (4) Patients diarrhea is inadequately controlled as defined by having at least four bowel movements per day, while on somatostatin analog (SSA) therapy.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Xermelo will be used in combination with a somatostatin analog (SSA) (e.g., octreotide). |
| **Age Restrictions** | 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or oncologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# XGEVA

## Products Affected

- XGEVA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Multiple myeloma, metastases from a solid tumor, giant cell tumor of bone, hypercalcemia of malignancy. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: [XGEVA]: Tried or contraindicated to Osenvelt. INITIAL: (A) MULTIPLE MYELOMA (1) Diagnosis of multiple myeloma AND (2) Requested drug will be used to prevent skeletal-related events (e.g., bone fractures, bone pain requiring radiation). (B) BONE METASTASES: (1) Diagnosis of bone metastases from a solid tumor AND Requested drug will be used to prevent skeletal-related events (e.g., bone fractures, bone pain requiring radiation). (C) GIANT CELL TUMOR: (1) Diagnosis of giant cell tumor of bone AND (2) Patients tumor is unresectable, or surgical resection is likely to result in severe morbidity. (D) HYPERCALCEMIA: (1) Diagnosis of hypercalcemia of malignancy AND (2) Patient is refractory to a bisphosphonate therapy (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate]).<br><br>CONTINUING THERAPY: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | PA Automated. |

# XIAFLEX

## Products Affected

- XIAFLEX

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Dupuytrens contracture, Peyronies disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | Peyronies plaques that involve the penile urethra |
| **Required Medical Information** | A. DUPUYTRENS CONTRACTURE (DC): INITIAL: (1) Prescriber attests to a diagnosis of Dupuytrens contracture AND (2) Prescriber attests to patient having a finger flexion contracture with a palpable cord of at least one finger (other than the thumb) involving the metacarpophalangeal (MP) joint or the proximal interphalangeal (PIP) joint. B. PEYRONIES DISEASE (PD): INITIAL: (1) Prescriber attests to patient having a diagnosis of Peyronies disease AND (2) Prescribers attests to a palpable plaque and curvature deformity of 30 degrees or greater at the start of therapy AND (3) Prescriber attests that patient has stable disease defined as symptoms that have remained unchanged for 3 months RENEWAL: (1) Patient must meet initial criteria every 3 months |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | DC: Prescribed by or in consultation with surgeon who has experience and training in hand surgeriesPD: Prescribed by or in consultation with a urologist |
| **Coverage Duration** | Initial: 3 months |
| **Other Criteria** | DC: one dose per cord per 28 days, maximum 3 doses per cordPD: Two Injections per plaque per 28 days, maximum 4 treatment cycles (2 injections/cycle) per plaque. PA Automated |

# XIFAXAN

## Products Affected

- XIFAXAN

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hepatic encephalopathy, irritable bowel syndrome without constipation, clostridium difficile, travelers diarrhea |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: (A) HEPATIC ENCEPHALOPATHY (HE) (request for the 550mg tablet): (1) Diagnosis of hepatic encephalopathy AND (2) The patient had a trial of lactulose or is currently on lactulose monotherapy OR (3) If request is for the 200 mg Xifaxan tablets, the patient has a diagnosis of HE AND (3a) Xifaxan it will be used in combination with lactulose (B) CLOSTRIDIUM DIFICILE INFECTION (CDI): (1) The request is for the 200 mg tablet and the patient meets all of the following: (2a) Therapy is prescribed by or in consultation with an infectious disease specialist AND (2b) The patient had at least one previous occurrence of Clostridium difficile infection AND (2c) Patient has been treated with vancomycin for the current Clostridium difficile infection. (C) TRAVELERS DIARRHEA CAUSED BY NON-INVASIVE STRAINS OF E. COLI (request for 200mg tablet): (1) Diagnosis of travelers diarrhea AND (2) Patient has a trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin. (D) IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D) (request for the 550mg tablet): (1) Diagnosis of IBS-D AND (2) Tried or contraindicated to a tricyclic antidepressant (TCA) (e.g. amitriptyline, nortriptyline, etc.) or dicyclomine (Bentyl). |
| **Age Restrictions** | [Travelers Diarrhea]: 12 years of age or older. [HE, IBS-D]: 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a [HE]: hepatologist. [IBS-D]: gastroenterologist. |
| **Coverage Duration** | SEE OTHER CRITERIA FOR COVERAGE DURATION |
| **Other Criteria** | CONTINUING THERAPY / RENEWAL: [HE]: (1) Patient has been on therapy for any number of days AND (2) Diagnosis of hepatic encephalopathy AND (3) Patient being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence. [IBS-D]: (1a) Patient is |

