Keystone 65 Rx HMO
Personal Choice℠ 65 Rx PPO
Select Option® Rx PDP
2024 Utilization Management Criteria: Prior Authorization

PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT SOME OF THE DRUGS WE COVER IN THIS PLAN

This document was updated on 11/19/2024 For more recent information or other questions, please contact our Member Help Team: Keystone 65 Rx at 1-844-352-1699, Personal Choice 65 Rx at 1-888-879-4293, Select Option Rx at 1-888-678-7009 or, for TTY/TDD users, 711, seven days a week from 8 a.m. to 8 p.m. Please note that on weekends and holidays from April 1 through September 30, your call may be sent to voicemail. Or, visit www.ibxmedicare.com to use our *Formulary (List of Covered Drugs)* search tool or view a downloadable document.

When this document refers to "we," "us," or "our," it means Independence Blue Cross. When it refers to "plan" or "our plan," it means Keystone 65 Rx, Personal Choice 65 Rx, and Select Option Rx.

You must generally use network pharmacies to use your prescription drug benefit. Benefits, formulary, pharmacy network, and/or copayments/coinsurance may change on January 1, 2025, and from time to time during the year. Independence Blue Cross offers Medicare Advantage plans with a Medicare contract. Enrollment in Independence Medicare Advantage plans depends on contract renewal.

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Keystone 65: Benefits underwritten by Keystone Health Plan East, a subsidiary of Independence Blue Cross — independent licensees of the Blue Cross and Blue Shield Association.

Personal Choice 65: Benefits underwritten by QCC Insurance Company, a subsidiary of Independence Blue Cross — independent licensees of the Blue Cross and Blue Shield Association.

Select Option: Benefits underwritten by QCC Insurance Company, a subsidiary of Independence Blue Cross — independent licensees of the Blue Cross and Blue Shield Association.

There may be restrictions to your drug coverage

Some covered drugs may have additional requirements or limits on coverage. We call this "utilization management." These requirements and limits may include:

- **Prior Authorization (PA):** Our plan requires you or your physician to get prior authorization for certain drugs. This means that you will need to get approval from our plan before you fill your prescriptions. If you don't get approval, our plan may not cover the drug. Drugs that require prior authorization are listed in this document.
- **Step Therapy (ST):** In some cases, our plan requires you to first try certain drugs to treat your medical condition before we will cover another drug for that condition. Drugs that require step therapy are listed in *2024 Utilization Management Criteria: Step Therapy*.
- **Quantity Limits (QL):** For certain drugs, our plan limits the amount of the drug that our plan will cover. Drugs that have quantity limits are listed in the *Keystone 65 Rx, Personal Choice 65 Rx, and Select Option Rx Formulary (List of Covered Drugs)*.

You can find out if your drug has any additional requirements or limits by looking in your plan *Formulary (List of Covered Drugs)*. You can also get more information about the restrictions applied to specific covered drugs by visiting www.ibxmedicare.com.

You can ask our plan to make an exception to these restrictions or limits, or for a list of other similar drugs that may treat your health condition. Your *Formulary (List of Covered Drugs)* and *Evidence of Coverage* will have more information about the exception request process.

How to use this document

This document, along with *2024 Utilization Management Criteria: Step Therapy*, is intended to be used with your *Formulary (List of Covered Drugs)*. If your prescription drug has the note "PA" in the "Requirements" column of the *Keystone 65 Rx, Personal Choice 65 Rx, and Select Option Rx Formulary (List of Covered Drugs)*, you can find more information on the restriction(s) in this document.

Locate your drug in the index on page 239. The restriction information includes:

- **Prior Authorization**
  - Covered uses
  - Exclusion criteria
  - Required medical information
  - Age restrictions
  - Prescriber restrictions
  - Coverage duration
  - Other criteria

Be sure to read all the information listed for your affected drug. If you have any questions or need assistance with the information contained in this document, please call our Member Help Team: Keystone 65 Rx at 1-844-352-1699, Personal Choice 65 Rx at 1-888-879-4293, or Select Option Rx at 1-888-678-7009 or, for TTY/TDD users, 711.

ABILIFY MYCITE

Products Affected

- ABILIFY MYCITE MAINTENANCE KIT ORAL TABLET THERAPY PACK 15 MG, 2 MG, 20 MG, 30 MG, 5 MG
- ABILIFY MYCITE STARTER KIT ORAL TABLET THERAPY PACK 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Schizophrenia: (1) Attestation that tracking ingestion of the medication is medically necessary. Bipolar 1 Disorder (BP): (1) Attestation that tracking ingestion of the medication is medically necessary. Adjunctive Treatment for Major Depressive Disorder (MDD): (1) Attestation that medication will be used as adjunct therapy. (2) Attestation that tracking ingestion of the medication is medically necessary.
Age Restrictions	(Schizophrenia, BP, MDD): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ABUSE DETERRENT OPIOID

Products Affected

- *hydrocodone bitartrate er oral capsule extended release 12 hour*
- XTAMPZA ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of one of the following: (1) Prior use of TWO generic opioids OR (2) BOTH of the following: (a) there is a history of or a potential for drug abuse among the individual or a member of the individual's household AND (b) documentation of current patient-prescriber opioid treatment agreement
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ACTEMRA SQ

Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	(PJIA, SJIA, RA, GCA, SSc-ILD): Concurrent therapy with any other biologic disease modifying antirheumatic drug (DMARD), e.g. tumor necrosis factor antagonists.
Required Medical Information	Part D is medically necessary when there is documentation of the following: Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Diagnosis of PJIA. (2) Inadequate response or inability to tolerate TWO of the following: (a) adalimumab (Humira), (b) etanercept (Enbrel), (c) Xeljanz, (d) Orencia, (e) Cyltezo, (f) Yuflyma, (g) Rinvoq/Rinvoq LQ OR documentation demonstrating that a trial may be inappropriate. Systemic Juvenile Idiopathic Arthritis (SJIA): (1) Diagnosis of SJIA. (2) Inadequate response or inability to tolerate ONE of the following: (a) Non-steroidal anti-inflammatory drug (NSAID), (b) Systemic glucocorticoid, (c) Methotrexate. Moderate to severe rheumatoid arthritis (RA): (1) Diagnosis of moderate to severe RA. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, (f) Cyltezo, (g) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Giant Cell Arteritis (GCA): (1) Diagnosis of GCA. (2) Documentation of inadequate response/inability to tolerate oral corticosteroids. Systemic Sclerosis (SSc-ILD) (1): Diagnosis of SSc-ILD (2) Documentation of inadequate response/inability to tolerate a 3-month trial of ONE of the following:(a) mycophenolate mofetil, (b) cyclophosphamide, OR (c) azathioprine (3) Diagnosis of SSc-ILD confirmed by a high-resolution CT scan or biopsy
Age Restrictions	(PJIA, SJIA): Member is 2 years of age or older (RA, GCA, SSc-ILD): Member is 18 years of age or older
Prescriber Restrictions	(PJIA, SJIA, RA, GCA): Prescribed by or in consultation with a Rheumatologist (SSc- ILD) -Prescribed by or in consultation with a rheumatologist or pulmonologist
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ACTHAR HP

Products Affected

- ACTHAR
- CORTROPHIN

PA Criteria	Criteria Details
Exclusion Criteria	(All Indications): Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, sensitivity to proteins or porcine origin, or where congenital infections are suspected in infants. OR Administration of live or live attenuated vaccines in members receiving immunosuppressive doses of H.P. Acthar Gel.
Required Medical Information	Part D is medically necessary when ONE of the following is present: (1) Infantile Spasms (IS): (A) Diagnosis of IS. (2) Acute Exacerbation of Multiple Sclerosis (AEMS): (A) Diagnosis of an AEMS, (B) Currently receiving maintenance treatment for MS (e.g. Avonex, Betaseron, Copaxone, Tecfidera, etc.), (C) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (3) Acute Exacerbation of Psoriatic Arthritis (AEPsA): (A) Diagnosis of an AEPsA, (B) Currently receiving a DMARD, (C) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (4) Acute Exacerbation of Rheumatoid Arthritis (AERA): (A) Diagnosis of an AERA, (B) Currently receiving a DMARD, (C) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (5) Acute Exacerbation of Juvenile Rheumatoid Arthritis (AEJRA): (A) Diagnosis of an AEJRA, (B) Currently receiving a DMARD, (C) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (6) Acute Exacerbation of Ankylosing Spondylitis (AEAS): (A) Diagnosis of an AEAS, (B) Currently receiving a DMARD, (C) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (7) Nephrotic Syndrome (NS): (A) Diagnosis of NS, (B) Proteinuria greater than 3.5g/ 24 hours, (C) serum albumin less than 3 mg/dL, (D) Peripheral edema. (F) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (8) Systemic Lupus Erythematosus (SLE): (A) Diagnosis of SLE, (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone).
Age Restrictions	(IS): Member is younger than 2 years of age. (MS): Member is 18 years of age and older. (All Other Indications): Member is 2 years of age and older

PA Criteria	Criteria Details
Prescriber Restrictions	(IS): Prescribed by or in consultation with an neurologist or neonatologist. (All Other Indications): Prescribed by or in consultation with a neurologist, rheumatologist, nephrologist, pulmonologist, ophthalmologist, dermatologist, allergist, immunologist.
Coverage Duration	(IS): 1 year (All Other Indications): 1 month
Other Criteria	Subject to Part B vs Part D review. (9) Systemic Dermatomyositis (SDM): (A) Diagnosis of SDM (polymyositis), (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (10) Severe Erythema Multiforme (SEM): (A) Diagnosis of SEM, (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (11) Stevens-Johnson Syndrome (SJS): (A) Diagnosis of SJS, (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (12) Serum Sickness (SS): (A) Diagnosis of SS, (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (13) Inflammatory Ophthalmic Disease (IOD): (A) Diagnosis of IOD, (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (14) Symptomatic Sarcoidosis (SSD): (A) Diagnosis of SSD, (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (ALL INDICATIONS): Dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ACUTE HAE AGENTS

Products Affected

- BERINERT
- FIRAZYR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- *icatibant acetate subcutaneous solution prefilled syringe*
- SAJAZIR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when the following inclusion criteria is met: Hereditary Angioedema (HAE): (1) Used for the treatment of acute abdominal, facial or laryngeal attacks of HAE.
Age Restrictions	
Prescriber Restrictions	(HAE): Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ACUTE SEIZURE ACTIVITY AGENTS