| PA Criteria | Criteria Details |
| --- | --- |
| | completing therapy for no more than 8 weeks total OR (1b) Patients last treatment course of Xifaxan has been at least 6 weeks ago AND (2) Diagnosis of approvable indication AND (3) Patient has experienced at least 30 percent decrease in abdominal pain (on a 0-10 point pain scale) AND (4) Patient has experienced at least 50 percent 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). PA Automated. COVERAGE DURATION: [HE]: Initial: 12 months, Renewal: 12 months. [IBS-D]: Initial: 8 weeks, Renewal: 12 months (2 fills separated by 8 weeks in 12 months), [Travelers diarrhea]: Initial: 3 days. [CDI]: 20 days. |

# XOLAIR

## Products Affected

- XOLAIR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe persistent Asthma, Chronic spontaneous urticaria (CSU) also known as: chronic idiopathic urticaria (CIU), Chronic rhinosinusitis nasal polyps (CRSwNP), IgE-mediated food allergy. |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Dupixent [dupilumab, Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the same indication. |
| **Required Medical Information** | INITIAL: (A) ASTHMA: (1) Diagnosis of moderate to severe persistent asthma AND (2) Patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen AND (3) Baseline IgE serum level of at least 30 IU/mL AND (4) Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (beclomethasone, budesonide, mometasone) AND at least ONE other maintenance medication (long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or oral corticosteroid [e.g., prednisone]) AND (5) Patient meets one of the following: (5a) Patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR (5b) Patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months OR (5c) Patient have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: Daytime asthma symptoms more than twice per week, any night waking due to asthma, use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week, any activity limitation due to asthma. (B) CIU: (1) Diagnosis of CIU/CSU AND (2) Patient still experiences hives or angioedema on most days of the week for at least 6 weeks AND (3) Patient had a trial of and is maintained on, or contraindication to, 4-times the maximally labeled dose of a second generation H1 antihistamine (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day. SEE OTHER CRITERIA |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | [ASTHMA]: 6 years of age or older. [CSU]: 12 years of age or older. [CRSwNP]: 18 years of age or older. [FOOD ALLERGY]: 1 year of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with [Asthma]: allergist or pulmonologist. [CRSwNP]: allergist, immunologist, or otolaryngologist. [FOOD ALLERGY]: allergist or immunologist. [CSU]: allergist, dermatologist, or immunologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months [FOOD ALLERGY]: Initial: 12 months, Renewal: 24 months |
| **Other Criteria** | (C) CRSwNP: (1) Diagnosis of CRSwNP AND (2) Evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan AND (3) Patient has inadequately controlled disease AND (4) Patient has tried ONE intranasal corticosteroid (ie. fluticasone) for a 56-day trial AND (5) Xolair will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids). (D) IGE-MEDIATED FOOD ALLERGY: (1) Diagnosis of a IgE-mediated food allergy AND (2) Patient will practice food allergen avoidance AND (3) Patient has IgE serum level of at least 30 IU/mL AND (4) Patient has one of the following: (4a) an allergen specific IgE of greater than or equal to 6 kUA/L, (4b) a positive skin prick test or (4c) positive medically monitored food challenge to at least 1 food AND (4) Patient has an active prescription for epinephrine auto-injector/injection.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Diagnosis confirmed by appropriate specialist AND (4) Exclusion Criteria AND [Asthma]: (5) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid). [CIU]: (5) Patient is maintained on or contraindication to 4-times the maximally labeled dose of a second generation H1 antihistamine (e.g., Allegra, Clarinex, Claritin, Xyzal, Zyrtec). [FOOD ALLERGY]: (5) Patient has an active prescription for epinephrine auto-injector/injection AND (6) Patient is not on concurrent peanut-specific immunotherapy.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Not used concurrently with another systemic biologic or targeted small molecules for the same indication AND [ASTHMA]: (3) Patient will continue to use an ICS AND at least ONE other maintenance medication (e.g., LABA, LAMA, LTRA, theophylline, or an oral corticosteroid) AND (4) Patient has shown a clinical response as evidenced by ONE of the following: (4a) Reduction in asthma exacerbations from baseline OR (4b) Decreased |

| PA Criteria | Criteria Details |
| --- | --- |
| | utilization of rescue medications (e.g., albuterol OR (4c) Increase in percent predicted FEV1 from pre-treatment baseline OR (4d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing). [CRSwNP]: (3) Patient has shown clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps). [CIU]: (3) Patient is maintained on or contraindication to 4-times the maximally labeled dose of a second generation H1 antihistamine (e.g., Allegra, Clarinex, Claritin, Xyzal, Zyrtec). [FOOD ALLERGY]: (3) Patient has an active prescription for epinephrine auto-injector/injection. PA Auto |

# XOLREMDI

## Products Affected

- XOLREMDI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A.INITIAL:WHIM (warts, hypogammaglobulinemia, infections and myelokathexis). (1) Prescriber attests to a diagnosis of WHIM. CONTINUATION OF THERAPY: (1) Diagnosis of an approvable indication |
| **Age Restrictions** | 12 years of age and older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months |
| **Other Criteria** | QUANTITY LIMIT APPLIES |

# XROMI

## Products Affected

- XROMI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Sickle cell anemia |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) SICKLE CELL ANEMIA (1) Diagnosis of sickle cell anemia AND (2) Patient has recurrent moderate to severe painful crises AND (3) Tried or contraindicated, or unable to swallow generic hydroxyurea capsules. CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 6 months to 17 years of age and older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# XYREM

## Products Affected

- *sodium oxybate*
- XYREM

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Idiopathic hypersomnia (IH), cataplexy in narcolepsy, excessive daytime sleepiness (EDS) in narcolepsy. |
| **Exclusion Criteria** | Used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam]). |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to generic sodium oxybate prior to Xyrem. INITIAL: (A) EXCESSIVE DAYTIME SLEEPINESS (EDS) in NARCOLEPSY: (1) Diagnosis of EDS in narcolepsy (2) Diagnosis confirmed by one of the following: (2a) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least two early-onset REM sleep periods (SOREMPs) OR (2b) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [Note to Pharmacist: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals] OR (2c) Patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay AND (3) Patient has EDS persisting for at least 3 months AND (4) Patient has an Epworth Sleepiness Scale (ESS) score of greater than 10 AND (5) Tried or contraindicated to a generic typical stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate) AND (6) Patient is 18 years of age or older AND tried or contraindicated to armodafinil (Nuvigil) OR modafinil (Provigil). (B) CATAPLEXY IN NARCOLEPSY: (1) Diagnosis of cataplexy in narcolepsy AND (2) Tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil]). SEE OTHER CRITERIA |
| **Age Restrictions** | [Cataplexy, EDS]: 7 years of age or older. [IH]: 18 years of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | (C) IDIOPATHIC HYPERSOMNIA (IH): (1) Diagnosis of IH AND (2) Patient does NOT have cataplexy AND (3) Patient has a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less AND (4) Patient has one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log AND (5) Patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months AND (6) Tried or contraindicated to armodafinil (Nuvigil) OR modafinil (Provigil). CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent AND [CATAPLEXY]: (4) Demonstrated improvement of cataplexy symptoms compared to baseline. [EDS]: (4a) Maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline OR (4b) Demonstrated improvement in sleep latency compared to baseline. [IH]: (4a) Patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline OR (4b) Patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline. PA Automation |