Products Affected

- LIBERVANT
- NAYZILAM
- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE
- VALTOCO 20 MG DOSE
- VALTOCO 5 MG DOSE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescriber is a neurologist/epilepsy specialist
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ADALIMUMAB PREFERRED PRODUCTS

Products Affected

- CYLTEZO (2 PEN)
- CYLTEZO (2 SYRINGE)
- CYLTEZO-CD/UC/HS STARTER
- CYLTEZO-PSORIASIS/UV STARTER
- YUFLYMA (1 PEN)
- YUFLYMA (2 SYRINGE)
- YUFLYMA-CD/UC/HS STARTER

PA Criteria	Criteria Details
Exclusion Criteria	(RA, AS, JIA, PsA, PsO, CD, UC, HS, UV): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g., tumor necrosis factor antagonists
Required Medical Information	Rheumatoid Arthritis (RA): (1)Diagnosis of moderate to severe RA. (2) Inadequate response or inability to tolerate one DMARD: (e.g., methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Ankylosing Spondylitis (AS): (1) Diagnosis of AS. (2) Inadequate response or inability to tolerate one other treatment such as NSAIDs, COX2 inhibitors or methotrexate. Juvenile Idiopathic Arthritis (JIA): (1) Diagnosis of moderate to severe JIA. (2) Inadequate response or inability to tolerate one of the following: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine. Psoriatic Arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least one DMARD: (e.g., methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe chronic PsO.
Age Restrictions	Member is within the age group listed in the FDA labeling for the indication
Prescriber Restrictions	(RA, JIA, AS): Prescribed by or in consultation with a rheumatologist. (PsA): Prescribed by or in consultation with a dermatologist or rheumatologist. (PsO, HS): Prescribed by or in consultation with a dermatologist. (CD, UC): Prescribed by or in consultation with a gastroenterologist. (UV): Prescribed by or in consultation with a rheumatologist or ophthalmologist.
Coverage Duration	Indefinite

PA Criteria	Criteria Details
Other Criteria	Crohn's Disease (CD): (1) Diagnosis of CD. (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g., corticosteroid, methotrexate, azathioprine or 6-mercaptopurine). Ulcerative Colitis (UC): (1) Diagnosis of UC. (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g., corticosteroid, Aminosalicylate, azathioprine or 6-mercaptopurine). Hidradenitis Suppurativa (HS): (1) Diagnosis of HS. Uveitis (UV)(Initial): (1) Diagnosis of non-infectious intermediate, posterior, or pan-uveitis. (2) Inadequate response or inability to tolerate corticosteroids and at least one immunosuppressive drug (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ADBRY

Products Affected

- ADBRY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis (AD): (1) Diagnosis of moderate to severe AD (2) inadequate response or inability to tolerate BOTH of the following: (a) one topical steroid (medium potency or higher) AND (b) topical tacrolimus.
Age Restrictions	Member is 12 years of age or older
Prescriber Restrictions	(AD): Prescribed by or in consultation with a dermatologist, allergist, immunologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	(PAH, CTEPH) (Initial, Reauth): Concurrent use of phosphodiesterase inhibitors, nitrates or nitric oxide donors, pregnancy, concurrent use with other soluble guanylate cyclase stimulators (e.g. Verquvo)
Required Medical Information	Pulmonary Arterial Hypertension (PAH) (initial): (1) Diagnosis of PAH WHO Group I with New York Heart Association (NYHA) Functional Class II - IV. (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography. (3) Mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion. Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (initial): (1) Diagnosis of persistent/recurrent CTPH (WHO Group 4) after surgical treatment or inoperable CTEPH.
Age Restrictions	(PAH, CTEPH) (Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(PAH, CTEPH) (initial, Reauth): Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	(Initial): 6 months (Reauth):12 months
Other Criteria	(PAH, CPTEH) (Reauth): Stabilization or improvement.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AIMOVIG

Products Affected

- AIMOVIG

PA Criteria	Criteria Details
Exclusion Criteria	Documentation of concomitant use with another injectable CGRP inhibitor.
Required Medical Information	Migraines (Initial): Approved when ONE of the following inclusion criteria are met: (1) Diagnosis of episodic migraines defined as 4 to 14 headache days per month AND inadequate response or inability to tolerate a 4-week trial of TWO of the following prophylactic medications (a) topiramate (b) divalproex sodium/ valproic acid (c) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (d) tricyclic antidepressants: amitriptyline, nortriptyline (e)SNRI antidepressants: venlafaxine, duloxetine. OR (2) Diagnosis of chronic migraines defined as greater than or equal to 15 headache days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (i) topiramate (ii) divalproex sodium/ valproic acid (iii) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (iv) tricyclic antidepressants: amitriptyline, nortriptyline (v)SNRI antidepressants: venlafaxine, duloxetine.
Age Restrictions	(Migraines)(Initial, Reauth): Member 18 years of age or older
Prescriber Restrictions	(Migraines)(Initial, Reauth): Prescribed by or in consultation with a neurologist or headache specialist certified by the United Council for Neurologic Subspecialties, or pain specialist
Coverage Duration	(Migraines)(Initial): 6 months (Migraines)(Reauth): 12 months
Other Criteria	(Migraines)(REAUTH): (1) Response to therapy as defined by a reduction in headache days per month (defined as at least 4 hours duration and moderate intensity).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ALLERGEN SPECIFIC IMMUNOTHERAPY (SL)

Products Affected

- GRASTEK
- ODACTRA
- ORALAIR

PA Criteria	Criteria Details
Exclusion Criteria	(Initial): Deny with documentation of any of the following: (1) Severe, unstable or uncontrolled asthma (2) History of eosinophilic esophagitis
Required Medical Information	(Initial): (1) Member has a positive skin test or in vitro test for the listed pollen-specific IgE antibody. (2) Inadequate response or inability to tolerate an intranasal corticosteroid and an oral or intranasal antihistamine.
Age Restrictions	
Prescriber Restrictions	(Initial, Reauth): Prescribed by or in consultation with an allergist or immunologist.
Coverage Duration	(Initial, Reauth): Remainder of contract year
Other Criteria	(Reauth): (1) Member has experienced improvement in the symptoms of their allergic rhinitis or a decrease in the number of medications needed to control allergy symptoms
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AMPYRA

Products Affected

- AMPYRA
- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	MS (Initial): Deny if member has history of seizure or moderate to severe renal impairment (CrCL less than or equal to 50 mL/min)
Required Medical Information	Multiple Sclerosis (MS) (Initial): (1) Diagnosis of multiple sclerosis. (2) Confirmation that member has difficulty walking. (3) Inadequate response or inability to tolerate dalfampridine (applies to brand Ampyra).
Age Restrictions	
Prescriber Restrictions	(MS) (Initial and Reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	(Initial, Reauth): Remainder of contract year
Other Criteria	(MS) (Reauth): Improvement in walking speed
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

APOKYN

Products Affected

- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE
- *apomorphine hcl subcutaneous*

PA Criteria	Criteria Details
Exclusion Criteria	(PD): Member not using medication with any 5-HT3 antagonist (e.g. ondansetron, granisetron, dolasetron, palonosetron, alosetron)
Required Medical Information	Parkinson's Disease (PD): (1) Diagnosis of Parkinson's disease, (2) Member is experiencing intermittent OFF Episodes, (3) Concomitant use of medication with other medications for the treatment of Parkinson's disease (e.g. carbidopa/levodopa, pramipexole, ropinirole, etc.)
Age Restrictions	
Prescriber Restrictions	(PD): Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(MAC): (1) Diagnosis of Mycobacterium avium complex (MAC) lung disease (2) Medication is being used as part of a combination antibacterial drug regimen (3) Used in patients who do not achieve at least two negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy
Age Restrictions	Member is 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or an infectious disease specialist
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ARMODAFINIL

Products Affected

- *armodafinil*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	NARCOLEPSY: (1) Diagnosis of Narcolepsy confirmed by a sleep study (unless prescriber provides justification that a sleep study is not feasible). OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS): (1) Diagnosis confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). SHIFT WORK SLEEP DISORDER (SWSD): (1) One of the following: (a) Symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR (b) A sleep study demonstrating loss of a normal sleep-wake pattern (i.e., disturbed chronobiologic rhythmicity). (2) Documentation that the member has no other medical or mental disorder accounting for the symptoms.
Age Restrictions	
Prescriber Restrictions	(Narcolepsy, SWSD, OSAHS): Prescribed by or in consultation with a neurologist or sleep specialist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AUSTEDO

Products Affected

- AUSTEDO & 18 & 24 & 30 MG
- AUSTEDO XR
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tardive Dyskinesia (TD)(Initial): (1) Diagnosis of TD, (2) Documentation is provided of ONE of the following: (a) Persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering or discontinuation of the offending medication, or (b) Member is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Chorea-Huntington's Disease (CHD): (1) Diagnosis of chorea associated with Huntington's disease
Age Restrictions	
Prescriber Restrictions	(CHD): Prescribed by or in consultation with a neurologist or a psychiatrist. (TD)(Initial, Continuation): Prescribed by or in consultation with a neurologist or a psychiatrist.
Coverage Duration	(TD)(Initial): 3 months. (TD)(Reauth): Indefinite. (CHD): Indefinite.
Other Criteria	(TD)(Reauth): Positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AUVELITY

Products Affected

- AUVELITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Major Depressive Disorder (MDD): (1) Diagnosis of major depressive disorder (MDD) (2) Inadequate response or inability to tolerate two formulary antidepressants indicated for MDD (e.g., bupropion, venlafaxine extended-release tablet or capsule, sertraline tablet, etc.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	(MDD): Approve if for continuation of therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BENLYSTA SC

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when the following are met: Systemic Lupus Erythematosus (SLE): (1) Diagnosis of active, autoantibody-positive SLE. (2) Member is receiving concurrent treatment with at least ONE of the following: steroids, antimalarials, immunosuppressants, nonsteroidal anti-inflammatory drugs (NSAIDS). Lupus Nephritis (LN): (1) Diagnosis of active lupus nephritis confirmed by kidney biopsy. (2) Member is receiving concurrent standard therapy (e.g. corticosteroids, immunosuppressants, azathioprine).
Age Restrictions	
Prescriber Restrictions	(SLE): Prescribed by or in consultation with a rheumatologist. (LN): Prescribed by or in consultation with a nephrologist or rheumatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BESREMI