# XYWAV

## Products Affected

- XYWAV

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Cataplexy with narcolepsy, excessive daytime sleepiness (EDS) with narcolepsy, idiopathic hypersomnia (IH). |
| **Exclusion Criteria** | Concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]). |
| **Required Medical Information** | INITIAL: (A) EXCESSIVE DAYTIME SLEEPINESS (EDS) IN NARCOLEPSY: (1) Diagnosis of EDS in narcolepsy AND (2) Diagnosis confirmed by one of the following: (2a) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least two early-onset REM sleep periods (SOREMPs) OR (2b) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [Note to Pharmacist: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals] OR (2c) Patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay AND (3) Patient has EDS persisting for at least 3 months AND (4) Patient has an Epworth Sleepiness Scale (ESS) score of greater than 10 AND (5) Tried or contraindicated to a generic typical stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate [Ritalin]) AND (6) Patient is 18 years of age or older AND tried or contraindicated to armodafinil OR modafinil. (B) CATAPLEXY WITH NARCOLEPSY: (1) Diagnosis of cataplexy with narcolepsy AND (2) Tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil]). SEE OTHER CRITERIA |
| **Age Restrictions** | [Cataplexy, EDS]: 7 years of age or older. [IH]: 18 years of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 6 months, Renewal: 12 months |
| **Other Criteria** | (C) IDIOPATHIC HYPERSOMNIA (IH): (1) Diagnosis of IH AND (2) Patient does NOT have cataplexy AND (3) Patient has a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less AND (4) Patient has one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log AND (5) Patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months AND (6) Tried or contraindicated to armodafinil (Nuvigil) OR modafinil (Provigil). CONTINUING THERAPY / RENEWAL: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent AND [CATAPLEXY]: (4) Demonstrated improvement of cataplexy symptoms compared to baseline [EDS]: (4a) Maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline OR (4b) Demonstrated improvement in sleep latency compared to baseline. [IH]: (4a) Patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline OR (4b) Patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline. PA Automation. |

# YEZTUGO

## Products Affected

- YEZTUGO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pre-exposure prophylaxis (PrEP) of human immunodeficiency virus type 1 (HIV-1). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PrEP OF HIV-1: (1) Request is used for PrEP of HIV-1 AND (2) Patient weighs at least 35 kg (77 lbs) AND (2) Patient is at risk of sexually acquired HIV-1 AND (2) Patient has a negative HIV-1 test prior to initiating therapy.CONTINUING THERAPY / Renewal: Treat as Initial. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# YORVIPATH

## Products Affected

- YORVIPATH

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Hypoparathyroidism |
| **Exclusion Criteria** | None |
| **Required Medical Information** | INITIAL: A. HYPOPARATHYROIDISM (1) Patient has diagnosis of hypoparathyroidism AND (2) Patients hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis AND (3) Patient had a trial of activated vitamin D (e.g., calcitriol) and calcium.CONTINUATION OF THERAPY: (1) Diagnosis of approvable indication AND (2) Patient has been stable on therapy for 30 days AND (3) Patient is independent of or managed on a lowered dose of vitamin D and calcium supplementationRENEWAL:(1) Patient is independent of or managed on a lowered dose of vitamin D and calcium supplementation |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Initial: 6 months,  Renewal:  12 months |
| **Other Criteria** | PA Automated |

# YUTREPIA

## Products Affected

- YUTREPIA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Pulmonary arterial hypertension (PAH) (WHO GROUP 1), Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO TYVASO DPI. INITIAL: (A) PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Diagnosis of PAH (WHO Group 1) AND (2) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU) AND (5) Tried or contraindicated to TWO of the following agents from different drug classes: (5a) Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan]), (5b) Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil]), (5c) Oral cGMP stimulator (e.g., Adempas [riociguat]), OR (5d) IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil]). (B) PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (PH-ILD): (1) Diagnosis of PH-ILD (WHO Group 3) AND (2) PAH diagnosis has been confirmed by right heart catheterization with ALL of the following parameters: Mean pulmonary artery pressure (PAP) of greater than 20 mmHg AND (3) Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg AND (4) Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU). CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. RENEWAL: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or pulmonologist. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ZARXIO

## Products Affected

- ZARXIO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy and receiving myelosuppressive chemotherapy, Acute myeloid leukemia, Non-myeloid malignancy and undergoing myeloablative chemotherapy, mobilization of autologous hematopoietic progenitor cells, congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia, or Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | STEP ALERT: TRIED OR CONTRAINDICATED TO NIVESTYM. A. FOR ALL INDICATIONS: (1) Patient has one of the following: (1a) Non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever OR (1b) diagnosis of acute myeloid leukemia (AML) and is undergoing induction or consolidation chemotherapy treatment OR (1c) Non-myeloid malignancy, is undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT), and is experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia) OR (1d) Requested medication will be used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis OR (1e) Diagnosis of congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia OR (1f) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated |

# ZELSUVMI

## Products Affected

- ZELSUVMI

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Molluscum contagiosum (MC). |
| **Exclusion Criteria** | Used concurrently with another topical agent (e.g., Ycanth [cantharidin], Condylox [podofilox]) for Molluscum Contagiosum. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to podofilox 0.5% topical solution. INITIAL: (A) MOLLUSCUM CONTAGIOSUM (MC) (1) Diagnosis of MC. CONTINUING THERAPY: Treat as Initial. RENEWAL: Treat as Initial. |
| **Age Restrictions** | 1 year of age and older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 weeks |
| **Other Criteria** | PA Automated |

# ZEMBRACE

## Products Affected

- ZEMBRACE SYMTOUCH

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Acute Migraines, medically accepted indication will also be considered for approval. |
| **Exclusion Criteria** | Ischemic heart disease or signs or symptoms of ischemic heart disease; history of cerebrovascular syndromes; history of hemiplegic or basilar migraine; peripheral vascular disease (including ischemic bowel disease); uncontrolled hypertension; Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders; severe hepatic impairment |
| **Required Medical Information** | A. MIGRAINE: INITIAL: (1) Prescriber attest to diagnosis of migraine AND (2) Patient is intolerant to oral triptan formulations AND (3) Patient is intolerant to ODT triptan dosage forms AND (4) Patient is intolerant to other injectable triptan dosage forms AND (5) Patient is intolerant to nasal triptan dosage forms AND (6) Patient must have responded to another sumatriptan formulation but is unable to tolerate other formulation RENEWAL: (1) Prescriber attests that member has had disease stabilization or improvement with medication. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ZEPATIER

## Products Affected

- ZEPATIER

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Chronic hepatitis C genotype (GT) 1 or 4. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | FORMULARY ALERT: TRIED, FAILED OR INTOLERANT TO PRIMARY TREATMENT EPCLUSA, HARVONI OR MAVYRET PRIOR TO SECONDARY TREATMENT VIEKIRA AND ZEPATIER A.CHRONIC HEPATITIS C GT 1 or 4: (1) Must have a diagnosis of Chronic Hepatitis C infection genotype 1 or 4 AND (2) Must provide HCV RNA level dated within last 6 months AND (3) Patient is 12 years of age and older OR weighs at least 30 kg (66 lbs) AND (4) The patient does NOT meet any of the following: (4a) patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions, (4b) patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C), (4c) Zepatier will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., phenytoin, carbamazepine, rifampin, efavirenz [e.g., Atripla, Sustiva], atazanavir [e.g., Evotaz, Reyataz], darunavir [e.g., Prezcobix, Prezista], lopinavir, saquinavir, Aptivus [tipranavir], cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir [e.g., Stribild, Genvoya], atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, St. John?s wort), (4d) Zepatier will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir) AND (5) The patient treatment-na?ve AND had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni, or Mavyret AND SEE OTHER CRITERIA |
| **Age Restrictions** | 12 years of age or older |
| **Prescriber Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | 12-16 weeks, See OTHER CRITERIA Field |
| **Other Criteria** | (6)The patient meets ONE of the following criteria: (6a) The patient has genotype 1a infection AND does not have baseline NS5A polymorphisms, (6b) patient has genotype 1b infection, (6c) patient has genotype 4 infection, (6d) The patient is post-kidney transplant AND does not have baseline NS5A RAS polymorphisms OR (7) Patient meet ALL of the following criteria: (7a) patient has genotype 1a infection, (7b) patient has baseline NS5A polymorphisms, (7c) Zepatier will be used with ribavirin OR (8) Patient treatment-experienced AND meets the following criterion AND had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni, or Mavyret AND (9) The patient have genotype 1 infection and meet ONE of the following criteria: (9a) patient has genotype 1a infection, without baseline NS5A polymorphisms AND failed prior treatment with peginterferon/ribavirin, (9b) The patient has genotype 1b infection AND failed prior treatment with peginterferon/ribavirin, (9c) The patient failed prior treatment with a peginterferon/ribavirin/protease inhibitor triple regimen AND Zepatier will be used with ribavirin OR (10) Patient meet ONE of the following criteria: (10a) patient has genotype 1a infection with baseline NS5A polymorphisms, failed prior treatment with peginterferon/ribavirin AND Zepatier will be used with ribavirin, (10b) The patient has genotype 4 infection, failed prior treatment with peginterferon/ribavirin AND Zepatier will be used with ribavirin OR (11) Patient post-kidney transplant and meets ALL of the following criteria: (11a) patient failed prior treatment with a non-direct acting antiviral agent (e.g., interferon) AND (11b) The patient does not have baseline NS5A RAS polymorphisms OR(12) The patient does meet a condition as specified above but the requested regimen is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.Duration of approval is based on recommendations by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment.No PA Automation |