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when ANY of the following inclusion criteria is met: (1) Drug is FDA approved for indication and regimen requested, (2) The indication and regimen is classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, (3) narrative text in The American Hospital Formulary Service-Drug Information (AHFS-DI) or Clinical Pharmacology Compendium is supportive for the specific condition(s) requested, (4) The Micromedex Compendium and the strength of recommendation is listed as Class I, Class IIa, or Class IIb for the specific condition(s) requested, (5) Indication is listed in Lexi-Drugs as "off label" with evidence level A, (6) supported by Peer-Reviewed Medical Literature as defined in Chapter 15 Section 50.4.5 of the Medicare Benefit Policy Manual
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BYLVAY

Products Affected

- BYLVAY
- BYLVAY (PELLETS)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pruritus associated with progressive familial intrahepatic cholestasis (Pruritus with PFIC) (Initial): (1) Diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC), (2) Confirmed molecular diagnosis of PFIC type 1, 2, or 3, (3) Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6mg Cholestatic Pruritus with Alagille Syndrome (CPALGS) (Initial): (1) Diagnosis of Alagille Syndrome. (2) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene (3) Member is experiencing both of the following: (a) moderate to severe cholestatic pruritus (b) member has a serum bile acid concentrations above the upper limit of the normal reference for the reporting laboratory (4) An inadequate response or inability to tolerate at least two of the following treatments used for the relief of pruritus: (a) Ursodeoxycholic acid (e.g., Ursodiol) (b) Antihistamines (e.g., diphenhydramine, hydroxyzine) (c) Rifampin (d) Bile acid sequestrants (e.g., Questran, Colestid, Welchol).
Age Restrictions	(Pruritus with PFIC) (Initial, Reauth): Member is 3 months of age or older (CPALGS)(Initial, Reauth): Member is 1 year of age or older
Prescriber Restrictions	(Pruritus with PFIC)(CPALGS)(Initial, Reauth): Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	(All)(Initial):6 months (Pruritus w/PFIC)(Reauth):Indefinite (CPALGS)(Reauth):End of contract year
Other Criteria	(Pruritus with PFIC) (Reauth): (1) Documentation of positive clinical response to therapy (e.g. improvement in pruritus symptoms), (2) Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6mg. (CPALGS) (Reauth): Positive clinical response to therapy (e.g., reduced bile acids, reduction in pruritis symptoms or ItchRO pruritis score).
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

CAMZYOS

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Obstructive hypertrophic cardiomyopathy (HCM) (1) Diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM). (2) Member's baseline left ventricular ejection fraction (LVEF) is greater than or equal to 55%. (3) Documentation of Valsalva left ventricular outflow tract (LVOT) gradient assessment at baseline. (4) Inadequate response or inability to tolerate one of the following: (a) one non-vasodilating beta-blocker (e.g., bisoprolol, propranolol), (b) one calcium-channel blocker (e.g., diltiazem, verapamil)
Age Restrictions	(HCM) (Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(HCM) (Initial, Reauth): Prescribed by or in consultation with a cardiologist
Coverage Duration	(Initial): 6 months. (Reauth): 12 months
Other Criteria	(HCM) (Reauth): (1) Documentation of improvement in functional capacity and symptoms. (2) Member's left ventricular ejection fraction (LVEF) is greater than or equal to 50%. (3) Member does not have worsening heart failure symptoms.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CAPLYTA

Products Affected

- CAPLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Schizophrenia: (1) Diagnosis of schizophrenia (2) Inadequate response or inability to tolerate two generic antipsychotic products (e.g. aripiprazole, olanzapine, quetiapine, paliperidone). Bipolar Depression (BD): (1) Diagnosis of bipolar depression (2) Medication will be used as monotherapy or as adjunctive therapy with lithium or valproate (3) Inadequate response or inability to tolerate two medications indicated for bipolar depression (e.g. fluoxetine, Latuda, quetiapine, olanzapine)
Age Restrictions	(Schizophrenia, BP): member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	(Schizophrenia, BP): Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CARBAGLU

Products Affected

- CARBAGLU ORAL TABLET SOLUBLE
- *carglumic acid oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hyperammonemia Type III (HTIII): (1) Hyperammonemia due to the deficiency of the hepatic enzyme N-acetyl glutamate synthase (NAGS). Acute Hyperammonemia due to Propionic Acidemia or Methylmalonic Acidemia (AH): (1) Hyperammonemia due to propionic acidemia or methylmalonic acidemia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF): (1) Diagnosis of CF. (2) Evidence of Pseudomonas Aeruginosa in the lungs. (3) Susceptibility results indicating that the Pseudomonas aeruginosa is sensitive to aztreonam. (4) FEV1 between 25% and 75% of predicted
Age Restrictions	(CF): Member is 7 years of age or older
Prescriber Restrictions	(CF): Prescribed by or in consultation with a pulmonologist OR infectious disease specialist or Specialist affiliated with a CF care center.
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CERDELGA

Products Affected

- CERDELGA

PA Criteria	Criteria Details
Exclusion Criteria	(GD): Member is CYP2D6 Ultra Rapid Metabolizer (URM)
Required Medical Information	Gaucher disease (GD): (1) Diagnosis of Type 1 Gaucher disease and member is CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-cleared test for determining CYP2D6 genotype.
Age Restrictions	(GD): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CHOLBAM

Products Affected

- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	(BASD, PD)(Initial, Reauth): Deny if there is documentation of extrahepatic manifestations of bile acid synthesis disorders due to single enzyme defects or peroxisomal disorders including Zellweger spectrum disorders
Required Medical Information	Bile Acid Synthesis Disorder (BASD) (initial): (1) Diagnosis of bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorder (PD) (initial): (1) Diagnosis of peroxisomal disorder. (2) Used as adjunctive treatment. (3) Member exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption.
Age Restrictions	
Prescriber Restrictions	(BASD, PD): Hepatologist, Gastroenterologist, Medical geneticist, other specialist that treats inborn errors of metabolism
Coverage Duration	(Initial): 3 months. (Reauth): Indefinite
Other Criteria	(BASD,PD) (Reauth): Documentation of improved liver function tests from the start of treatment.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CIALIS

Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	(BPH): Concurrent use of nitrates.
Required Medical Information	Benign prostatic hyperplasia (BPH): (1) Diagnosis of BPH. (2) Inadequate response or inability to tolerate an alpha blocker (e.g. tamsulosin, terazosin) or a 5-alpha reductase inhibitor (e.g. dutasteride, finasteride).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CIBINQO

Products Affected

- CIBINQO

PA Criteria	Criteria Details
Exclusion Criteria	(AD): Concurrent use with any other biologic immunomodulator, Janus Kinase (JAK) inhibitors, or other immunosuppressants (e.g., azathioprine, cyclosporine)
Required Medical Information	Atopic Dermatitis (AD): (1) Diagnosis of refractory, moderate to severe AD (2) Inadequate response or inability to tolerate one systemic drug product, including biologics (e.g., Dupixent, methylprednisolone, prednisone) or documentation that a trial may be inappropriate.
Age Restrictions	(AD): Member is 12 years of age or older
Prescriber Restrictions	(AD): Prescribed by or in consultation with a dermatologist, allergist, immunologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CIMZIA

Products Affected

- CIMZIA (2 SYRINGE)
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	(AS, PsA, PsO, RA, CD, nr-axSpA): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Ankylosing Spondylitis (AS): (1) Diagnosis of AS. (2) Inadequate response or inability to tolerate two of the following: (a) secukinumab (Cosentyx), (b) adalimumab (Humira), (c) etanercept (Enbrel), (d) tofacitinib (Xeljanz/Xeljanz XR), (e) upadacitinib (Rinvoq), (f) adalimumab-adbm (Cyltezo), (g) adalimumab-aaty (Yuflyma) or documentation demonstrating that a trial may be inappropriate. Psoriatic Arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Xeljanz/Xeljanz XR (d) Rinvoq/Rinvoq LQ, (e) Skyrizi, (f) Cosentyx, (g) Stelara, (h) Orencia, (i) Otezla, (j) Cyltezo, (k) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe PsO. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Skyrizi (d) Cosentyx, (e) Stelara, (f) Otezla, (g) Cyltezo, (h) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Rheumatoid Arthritis (RA): (1) Diagnosis of moderate to severe RA. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, (f) Cyltezo, (g) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Crohn's Disease (CD): (1) Diagnosis of moderate to severe CD. (2) Inadequate response or inability to tolerate two of the following: (a) adalimumab (Humira), (b) ustekinumab (Stelara), (c) risankizumab (Skyrizi), (d) adalimumab-adbm (Cyltezo), (e) adalimumab-aaty (Yuflyma), (f) upadacitinib (Rinvoq) or documentation demonstrating that a trial may be inappropriate. Nonradiographic axial Spondyloarthritis (nr-axSpA): (1) Diagnosis of nr-axSpA. (2) Inadequate response or inability to tolerate one of the following: (a) two NSAIDs (b) Cosentyx (c) Rinvoq or (d) documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(AS, PsA, PsO, RA, CD, nraxSpA): Member is 18 years of age or older
Prescriber Restrictions	(CD): Prescribed by or in consultation with a gastroenterologist. (RA, AS, nr-axSpA): Prescribed by or in consultation with a rheumatologist. (PsA, PsO): prescribed by or in consultation with a dermatologist or rheumatologist.