# ZEPOSIA

## Products Affected

- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- ZEPOSIA STARTER KIT

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease. Moderately to severely active ulcerative colitis (UC). |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (Upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)] for the same indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [UC]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, YESINTEK), Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). INITIAL: (A) MULTIPLE SCLEROSIS (MS): (1) Diagnosis of a relapsing form of MS, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease. (B) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patient must not be taking any other systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication concurrently.<br><br>RENEWAL: [MS]: Refer to initial. [UC]: (1) Diagnosis of UC AND (2) Patient must not be taking any other systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication concurrently. |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | [MS]: None. [UC]: Prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ZIEXTENZO

## Products Affected

- ZIEXTENZO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Non-myeloid malignancy, hematopoietic syndrome of acute radiation syndrome (H-ARS). |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. NON-MYELOID MALIGNANCY: (1) Patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever. HEMATOPOIETIC SUBSYNDROME OF ACUTE RADIATION SYNDROME: (1) Requested medication will be used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (H-ARS).CONTINUATION OF THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Patient has a diagnosis of an approvable indication AND (3) Diagnosis confirmed by an appropriate specialist. RENEWAL: Treat as initial. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | PA Automated |

# ZILBRYSQ

## Products Affected

- ZILBRYSQ

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Generalized myasthenia gravis (gMG). |
| **Exclusion Criteria** | Used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]) or complement inhibitor (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG. |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to Rystiggo, Vyvgart, Vyvgart Hytrulo. INITIAL: (A) GENERALIZED MYASTHENIA GRAVIS (gMG): (1) Diagnosis of gMG AND (2) Patient has a positive serological test for anti-acetylcholine receptor antibody (AChR-Ab+) AND (3) Patient is Myasthenia Gravis Foundation of America class II, III or IV AND (4) Tried or contraindicated to ONE corticosteroid (e.g., prednisone) AND (5) Patient meets one of the following: (5a) Tried or contraindicated to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate) OR (4b) Tried or contraindicated to ONE non-steroidal immunosuppressive therapies, if on chronic plasmapheresis for plasma exchange.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Zilbrysq will NOT be used concurrently with another neonatal Fc receptor, complement inhibitor, or CD-19 antibody for the treatment of gMG.<br><br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Zilbrysq will NOT be used concurrently with another neonatal Fc receptor, complement inhibitor, or CD-19 antibody for the treatment of gMG AND (3) Patient has had clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool). |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | Initial: 12 months Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated |

# ZOLEDRONIC ACID

## Products Affected

- RECLAST
- *zoledronic acid*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | ZOMETA: Hypercalcemia of malignancy, Multiple myeloma, Bone metastases from solid tumors, RECLAST: Prevention or treatment of postmenopausal osteoporosis prophylaxis, Osteoporosis in men, Prevention or treatment of glucocorticoid-induced osteoporosis prophylaxis, Pagets disease, Medically accepted indications will also be considered for approval. |
| **Exclusion Criteria** | FOR ZOLEDRONIC ACID 4MG: Pregnant or nursing women, FOR ZOLEDRONIC ACID 5MG: Pregnant or nursing women, Hypocalcemia, Creatinine clearance < 35 ml/min and in those with evidence of acute renal impairment |
| **Required Medical Information** | A. RECLAST FOR OSTEOPOROSIS: (1) Prescriber attests that patient has a documented diagnosis of treatment or prevention of postmenopausal osteoporosis OR treatment of osteoporosis in men AND (2) Prescriber attests that patient is taking or diet includes adequate calcium and vitamin D supplementation AND (3) Prescriber attests that patient has tried and failed or have a contraindication (i.e., older patients with previous multiple vertebral fractures or hip fractures, or who have very low T-scores, those who have upper GI problems or lower GI problems, those where coordination of a bisphosphonate with other medication or remembering to take an oral medication exists, etc.) to an ORAL bisphosphonate treatment. B. RECLAST FOR GLUCOCORTICOID INDUCED OSTEOPOROSIS: (1) Prescriber attests that patient has a documented diagnosis of prevention or treatment of glucocorticoid induced osteoporosis AND (2) Prescriber attests that dosage of glucocorticoid therapy is equivalent to a dose that averages greater than or equal to 7.5mg of prednisone daily AND (3) Prescriber attests that patient is taking or diet includes adequate calcium and vitamin D supplementation AND (4) Prescriber attests that patient has tried and failed or has a contraindication (i.e., older patients with previous multiple vertebral fractures or hip fractures, or who have very low T-scores, those who have upper GI problems or lower GI problems, those where coordination of a bisphosphonate with other medication or remembering to take an oral medication exists, etc.) to an ORAL bisphosphonate treatment. C. RECLAST FOR PAGETS DISEASE: (1) Prescriber attests to a diagnosis of Pagets disease AND (2) Prescriber attests that the patient has been instructed to take adequate calcium and |

| PA Criteria | Criteria Details |
|---|---|
| | vitamin D, particularly in the 2 weeks following the administration AND SEE OTHER CRITERIA |
| **Age Restrictions** | 18 years of age or older |
| **Prescriber Restrictions** | Prescriber by or in conjunction with an endocrinologist, rheumatologist, hematologist, or an oncologist. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | (3) Prescriber attests that patient has one of the following: an elevated serum alkaline phosphatase of greater than 2 times or higher than the upper limit of the age-specific normal reference range OR the patient is symptomatic, OR patient is at risk for complications from the disease, to induce remission (normalization of serum alkaline phosphatase) prior to treatment with Reclast. RECLAST RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria AND (2) Prescriber attests that patient is having appropriate monitoring with a DXA scan at least two years after initial drug therapy for osteoporosis. D.ZOLEDRONIC ACID (4MG): INITIAL: (1) Prescriber attests that the patient has one of the following: hypercalcemia of malignancy, multiple myeloma, or bone metastases from solid tumors AND (2) Prescriber attests there will be a minimum of 7 days elapsed before re-treatment for response to the initial dose AND (3) FOR MULTIPLE MYELOMA AND BONE METASTASES OF SOLID TUMOR: Patients with prostate cancer have progressed after at least one hormonal therapy [if applicable] AND (4) Prescriber attests that patient is administered adequate calcium and vitamin D per day OR (5) HYPERCALCEMIA OF MALIGNANCY: Prescriber attests that patient has an albumin-corrected serum calcium of greater than or equal to 12 mg/dL. ZOLEDRONIC ACID (4MG) RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria AND (2) Prescriber attests to clinical benefit of continuation of therapy. Elixir Quantity Limit Applies. No PA Automation |

# ZONISADE

## Products Affected

- ZONISADE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Partial-onset seizures. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: SEIZURES: (1) Diagnosis of partial-onset seizures AND (2) Zonisade will be used as adjunctive treatment AND (3) Patient has a contraindication or is unable to swallow zonisamide capsules AND (4) Tried or contraindicated to THREE antiepileptic medications (e.g., carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide capsules, topiramate, lamotrigine).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication.<br><br>Renewal: (1) Diagnosis of approvable indication. |
| **Age Restrictions** | 16 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ZORYVE

## Products Affected

- ZORYVE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Plaque Psoriasis (PsO) [0.3% cream/foam only], Atopic Dermatitis [0.15% cream only], Seborrheic dermatitis [foam only]. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) PLAQUE PSORIASIS (PsO) [0.3% CREAM only]: (1) Diagnosis of PsO AND (2) Tried or contraindicated to one of the following: (2a) High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment) (2b) Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment) (2c) Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) (2d) Topical retinoid (e.g., tazarotene cream/gel) (2e) Anthralin. (B) PLAQUE PSORASIS (PsO [FOAM only]: (1) Diagnosis of PsO AND (2) Tried or contraindicated ONE of the following: (2a) High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment) AND (2b) Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment). SEE OTHER CRITERIA |
| **Age Restrictions** | [PsO foam]: 12 years of age or older. [AD (0.05% cream): 2 to 5 years of age]. [AD (0.15% cream), PsO (0.3% cream)]: 6 years of age or older. [Seborrheic dermatitis]: 9 years of age and older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months. |
| **Other Criteria** | (C) SEBORRHEIC DERMATITIS [Foam only]: (1) Diagnosis of seborrheic dermatitis AND (2a) Patient has had a prior successful treatment with roflumilast foam OR (2b) Tried or contraindicated to ONE of the following: (2b.i) High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or |