PA Criteria	Criteria Details
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CINRYZE

Products Affected

- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when: Hereditary Angioedema (HAE): (1) Diagnosis of hereditary angioedema (HAE) (2) For prophylaxis against HAE attacks.
Age Restrictions	(HAE): Member is 6 years of age or older
Prescriber Restrictions	(HAE): Prescribed by or in consultation with an allergist, immunologist, pulmonologist
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

COMBINATION NSAID PRODUCTS

Products Affected

- *ibuprofen-famotidine*
- *naproxen-esomeprazole mg*
- VIMOVO ORAL TABLET DELAYED RELEASE 500-20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(All Indications)(Initial): An inadequate response or inability to tolerate a two-week trial of BOTH of the following: (1) Concurrent administration of each of the components of the requested product, and (2) At least ONE generic alternative (when available) of each of the individual components of the requested product.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(All Indication) (Initial, Reauth): 1 year
Other Criteria	(All Indications)(Reauth): Positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CORLANOR

Products Affected

- CORLANOR
- *ivabradine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Heart Failure (CHF): (1)Diagnosis of chronic heart failure. (2) stable, symptomatic chronic heart failure (3) left ventricular ejection fraction less than or equal to 35% and (4) sinus rhythm with resting heart rate greater than or equal to 70 beats per minute. (5) Member is clinically stable for at least 4 weeks on an optimized regimen which includes: (a) maximally tolerated doses of beta blockers or inability to tolerate beta blockers, (b) ACE inhibitors or ARBs or inability to tolerate ACE inhibitor or ARB. Chronic Heart Failure due to Dilated Cardiomyopathy in pediatric patients ages 6 months and older (CHF-DC): (1) Diagnosis of chronic heart failure due to dilated cardiomyopathy (2) Member is in sinus rhythm with an elevated heart rate.
Age Restrictions	
Prescriber Restrictions	(CHF, CHF-DC): Prescribed by or in consultation with a cardiologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

COSENTYX

Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML
- COSENTYX UNOREADY

PA Criteria	Criteria Details
Exclusion Criteria	(PsA, PsO, AS, nr-axSpA,ERA, HS): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Psoriatic Arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least ONE DMARD:(e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe plaque psoriasis. Ankylosing Spondylitis (AS): (1) Diagnosis of AS. (2) Inadequate response or inability to tolerate one other treatment such as NSAIDs, COX2 inhibitors or methotrexate. Non-Radiographic Axial Spondyloarthritis (nr-axSpA): (1) Diagnosis of nr-axSpA, (2) Inadequate response or inability to tolerate two NSAIDs. Active Enthesitis-related Arthritis (ERA): (1) Diagnosis of active enthesitis-related arthritis (ERA), (2) Inadequate response or inability to tolerate methotrexate, (3) Inadequate response or inability to tolerate at least one NSAID (e.g. ibuprofen, naproxen, meloxicam, celecoxib). Hidradenitis Suppurativa (HS): (1) Diagnosis of HS.
Age Restrictions	(AS, nr-axSpA, HS): Member is 18 years of age or older. (PsO): Member is 6 years of age or older (PsA): Member is 2 years of age or older. (ERA): Member is 4 years of age or older.
Prescriber Restrictions	(PsO, HS): Prescribed by or in consultation with a dermatologist. (PsA): Prescribed by or in consultation with a rheumatologist or dermatologist. (AS, nr-axSpA, ERA): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CRESEMBA [ORAL]

Products Affected

- CRESEMBA ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Invasive Aspergillosis (IA): (1) For use in the treatment of invasive aspergillosis after inadequate response or inability to tolerate Voriconazole (oral Vfend). Mucormycosis (MC): (1) Diagnosis of invasive mucormycosis
Age Restrictions	(IA, MC): Member is 6 years of age or older
Prescriber Restrictions	(All Indications): Prescribed by or in consultation with an infectious disease specialist, oncologist, OR prescribed as part of chemotherapy prophylaxis protocol
Coverage Duration	Remainder of contract year
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CYSTEAMINE PRODUCTS

Products Affected

- CYSTADROPS
- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystinosis: (1) Diagnosis of cystinosis, (2) Member has corneal cystine crystal accumulation
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DAYBUE

Products Affected

- DAYBUE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rett syndrome (RS)(Initial): (1) Diagnosis of Rett syndrome (2) One of the following: (a) Presence of all of the following clinical signs and symptoms: (i) a pattern of development, regression, then recovery or stabilization (ii) partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose (iii) partial or complete loss of spoken language (iv) repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing (v) gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait (b) Molecular genetic testing confirms mutations in the MECP2 gene
Age Restrictions	(RS)(Initial)(Reauth): member is 2 years of age or older
Prescriber Restrictions	(RS)(Initial)(Reauth): Prescribed by or in consultation with one of the following specialists: geneticist, pediatrician, neurologist
Coverage Duration	(Initial)(Reauth): 12 months
Other Criteria	(RS)(Reauth): (1) Documentation of positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms from baseline (e.g., hand behavior, walking/standing, speech, quality of life)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DAYVIGO

Products Affected

- DAYVIGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Insomnia: (1) Diagnosis of insomnia. (2) Inadequate response or inability to tolerate generic ramelteon (Rozerem).
Age Restrictions	(Insomnia): Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DEFERASIROX

Products Affected

- *deferasirox granules*
- *deferasirox oral tablet*
- *deferasirox oral tablet soluble*
- JADENU
- JADENU SPRINKLE

PA Criteria	Criteria Details
Exclusion Criteria	(NTDT, CIO-BT)(Initial, Continuation): CrCl less than 40 mL/min or serum creatinine more than 2 times the age-appropriate ULN, platelet counts less than 50,000/mcL
Required Medical Information	Chronic Iron Overload in nontransfusion-dependent thalassemia (NTDT) (Initial): (1) Diagnosis of Chronic iron overload in nontransfusion-dependent thalassemia syndromes,(2) liver iron concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw), (3) serum ferritin greater than 300 mcg/L. (4) Serum ferritin levels consistently greater than 300 mcg/L (as demonstrated with at least two lab values within the previous two months). Chronic Iron Overload Caused by Blood Transfusions (CIO-BT)(Initial): (1) Diagnosis of chronic iron overload caused by blood transfusions (transfusional hemosiderosis). (2) Serum ferritin levels consistently greater than 1,000 mcg/L (as demonstrated with at least two lab values within the previous two months).
Age Restrictions	(NTDT)(Initial, Continuation): Member is 10 years of age or older. (CIO-BT) (Initial, Continuation): Member is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	(Initial):3 months. (Continuation): 6 months
Other Criteria	(CIO-BT)(Continuation): (1) Decreased serum ferritin level compared with the baseline level for transfusion- dependent anemia. (NTDT)(Continuation): (1) Decreased serum ferritin level compared with the baseline level or reduction in LIC (liver iron concentration).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DIACOMIT

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dravet syndrome (DS): (1) Diagnosis of seizures associated with Dravet syndrome (DS), (2) Used in combination with clobazam.
Age Restrictions	Member is 6 months of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DICLOFENAC 3% PRODUCTS

Products Affected

- *diclofenac sodium external gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Actinic Keratoses: (1) Diagnosis of Actinic Keratoses
Age Restrictions	Actinic Keratoses: Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	90 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DICLOFENAC EPOLAMINE

Products Affected

- *diclofenac epolamine external*

PA Criteria	Criteria Details
Exclusion Criteria	Previously experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Use for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
Required Medical Information	(1): Inadequate response or inability to tolerate at least 2 prescription strength topical NSAIDs (i.e. Diclofenac Gel 1%, Diclofenac Topical Solution 1.5%)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DOJOLVI

Products Affected

- DOJOLVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Long-Chain Fatty Acid Oxidation Disorders (LC-FAOD): (1) Diagnosis of molecularly confirmed LC-FAOD, (2) Will be used as a source of calories and fatty acids.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DOPTELET

Products Affected

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Liver Disease (CLD): (1) Baseline platelet count less than 50,000/mcL. Member is scheduled to undergo a procedure. Chronic Immune Thrombocytopenia (ITP)(Initial): (1) Baseline platelet count less than 30,000/mcL. (2) Inadequate response or inability to tolerate one of the following: (a) corticosteroids (b) immunoglobulins (c) splenectomy (d) Rituxan (rituximab)
Age Restrictions	
Prescriber Restrictions	(ITP)(Initial, Continuation): Prescribed by or in consultation with hematologist/oncologist
Coverage Duration	(CLD): 1 month. (ITP): 12 months
Other Criteria	(ITP)(Continuation): (1) Positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes

DUPIXENT

Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/1.14ML, 300

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis (AD): (1) Diagnosis of moderate-severe atopic dermatitis. (2) inadequate response or inability to tolerate ONE of the following: (a) one topical steroid (medium potency or higher), (b) topical tacrolimus, (c) topical pimecrolimus, (d) topical Eucrisa (crisaborole). Asthma (Initial): (1) ONE of the following: (a) Member has oral corticosteroid-dependent asthma or (b) Member has blood eosinophil levels of at least 150 cells/mcL at baseline or at least 300 cells/mcL within the past 12 months, (2) the requested medication will be used in addition to BOTH of the following: (a) medium to high dose inhaled corticosteroid (e.g. greater than or equal to 500mcg fluticasone propionate equivalent/day) AND (b) one additional controller medication. Chronic Rhinosinusitis with Nasal Polyposis(CRSwNP)(Initial): (1) Diagnosis of chronic rhinosinusitis with nasal polyposis, (2) concurrent use of intranasal corticosteroid. Eosinophilic esophagitis (EoE)(Initial): (1) Diagnosis of eosinophilic esophagitis (EoE) (2) Member has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain (3) Member has at least 15 intraepithelial eosinophils per high power (HPF) (4) Other causes of esophageal eosinophilia have been excluded (5) Member weighs at least 15 kg (6) Inadequate response or inability to tolerate at least an 8 week trial of one of the following: (a) proton pump inhibitors (e.g., pantoprazole, omeprazole (b) Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone). Prurigo Nodularis (PN)(Initial): (1) Diagnosis of Prurigo Nodularis (PN) (2) inadequate response or inability to tolerate one medium or higher potency topical corticosteroid.
Age Restrictions	(Asthma)(Initial, Reauth): Member is 6 years old or older. (AD): Member is 6 months of age or older. (CRSwNP)(Initial, Reauth): Member is 12 years of age or older (PN)(COPD)(Initial, Reauth): Member is 18 years of age or older (EoE)(Initial, Reauth): Member is 1 year of age or older

PA Criteria	Criteria Details
Prescriber Restrictions	(Initial/Reauth) Prescribed by/in consultation with: (AD): Dermatologist, allergist, or immunologist (Asthma)(COPD): Allergist, immunologist or pulmonologist (CRSwNP): Allergist, immunologist or ENT specialist (EoE): Gastroenterologist, allergist, or immunologist (PN): Allergist/immunologist or dermatologist
Coverage Duration	(AD): Indefinite (Asthma, CRSwNP, EoE, PN, COPD): 12 months
Other Criteria	Chronic obstructive pulmonary disease (COPD)(Initial): (1) Diagnosis of COPD (2) Presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells/mcL at baseline (3) Member is receiving ONE of the following therapies for at least 3 months: (a) Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA) (b) If ICS are contraindicated, a LAMA and a LABA (4) Member has had ONE of the following within the past 12 months: (a) At least two exacerbations where systemic corticosteroids [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once (b) COPD-related hospitalization (5) Member experiences dyspnea during everyday activities (e.g., needs to stop for breath when walking on level ground). (Asthma)(Reauth): (1) Documentation of positive clinical response to therapy (e.g. reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) (2) the requested medication will be used in addition to BOTH of the following: (a) medium to high dose inhaled corticosteroid (e.g. greater than or equal to 500mcg fluticasone propionate equivalent/day) AND (b) one additional controller medication. (CRSwNP) (Reauth): (1) Documentation of positive clinical response to therapy (e.g. reduction of nasal polyps score [NPS: 0-8 scale], improvement in nasal congestion/obstruction score [NC: 0-3 scale]), (2) Used in combination with another agent for CRSwNP. (EoE)(Reauth): (1) Documentation of a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline: (a)Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain), (b) Histologic measures (e.g., esophageal intraepithelial eosinophil count), (c) Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures). (PN)(Reauth): (1) Documentation of a positive clinical response to therapy (e.g., reduction in the number of nodular lesions from baseline, or improvement in symptoms from baseline) (COPD)(Reauth): (1) Member demonstrates a positive clinical response to therapy (e.g., improved lung function, a reduction in COPD exacerbations) (2) Member continues to receive ONE of the following therapies: (a) Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta agonist (LABA) (b) If ICS are contraindicated, a LAMA and a LABA
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

EMFLAZA

Products Affected

- *deflazacort*
- EMFLAZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Duchenne Muscular Dystrophy (MDM): (1) Diagnosis confirmed by ONE of the following: (a) Mutation of the dystrophin gene (b) Absence of the dystrophin protein confirmed by muscle biopsy (2) Inadequate response or inability to tolerate prednisone or prednisolone
Age Restrictions	(DMD): Member is 2 years of age or older
Prescriber Restrictions	(DMD): Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EMGALITY

Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Documentation of concomitant use with another injectable CGRP inhibitor.
Required Medical Information	Migraines (Initial): Approved when ONE of the following inclusion criteria are met: (1) Diagnosis of episodic migraines defined as 4 to 14 headache days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (a) topiramate (b) divalproex sodium/ valproic acid (c) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (d) tricyclic antidepressants: amitriptyline, nortriptyline (e)SNRI antidepressants: venlafaxine, duloxetine. OR (2) Diagnosis of chronic migraines defined as greater than or equal to 15 headache days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (i) topiramate (ii) divalproex sodium/ valproic acid (iii) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (iv) tricyclic antidepressants: amitriptyline, nortriptyline (v)SNRI antidepressants: venlafaxine, duloxetine. Episodic Cluster Headaches (ECH) (Initial): (1) Diagnosis of episodic cluster headache, (2) Member has experienced at least 2 cluster periods lasting 6 days to 365 days, separated by pain-free periods lasting at least three months
Age Restrictions	(Migraine, ECH)(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(Migraine, ECH)(Initial, Reauth): Prescribed by or in consultation with a neurologist or headache specialist certified by the United Council for Neurologic Subspecialties, pain specialist
Coverage Duration	(Migraine, ECH)(Initial): 6 months, (Migraine, ECH)(Reauth):12 months
Other Criteria	(Migraine)(REAUTH): (1) Response to therapy as defined by a reduction in headache days per month (defined as at least 4 hours duration and moderate intensity). (ECH)(REAUTH): (1) Response to therapy as defined by a reduction in weekly cluster headache attacks.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

EMSAM

Products Affected

- EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Major depressive disorder (MDD): (1) Diagnosis of major depressive disorder. (2) Inadequate response or inability to tolerate ONE SSRI or SNRI. (3) 4-5 half-lives (approximately 1 week) has elapsed after discontinuation of antidepressants without long half-lives OR at least 5 weeks has elapsed after discontinuation with antidepressants with long half-lives (e.g. fluoxetine).
Age Restrictions	(MDD): Member is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ENBREL

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	(RA, PsA, PJIA, PsO, AS): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Rheumatoid Arthritis (RA): (1) Diagnosis of moderate to severe RA. (2 Inadequate response or inability to tolerate ONE DMARD: (e.g. Methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine). Psoriatic Arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least ONE DMARD: (e.g. Methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine). Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Diagnosis of moderate to severe PJIA, (2) Inadequate response or inability to tolerate ONE of the following: Methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine. Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe chronic PsO. Ankylosing Spondylitis (AS): (1) Diagnosis of AS, (2) Inadequate response or inability to tolerate one other treatment such as NSAIDs, COX2 inhibitors or methotrexate.
Age Restrictions	(PJIA, PsA): Member is 2 years of age or older. (RA, AS): Member is 18 years of age or older. (PsO): Member is 4 years of age or older
Prescriber Restrictions	(RA, PJIA, AS): Prescribed by or in consultation with a rheumatologist. (PsA): Prescribed by or in consultation with a rheumatologist or dermatologist. (PsO): Prescribed by or in consultation with a dermatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ENDARI

Products Affected

- ENDARI
- *l-glutamine oral packet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Sickle Cell Disease (SC)(Initial): (1) One of the following: (A) Member is using L-Glutamine with concurrent hydroxyurea therapy, OR (B) Member has an inadequate response or inability to tolerate hydroxyurea. (2) Member has had 2 or more painful sickle cell crises within the past 12 months.
Age Restrictions	
Prescriber Restrictions	(SC)(Initial, Reauth): Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy (e.g. reduction in the number of sickle cell crises)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ENSPRYNG

Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neuromyelitis Optica Spectrum Disorder (NMOSD)(Initial): (1) Diagnosis of NMSOD, (2) Member is anti-aquaporin-4 (AQP4) antibody positive.
Age Restrictions	
Prescriber Restrictions	(NMOSD)(Initial, Reauth): Prescribed by or in consultation with a neurologist or ophthalmologist
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(NMOSD)(Reauth): Positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ENTYVIO SQ 2024

Products Affected

- ENTYVIO PEN

PA Criteria	Criteria Details
Exclusion Criteria	(UC, CD): Concurrent therapy with any other biologic disease modifying antirheumatic drug (DMARD), e.g., tumor necrosis factor antagonists
Required Medical Information	Ulcerative Colitis (UC): (1) Diagnosis of moderately to severely active Ulcerative Colitis (2) One of the following: (a) Inadequate response or inability to tolerate two of the following: (a) adalimumab (Humira), (b) ustekinumab (Stelara), (c) upadacitinib (Rinvoq), (d) tofacitinib (Xeljanz/Xeljanz XR), (e) adalimumab-adbm (Cyltezo), (f) adalimumab-aaty (Yuflyma), (g) risankizumab (Skyrizi) OR documentation demonstrating that a trial may be inappropriate. (b) One of the following: (i) Medication will be used as a maintenance dose following two doses of Entyvio IV for induction (ii) Member is currently established on Entyvio IV. Crohn's Disease (CD): (1) Diagnosis of moderately to severely active CD (2) One of the following: (a) Inadequate response or inability to tolerate TWO of the following (a) adalimumab (Humira), (b) ustekinumab (Stelara), (c) Risankizumab (Skyrizi), (d) adalimumab-adbm (Cyltezo), (e) adalimumab-aaty (Yuflyma), (f) upadacitinib (Rinvoq) OR documentation demonstrating that a trial may be inappropriate (b) One of the following: (i) Medication will be used as a maintenance dose following two doses of Entyvio IV for induction (ii) Member is currently established on Entyvio IV.
Age Restrictions	(UC, CD): Member is 18 years of age or older
Prescriber Restrictions	UC, CD): Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dravet Syndrome (DS): (1) Inadequate response or inability to tolerate ONE of the following: (a) clobazam (b) valproic acid or (c) topiramate. (2) Baseline CBC, serum transaminases and total bilirubin prior to initiating therapy. Lennox-Gastaut Syndrome (LGS): (1) Inadequate response or inability to tolerate ONE of the following: (a) clobazam (b) valproic acid, or (c) topiramate. (2) Baseline CBC, serum transaminases and total bilirubin prior to initiating therapy. Tuberous Sclerosis Complex (TSC): (1) Concurrent use with additional anti-epileptic(s). (2) Baseline CBC, serum transaminases and total bilirubin prior to initiating therapy
Age Restrictions	(DS, LGS, TCS): Member is 1 year of age or older
Prescriber Restrictions	(DS, LGS, TCS): Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ESBRIET

Products Affected

- ESBRIET
- *pirfenidone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Idiopathic Pulmonary Fibrosis (IPF): (1) Diagnosis of IPF confirmed by high resolution CT scan or biopsy.
Age Restrictions	
Prescriber Restrictions	(IPF): Prescribed by or in consultation a pulmonologist or lung transplant specialist.
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(REAUTH) (IPF): BOTH of the following (1) stabilization from baseline AND (2) no elevations in AST or ALT greater than 5 times upper limit of normal or greater than 3 times upper limit of normal with signs or symptoms of severe liver damage.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EUCRISA

Products Affected

- EUCRISA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis (AD): (1) Inadequate response or inability to tolerate at least ONE of the following: (a) topical tacrolimus OR topical pimecrolimus , OR (b) generic, prescription medium potency or higher topical steroid.
Age Restrictions	(AD): Member is 3 months of age or older
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EVEKEO

Products Affected

- *amphetamine sulfate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Attention Deficit Hyperactivity Disorder (ADHD): (1) Diagnosis of ADHD. (2) Inadequate response or inability to tolerate TWO generic stimulant products (e.g. amphetamine/dextroamphetamine, methylphenidate) Narcolepsy: (1) Diagnosis of narcolepsy.
Age Restrictions	(ADHD): Member is 3 years of age or older. (Narcolepsy): Member is 6 years of age or older.
Prescriber Restrictions	
Coverage Duration	Remainder of Contract Year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EVENITY

Products Affected

- EVENITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary for: Post Menopausal Osteoporosis (PMO): (1) Diagnosis of PMO defined as ONE of the following: (a) Bone mineral density T-score less than or equal to -2.50 OR (b) Documented history of an osteoporotic non- collision fracture [e.g. vertebral, hip, nonvertebral]) AND (3) Member is at high risk of fracture as defined by one of the following: (a) Member has risk factors for a fracture (e.g. endocrine disorders, gastrointestinal disorders, use of medications associated with low bone mass or bone loss such as corticosteroids) OR (b) Inadequate response or inability to tolerate ONE of the following: (i) bisphosphonates, (ii) hormone replacement therapy, (iii) selective-estrogen receptor modulators (SERMs), OR (iv) Denosumab (Prolia). (4) Cumulative lifetime therapy does not exceed 12 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EVRYSDI