| PA Criteria | Criteria Details |
| --- | --- |
| | a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment) OR (2b.ii) Topical antifungal (e.g., ketoconazole, ciclopirox) or (2b.iii) Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus). (D) ATOPIC DERMATITIS (AD) [0.15% cream only]: (1) Diagnosis of mild to moderate AD AND (2a) Tried or contraindicated to a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR (2b) Tried or contraindicated to a calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus]).<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication .<br><br>RENEWAL: [Seborrheic dermatitis]: Refer to initial. (1) Diagnosis of approvable indication AND [AD]: (2) Patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement. [PsO]: (2) Patient has achieved or maintained clear or minimal disease AND [PsO for FOAM]: (3) Patients plaque psoriasis involves the scalp and/or body. PA Automated. |

# ZTALMY

## Products Affected

- ZTALMY

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) SEIZURES: (1) Diagnosis of seizures AND (2) Patients seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication AND (3) Patients seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). |
| **Age Restrictions** | 2 years of age or older. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated |

# ZURZUVAE

## Products Affected

- ZURZUVAE

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Postpartum depression |
| **Exclusion Criteria** | None |
| **Required Medical Information** | A. POSTPARTUM DEPRESSION: INITIAL: (1) Prescriber attests to a diagnosis of postpartum depression AND (4) Patient will not exceed 14 days of therapy. CONTINUATION OF COVERAGE: (1)Diagnosis of approvable indication AND (2) Patient has been stable on therapy for more than a day but has not exceeded 14 days of therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial: 30 days |
| **Other Criteria** | None |

# ZYCUBO

## Products Affected

- ZYCUBO

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Menkes disease. |
| **Exclusion Criteria** | None. |
| **Required Medical Information** | INITIAL: (A) MENKES DISEASE: (1) Diagnosis of Menkes disease.<br><br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 30 days AND (2) Diagnosis of approvable indication. |
| **Age Restrictions** | 17 years of age or younger. |
| **Prescriber Restrictions** | None. |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |
| **Other Criteria** | PA Automated. |

# ZYMFENTRA

## Products Affected

- ZYMFENTRA (1 PEN)
- ZYMFENTRA (2 PEN)
- ZYMFENTRA (2 SYRINGE)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | Moderate to severe ulcerative colitis (UC), moderate to severe Crohns disease (CD) |
| **Exclusion Criteria** | Used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for an autoimmune indication |
| **Required Medical Information** | STEP ALERT: Tried or contraindicated to [UC]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek), Xeljanz (XR) (Tried a TNF prior to Rinvoq/Xeljanz). [CD]: TWO agents: adalimumab (-adaz, Humira, Simlandi), Omvoh, Rinvoq tab, Skyrizi, Tremfya, ustekinumab (-aekn, Stegeyma, Yesintek) (Tried a TNF prior to Rinvoq). INITIAL: (A) ULCERATIVE COLITIS (UC): (1) Diagnosis of moderate to severe UC AND (2) Zymfentra will be used following treatment with an intravenous infliximab agent. (B) CROHNS DISEASE (CD) (1) Diagnosis of moderate to severe CD AND (2) Zymfentra will be used following treatment with an intravenous infliximab agent.<br>CONTINUING THERAPY: (1) Patient has been on therapy for at least 90 days AND (2) Diagnosis of approvable indication AND (3) Zymfentra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication.<br>RENEWAL: (1) Diagnosis of approvable indication AND (2) Zymfentra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. |
| **Age Restrictions** | 18 years of age and older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | Initial: 12 months, Renewal: 12 months |

| PA Criteria | Criteria Details |
| --- | --- |
| **Other Criteria** | PA Automated |

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