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Spinal Muscular Atrophy (SMA)(Initial): (1) Diagnosis of SMA, (2) Member has confirmed mutations in chromosome 5q that leads to SMN protein deficiency.
Age Restrictions	
Prescriber Restrictions	(SMA)(Initial, Reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	(Initial)(Reauth): 12 months
Other Criteria	(SMA)(Reauth): (1) Positive clinical response to therapy (e.g. improvement in ability to sit without support)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EXTENDED RELEASE METFORMIN

Products Affected

- GLUMETZA
- *metformin hcl er (mod)*

PA Criteria	Criteria Details
Exclusion Criteria	(DM2)(Initial, Reauth): (1) Serum creatinine levels greater than or equal to 1.5 mg/dL in males, or serum creatinine levels greater than or equal to 1.4 mg/dL in females. (2) Hepatic impairment. (3) Metabolic acidosis, including diabetic ketoacidosis. (4) Used for preventing weight gain.
Required Medical Information	Diabetes Mellitus Type 2 (DM2)(Initial): (1) Diagnosis of DM2. (2) Member has a HgbA1C greater than 7.0%. All Indications: (1) Inadequate response or inability to tolerate both of the following: (a) Immediate release metformin, and (b) Extended-release metformin (generic Glucophage XR).
Age Restrictions	(DM2 for tablets) (Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	(Initial, Reauth): End of contract year.
Other Criteria	(DM2)(Reauth): Member has had a positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EYSUVIS

Products Affected

- EYSUVIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dry Eye Disease (DED)(Initial): (1) Diagnosis of DED
Age Restrictions	
Prescriber Restrictions	(DED)(Initial, Reauth): Prescribed by or in consultation with an ophthalmologist or optometrist.
Coverage Duration	(Initial, Reauth): 14 days
Other Criteria	(DED)(Reauth): (1) Positive clinical response to therapy (e.g. improvement in dry eye symptoms).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FASENRA

Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when there is a documentation of the following: Severe Asthma (SA)(Initial): (1) Diagnosis of severe asthma with eosinophilic phenotype as defined by ONE of the following at initiation of therapy (a) blood eosinophil levels are at least 150 cells/microliter if dependent on daily oral corticosteroids or (b) blood eosinophil levels are at least 300 cells/microliter AND, (2) ONE of the following: (a) Member has had at least one asthma exacerbation requiring systemic corticosteroids within the past 12 months, or (b) Any prior intubation for asthma exacerbation, or (c) prior asthma-related hospitalization within the past 12 months, AND (3) Member is currently treated with ONE of the following unless there is a contraindication or intolerance to these medications: (a) high-dose inhaled corticosteroids (ICS) (e.g. greater than or equal to 500 mcg fluticasone propionate equivalent/day) AND an additional asthma controller medication (e.g. leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline) OR (b) one maximally-dosed combination ICS/LABA product).
Age Restrictions	(SA)(Initial): Member is 6 years of age or older
Prescriber Restrictions	(SA)(Initial): Prescribed by or in consultation with pulmonologist or allergy/immunology specialist
Coverage Duration	(Initial): 12 months. (Reauth): 12 months
Other Criteria	Subject to Part B vs Part D review (SA) (Reauth): (1) Member is currently treated with ONE of the following unless there is a contraindication or intolerance to these medications: (a) high-dose inhaled corticosteroids (ICS) (e.g. greater than or equal to 500 mcg fluticasone propionate equivalent/day) AND an additional asthma controller medication (e.g. leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline) OR (b) one maximally-dosed combination ICS/LABA product). (2) Positive clinical response to therapy (e.g. reduction in exacerbations, decreased use of rescue medications)

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FERRIPROX

Products Affected

- *deferiprone*
- FERRIPROX
- FERRIPROX TWICE-A-DAY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Transfusional Iron Overload (TIO): (1) Diagnosis of transfusional iron overload due to one of the following: (a) Thalassemia syndromes, (b) sickle cell disease, (c) other transfusion-dependent anemias. (2) Inadequate response or inability to tolerate current chelation therapy.
Age Restrictions	(TIO): Member is 3 years of age or older
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FILSPARI

Products Affected

- FILSPARI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Immunoglobulin A nephropathy (IgAN)(Initial): (1) Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy (2) Member is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] (3) Used to reduce proteinuria (4) Member has an estimated glomerular filtration rate (eGFR) of greater than or equal to 30 mL/min/1.75 m2 (5) Member has had an inadequate response or inability to tolerate at minimum 90-day trial of a maximally tolerated dose of one of the following (a) Angiotensin-receptor blockers (ARB) (e.g., losartan, valsartan), (b) Angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril) (6) Medication will not be used in combination with any of the following (a) Angiotensin receptor blockers, (b) Endothelin receptor antagonists (ERAs) (e.g., ambrisentan, bosentan, Opsumit), (c) Aliskiren)
Age Restrictions	(IgAN)(Initial)(Continuation): Member is 18 years of age or older
Prescriber Restrictions	(IgAN)(Initial)(Continuation): Prescribed by or in consultation with a nephrologist
Coverage Duration	(Initial)(Continuation): 12 months
Other Criteria	(IgAN)(Continuation): (1) Documentation of positive clinical response to therapy from baseline as demonstrated by a decrease in urine protein-to-creatinine ration (UPCR).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dravet Syndrome (DS): Inadequate response or inability to tolerate ONE of the following: (a) clobazam, (b) valproic acid, (c) divalproex sodium, (d) topiramate. Lennox-Gastaut Syndrome (LGS): (1) Diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS) (2) Inadequate response or inability to tolerate ONE of the following: valproic acid, lamotrigine, topiramate, felbamate, clobazam.
Age Restrictions	(DS, LGS): Member is 2 years of age or older.
Prescriber Restrictions	(DS, LGS): Prescribed by or in consultation with a neurologist.
Coverage Duration	Indefinite.
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FIRDAPSE

Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	(LEMS)(Initial, Continuation): history of seizures
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS)(Initial): (1) Diagnosis of LEMS. (2) Neurological symptoms persist after treatment of malignancy, when malignancy is present.
Age Restrictions	(LEMS)(Initial, Continuation): Member is 6 years of age or older
Prescriber Restrictions	(LEMS)(Initial, Continuation): Prescribed by or in consultation with a neurologist.
Coverage Duration	(Initial):90 Days, (Continuation): Indefinite
Other Criteria	(LEMS)(CONTINUATION): positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GALAFOLD

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	(FD)(Initial, Reauth): Will not be used in combination with Fabrazyme (agalsidase beta)
Required Medical Information	Fabry Disease (FD)(Initial): (1) Member has amenable galactosidase alpha gene (GLA) variant based on in vitro assay data
Age Restrictions	(FD)(Initial, Reauth): Member is 16 years of age or older
Prescriber Restrictions	(FD)(Initial, Reauth): Prescribed by or in consultation with a clinical genetics specialist OR a nephrologist
Coverage Duration	(Initial): 6 months, (Reauth): Indefinite
Other Criteria	(FD)(Reauth): Positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GATTEX

Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Short Bowel Syndrome (SBS)(Initial): (1) Diagnosis of Short Bowel Syndrome, (2) individual receives parenteral support at least three times per week for at least 12 months.
Age Restrictions	
Prescriber Restrictions	(SBS): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	(Initial, Reauth): 6 months
Other Criteria	(SBS)(REAUTH): (1)Reduction in parenteral support from baseline (prior to initiation of Gattex therapy)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GOCOVRI

Products Affected

- GOCOVRI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dyskinesia in Parkinson's disease (DPD): (1) Diagnosis of PD (2) Member is experiencing dyskinesia. (3) Member is receiving levodopa based therapy (4) Inadequate response or inability to tolerate amantadine immediate-release. Parkinson's Disease with OFF episodes (PD with OFF episodes): (1) Diagnosis of Parkinson's disease. (2) Concurrent use of carbidopa/levodopa containing product. (3) Member is experiencing intermittent OFF episodes. (4) Member had inadequate response or inability to tolerate ONE of the following: (a) MAO-B inhibitor (e.g. rasagiline, selegiline), (b) Dopamine agonist (e.g. pramipexole, ropinirole), (c) COMT inhibitor (e.g. entacapone).
Age Restrictions	
Prescriber Restrictions	(DPD, PD with OFF episodes): Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GROWTH HORMONES

Products Affected

- GENOTROPIN MINIQUICK SUBCUTANEOUS PREFILLED SYRINGE
- GENOTROPIN SUBCUTANEOUS CARTRIDGE
- HUMATROPE INJECTION CARTRIDGE
- NORDITROPIN FLEXPRO SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 10 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 20 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 5 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED
- ZOMACTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) Growth Failure in Children (GFC)(Initial): (A) Diagnosis of growth hormone deficiency confirmed by one of the following: (I) Height is documented by one of the following (utilizing age and gender growth charts related to height): (a) Height is greater than 2.0 standard deviations [SD] below midparental height (b) Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) (II) Growth velocity is greater than 2 SD below mean for age and gender (III) Delayed skeletal maturation of greater than 2 SD below mean for age and gender (eg, delayed is greater than 2 years compared with chronological age), (B) documentation of bone age, (C) abnormal response from provocative testing, such as insulin-induced hypoglycemia test, levodopa, or clonidine. (2) Small for Gestational Age (SGA)(Initial): (A) Diagnosis of SGA, (B) Clinical documentation of no catch-up growth by 2 to 4 years of age. (3) Growth Failure Associated with Chronic Kidney Disease (GF-CKD) (Initial), (4) Growth failure associated with Noonan Syndrome, Prader-Willi Syndrome, Turner Syndrome or short stature homeobox-containing gene (SHOX) deficiency (Initial), (5) Diagnostically confirmed Growth Hormone Deficiency in adults (GHDA)(Initial), OR (6) Idiopathic Short Stature (ISS)(Initial): (A) Diagnosis of ISS defined by height standard deviation score (SDS) less than or equal to 2.25, (B) Documentation of growth velocity less than 25th percentile for bone age.
Age Restrictions	
Prescriber Restrictions	(All Other Indications)(Initial): Prescribed by or in consultation with an endocrinologist. (GF-CKD)(Initial) : Prescribed by or in consultation with an endocrinologist or nephrologist
Coverage Duration	(Initial, Continuation): 12 months

PA Criteria	Criteria Details
Other Criteria	(GHDA)(Continuation): Annual clinical re-evaluation by the treating endocrinologist. (GFC)(Continuation): (1) Annual clinical re-evaluation by the treating endocrinologist, (2) Growth velocity greater than or equal to 2.5cm/year. (SGA, ISS)(Continuation): (1) Increase in growth velocity from baseline, (2) Annual clinical re-evaluation by the treating endocrinologist. (GF-CKD)(Continuation): (1) No history of renal transplant, (2) Annual clinical re-evaluation by the treating endocrinologist. (Growth Failure Associated with Noonan Syndrome, Prader-Willi Syndrome, Turner Syndrome or Short Stature Homeobox-Containing Gene (SHOX) Deficiency)(Continuation): (1) Annual clinical re-evaluation by the treating endocrinologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HAEGARDA

Products Affected

- HAEGARDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hereditary Angioedema (HAE): (1) Diagnosis of hereditary angioedema (HAE), (2) For prophylaxis against HAE attacks.
Age Restrictions	(HAE): Member is 6 years of age or older
Prescriber Restrictions	(HAE): Prescribed by or in consultation with an allergist, immunologist, pulmonologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HETLIOZ

Products Affected

- HETLIOZ
- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-24 Hour Sleep-Wake Cycle (Non-24)(Initial): (1) Diagnosis of a circadian period greater than 24 hours (also known as non-24-hour sleep-wake disorder), (2) Member is totally blind (has no light perception). Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS)(Initial): (1) Diagnosis of SMS, (2) Member is experiencing nighttime sleep disturbances.
Age Restrictions	(SMS)(Initial): Member is 16 years of age or older
Prescriber Restrictions	(Non-24, SMS)(Initial, Reauth): Prescribed by or in consultation with a sleep specialist or neurologist.
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(Non-24)(Reauth): Documentation of positive clinical response (SMS)(Reauth): Documentation of positive clinical response to therapy (e.g. improvement in nighttime total sleep time, improvement in nighttime sleep quality)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HETLIOZ LQ

Products Affected

- HETLIOZ LQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)(Initial): (1) Diagnosis of SMS, (2) Member is experiencing nighttime sleep disturbances
Age Restrictions	(SMS)(Initial): Member is 3 to 15 years of age
Prescriber Restrictions	(SMS)(Initial, Reauth): Prescribed by or in consultation with a sleep specialist or neurologist.
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(SMS)(Reauth): Documentation of positive clinical response to therapy (e.g. improvement in nighttime total sleep time, improvement in nighttime sleep quality)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HIGH DOSE OPIOIDS

Products Affected

- *fentanyl transdermal patch 72 hour 100 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 50 mcg/hr, 62.5 mcg/hr, 75 mcg/hr, 87.5 mcg/hr*
- *hydromorphone hcl er oral tablet extended release 24 hour*
- *hydromorphone hcl oral tablet 4 mg, 8 mg*
- *methadone hcl oral solution*
- *methadone hcl oral tablet*
- *morphine sulfate er beads oral capsule extended release 24 hour 120 mg*
- *morphine sulfate er oral capsule extended release 24 hour 100 mg, 60 mg, 80 mg*
- *morphine sulfate er oral tablet extended release 100 mg, 200 mg, 60 mg*
- *oxycodone hcl oral tablet 30 mg*
- *oxymorphone hcl er oral tablet extended release 12 hour 20 mg, 30 mg*
- *oxymorphone hcl er oral tablet extended release 12 hour 40 mg*
- *oxymorphone hcl oral tablet 10 mg*
- XTAMPZA ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	NEW TO HIGH DOSE OPIOID THERAPY : ONE of the following (A) pain associated with cancer, (B) chronic non-cancer pain and BOTH of the following (1) member is opioid tolerant (e.g. at least one week where total daily dose is at least one of the following: 30mg of oxycodone, 60mg of oral morphine, 8mg of oral hydromorphone, 25mg of oral oxymorphone or an equianalgesic dose of another opioid) AND (2) the member has been evaluated for non-opioid prescription pharmacologic treatment prior to initiation of high dose opioid therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable. CONTINUING HIGH DOSE OPIOID THERAPY (morphine equivalent dose 90mg per day or greater): ONE of the following (1) pain associated with cancer OR (2) chronic non-cancer pain and ALL (a) member's pain has been assessed within the last 6 months AND (b) member has clinically meaningful improvement in pain and functioning that outweighs risks to patient safety AND (c) member is not being treated for substance abuse
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

HRM

Products Affected

- *butalbital-acetaminophen oral capsule*
- *butalbital-acetaminophen oral tablet 50-300 mg, 50-325 mg*
- *butalbital-apap-caff-cod*
- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *butalbital-aspirin-caffeine oral capsule*
- *chlordiazepoxide-clidinium*
- *clemastine fumarate oral syrup*
- *dipyridamole oral*
- INDOCIN ORAL
- *indomethacin oral suspension*
- LIBRAX
- *metaxalone*
- *promethazine hcl oral solution*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly
Age Restrictions	Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	2 years
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM ESTROGENS

Products Affected

- BIJUVA
- CLIMARA PRO
- COMBIPATCH
- DOTTI
- *estradiol transdermal gel 0.25 mg/0.25gm, 0.5 mg/0.5gm, 0.75 mg/0.75gm, 1 mg/gm, 1.25 mg/1.25gm*
- *estradiol transdermal patch twice weekly*
- *estradiol transdermal patch weekly*
- *estradiol-norethindrone acet*
- FYAVOLV
- JINTELI
- LYLLANA
- MENOSTAR
- MIMVEY
- *norethindrone-eth estradiol*
- PREMARIN ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ONE of the following: (1) Inadequate response or inability to tolerate vaginal estrogen preparations (e.g. vaginal tablets, rings, or cream, etc.) OR (2) Risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly
Age Restrictions	Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	2 years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM KETOROLAC

Products Affected

- *ketorolac tromethamine oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	ONE of the following: (1) Inadequate response or inability to tolerate TWO alternative NSAIDs such as meloxicam, naproxen, celecoxib, ibuprofen, etc. OR (2) Risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly
Age Restrictions	Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	One Month
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM NON BENZODIAZEPINE HYPNOTICS

Products Affected

- *eszopiclone oral tablet 3 mg*
- *zolpidem tartrate er oral tablet extended release 12.5 mg*
- *zolpidem tartrate oral tablet 10 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Initial): Risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly
Age Restrictions	(Initial, Reauth): Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	(Initial): 3 months. (Reauth): 2 years
Other Criteria	(REAUTH): Prescriber is aware of the risk versus benefit of using the medication chronically (greater than 90 days)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM NORGESIC

Products Affected

- NORGESIC
- *orphenadrine-aspirin-caffeine oral tablet 25-385-30 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) For age 65 and older: Risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly. (2) Inadequate response or inability to tolerate two generic skeletal muscle relaxants (e.g., tizanidine, chlorzoxazone 500mg, etc.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM SHORT TERM SKELETAL MUSCLE RELAXANTS

Products Affected

- *carisoprodol oral*
- *cyclobenzaprine hcl er*
- *cyclobenzaprine hcl oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute Muscle Spasms (AMS): Prescriber attestation that drug will be used only for short periods (up to 2 or 3 weeks). All Indications: Risk versus benefit has been assessed for this request of a high risk medication (HRM) in elderly.
Age Restrictions	Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	(AMS): 1 year. (All other indications): 2 years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HUMIRA

Products Affected

- HUMIRA (2 PEN) SUBCUTANEOUS AUTO-INJECTOR KIT
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS AUTO-INJECTOR KIT 80 MG/0.8ML
- HUMIRA-PSORIASIS/UVEIT STARTER SUBCUTANEOUS AUTO-INJECTOR KIT

PA Criteria	Criteria Details
Exclusion Criteria	(RA, AS, JIA, PsA, PsO, CD, UC, HS, UV): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Rheumatoid Arthritis (RA): (1)Diagnosis of moderate to severe RA. (2) Inadequate response or inability to tolerate one DMARD: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Ankylosing Spondylitis (AS): (1) Diagnosis of AS. (2) Inadequate response or inability to tolerate one other treatment such as NSAIDs, COX2 inhibitors or methotrexate. Juvenile Idiopathic Arthritis (JIA): (1) Diagnosis of moderate to severe JIA. (2) Inadequate response or inability to tolerate one of the following: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine. Psoriatic Arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least one DMARD: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe chronic PsO.
Age Restrictions	(JIA, UV): Member is 2 years of age or older. (CD): Member is 6 years of age or older. (HS): Member is 12 years of age or older. (RA, AS, PsA, PsO): Member is 18 years of age or older. (UC): Member is 5 years of age or older.
Prescriber Restrictions	(RA, JIA, AS): Prescribed by or in consultation with a rheumatologist. (PsA): Prescribed by or in consultation with a dermatologist or rheumatologist. (PsO, HS): Prescribed by or in consultation with a dermatologist. (CD, UC): Prescribed by or in consultation with a gastroenterologist. (UV): Prescribed by or in consultation with a rheumatologist or ophthalmologist.
Coverage Duration	Indefinite

PA Criteria	Criteria Details
Other Criteria	Crohn's Disease (CD): (1) Diagnosis of CD. (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g. corticosteroid, methotrexate, azathioprine or 6-mercaptopurine). Ulcerative Colitis (UC): (1) Diagnosis of UC. (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g. corticosteroid, Aminosalicylate, azathioprine or 6-mercaptopurine). Hidradenitis Suppurativa (HS): (1) Diagnosis of HS. Uveitis (UV)(Initial): (1) Diagnosis of non-infectious intermediate, posterior, or pan-uveitis. (2) Inadequate response or inability to tolerate corticosteroids and at least one immunosuppressive drug (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HYFTOR

Products Affected

- HYFTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Facial Angiofibroma (FA)(Initial): (1) Diagnosis of facial angiofibroma associated with tuberous sclerosis complex
Age Restrictions	(FA) (Initial, Reauth): Member is 6 years of age or older
Prescriber Restrictions	(FA) (Initial, Reauth): Prescribed by or in consultation with a dermatologist, neurologist, or geneticist.
Coverage Duration	(Initial): 6 months, (Reauth): Indefinite
Other Criteria	(FA) (Reauth): (1) Documentation of positive clinical response to therapy (e.g., improvement in size or redness of facial angiofibroma)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ILUMYA

Products Affected

- ILUMYA

PA Criteria	Criteria Details
Exclusion Criteria	(PsO): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe PsO. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Skyrizi, (d) Cosentyx, (e) Stelara, (f) Otezla, (g) Cyltezo, (h) Yuflyma OR documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(PsO): Member is 18 years of age or older.
Prescriber Restrictions	(PsO): Prescribed by or in consultation with a dermatologist
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INBRIJA

Products Affected

- INBRIJA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Parkinson's Disease (PD): (1) Diagnosis of Parkinson's disease. (2) concurrent use of carbidopa/levodopa containing product, (3) Member is experiencing intermittent OFF episodes, (4) member had inadequate response or inability to tolerate ONE of the following: (a) MAO-B inhibitor (e.g. rasagiline, selegiline), (b) Dopamine agonist (e.g. pramipexole, ropinirole), (c) COMT inhibitor (e.g. entacapone)
Age Restrictions	
Prescriber Restrictions	(PD): Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	(GHGD, PIGF-1D) (Initial and Continuation): Known or suspected malignancy, closed epiphyses, concurrent GH therapy
Required Medical Information	Growth Hormone Gene Deletion (GHGD): (Initial) (1) Diagnosis of growth hormone gene deletion who have developed neutralizing antibodies to growth hormone. Severe Primary IGF-1 Deficiency (PIGF-1D): (Initial) (1) Diagnosis of Severe primary IGF-1 deficiency (2) height standard deviation score less than or equal to -3.0 (3) basal IGF-1 standard deviation score less than or equal to -3.0 AND normal or elevated growth hormone.
Age Restrictions	(GHGD, PIGF-1D) (Initial and Continuation): Member is 2 years of age or older
Prescriber Restrictions	(GHGD, PIGF-1D) (Initial and Continuation) Prescribed by or in consultation with an endocrinologist
Coverage Duration	(Initial and continuation): 12 months
Other Criteria	(GHGD, PIGF-1D)(CONTINUATION): (1) Documentation of increase in growth velocity from baseline AND (2) Annual clinical re-evaluation by an endocrinologist AND (3) BOTH of the following: (a) Expected adult height is not obtained (b) documentation of expected adult height goal
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INGREZZA

Products Affected

- INGREZZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tardive Dyskinesia (TD) (Initial): (1) Diagnosis of moderate to severe tardive dyskinesia (2) documentation of baseline AIMS and (3) one of the following: (a) persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, or (b) member is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Chorea- Huntington's Disease (CHD): (1) Diagnosis of chorea associated with Huntington's disease
Age Restrictions	
Prescriber Restrictions	(TD) (Initial, Reauth): Prescribed by or in consultation with a neurologist or a psychiatrist. (CHD): Prescribed by or in consultation with a neurologist or a psychiatrist.
Coverage Duration	(TD) (Initial): 3 months (TD)(Reauth): indefinite (CHD): Indefinite
Other Criteria	(TD) (Reauthorization): Valbenazine (Ingrezza) is reapproved with documentation of positive clinical response, as demonstrated by improvement in AIMS, to Ingrezza therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INHALED TOBRAMYCIN

Products Affected

- TOBI PODHALER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF): (1) Diagnosis of cystic fibrosis AND (2) evidence of P. aeruginosa in the lungs (3) FEV1 between 25% and 80%, (4) Member not colonized with Burkholderia cepacia.
Age Restrictions	(CF): Member is 6 years of age or older
Prescriber Restrictions	(CF): Prescribed by or in consultation with a pulmonologist, infectious disease specialist or Specialist affiliated with a CF care center.
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INJECTABLE METHOTREXATE

Products Affected

- OTREXUP SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.4ML, 12.5 MG/0.4ML, 15 MG/0.4ML, 17.5 MG/0.4ML, 20 MG/0.4ML, 22.5 MG/0.4ML, 25 MG/0.4ML
- RASUVO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.2ML, 12.5 MG/0.25ML, 15 MG/0.3ML, 17.5 MG/0.35ML, 20 MG/0.4ML, 22.5 MG/0.45ML, 25 MG/0.5ML, 30 MG/0.6ML, 7.5 MG/0.15ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid arthritis (RA): (1) Diagnosis of severe, active rheumatoid arthritis (RA), (2) Inadequate response or inability to tolerate oral methotrexate. Psoriatic Arthritis (PsA): (1) Diagnosis of PsA, (2) Inadequate response or inability to tolerate oral methotrexate. Polyarticular juvenile idiopathic arthritis (pJIA): (1) Diagnosis of pJIA, (2) Inadequate response or inability to tolerate oral methotrexate. Psoriasis: (1) Diagnosis of severe psoriasis, (2) Inadequate response to BOTH of the following: (a) oral methotrexate AND (b) topical steroids (e.g. clobetasol propionate cream/ointment, betamethasone cream/ointment, etc.).
Age Restrictions	(Psoriasis): Member is 18 years of age or older
Prescriber Restrictions	(RA, pJIA): Recommended by rheumatologist. (PSA): Recommended by a rheumatologist or dermatologist. (Psoriasis): Recommended by dermatologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INTRAVENOUS IMMUNE GLOBULINS (IVIG)

Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML
- PANZYGA
- PRIVIGEN INTRAVENOUS SOLUTION 20 GM/200ML

PA Criteria	Criteria Details
Exclusion Criteria	(Initial): History of hypersensitivity (including anaphylaxis or severe systemic reaction) to immune globulin or any component of the preparation.
Required Medical Information	Part D is medically necessary when ONE of the following is present: (1) Autoimmune mucocutaneous blistering disease pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid , benign mucous membrane pemphigoid, epidermolysis bullosa acquisita and ONE of the following: (a) inadequate response or inability to tolerate conventional therapy (i.e. steroids, immunosuppressants) OR (b) rapidly progressive disease in conjunction with conventional therapy (i.e. steroids, immunosuppressants). (2) Acute Idiopathic Thrombocytopenia Purpura (ITP) and ONE of the following (a) management of acute bleeding (b) used to increase platelet count prior to surgical procedures) (c) severe thrombocytopenia (platelets less than 20, 000 per uL) or (d) high risk for intracerebral hemorrhage. (3) Chronic ITP and ALL of the following (a) inadequate response or inability to tolerate corticosteroids (b) duration of illness greater than 6 months (c) platelets persistently less than 20,000/ uL. (4) Chronic B-cell lymphocytic leukemia with IgG less than 600mg/dL and recurrent, serious bacterial infections requiring antibiotic therapy. (5) Hematopoietic stem cell transplant and IgG less than 400mg/dL. (6) HIV and all of the following (a) less than 14 years of age (b) evidence of qualitative or quantitative humoral immunologic defects and (c) current bacterial infection despite antimicrobial prophylaxis. (7) Solid organ transplant. (8) Chronic Inflammatory Demyelinating Polyneuritis confirmed by electrodiagnostic testing or nerve biopsy and an inadequate response or inability to tolerate corticosteroids. (9) Dermatomyositis or Polymyositis diagnosed by laboratory testing (antinuclear or myositis specific antibodies), biopsy, EMG, or MRI) and inadequate response or inability to tolerate steroids or immunosuppressants. (10) Guillain Barre syndrome with impaired function (i.e. unable to stand or walk without aid).
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g. immunologist, hematologist, neurologist).
Coverage Duration	(All Indications): 6 months
Other Criteria	Subject to Part B vs Part D review. (11) Lambert Eaton myasthenic syndrome and an inadequate response or inability to tolerate steroids, immunosuppressants, or cholinesterase inhibitors (12) Multifocal motor neuropathy diagnosed by electrodiagnostic studies. (13) Acute exacerbations of multiple sclerosis (MS) unresponsive to steroids. (14) Myasthenia gravis and an inadequate response or inability to tolerate at least 8 weeks of standard therapy (e.g., corticosteroids, azathioprine, cyclosporine, cyclophosphamide, cholinesterase inhibitors) (15) Myasthenic crisis (16) Stiff person syndrome and an inadequate response or inability to tolerate standard therapy (e.g., muscle relaxants, benzodiazepines, and gabapentin-related medications) (17) Severe, active SLE and an inadequate response or inability to tolerate steroids (18) Kawasaki disease. (All Indications)(CONTINUATION): (1) Documentation of clinical improvement as appropriate to the diagnosis (e.g. clinical improvement in symptoms, Rankin score and Activities of Daily Living (ADL) scores, etc.)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ISTURISA

Products Affected

- ISTURISA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cushing's disease (CD): (1) Diagnosis of (pituitary) Cushing's disease. (2) Pituitary surgery is not an option or has not been curative (3) Member has inadequate response or inability to tolerate Signifor [LAR].
Age Restrictions	(CD): Member is 18 years of age or older
Prescriber Restrictions	(CD): Prescribed by or in consultation with an endocrinologist
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

JOENJA

Products Affected

- JOENJA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(APDS)(Initial): (1) Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS) (2) Molecular genetic testing confirms mutations in the PIK3CD or PIK3R1 gene (3) Member weighs greater than or equal to 45kg (4) Both of the following (a) Presence of nodal and/or extranodal proliferation (e.g., lymphadenopathy, splenomegaly, hepatomegaly) (b) Presence of other clinical findings and manifestations consistent with APDS (e.g., recurrent sino-pulmonary infections, bronchiectasis, enteropathy) (5) Inadequate response or inability to tolerate at least one standard of care treatment for APDS (e.g., Immunoglobulin replacement therapy)
Age Restrictions	(APDS)(Initial)(Reauth): Member is 12 years of age or older
Prescriber Restrictions	(APDS)(Initial)(Reauth): Prescribed by or in consultation with hematologist, geneticist or immunologist
Coverage Duration	(Initial): 6 months. (Reauth): 12 months
Other Criteria	(APDS)(Reauth): (1) Documentation of positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

JUXTAPID

Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	(HoFH)(Initial, Reauth): Moderate-severe liver impairment, active liver disease, unexplained LFT abnormalities. Juxtapid: Pregnancy, concomitant use with strong or moderate CYP3A4 inhibitors.
Required Medical Information	Homozygous Familial Hypercholesterolemia (HoFH): (1) Diagnosis of HoFH with ONE of the following: (a) Genetic confirmation of 2 mutant alleles at the LDL receptor. Apo B, PCSK9, or ARH adaptor protein gene locus (b) Untreated LDL-C greater than 500 mg/dL or treated LDL cholesterol greater than or equal to 300 mg/dL or treated non-HDL cholesterol greater than or equal to 330 mg/dL together with either of the following: (i) Tendinous xanthoma prior to 10 years of age (ii) Elevated LDL cholesterol prior to lipid-lowering therapy consistent with HeFH in both parents AND (2) Inadequate response or inability to tolerate the combination of BOTH of the following: (a) Either ezetimibe or a Bile Acid Sequestrant (e.g. cholestyramine) AND (b) ONE of the following: (i) ONE high potency statin at the maximally tolerated dose (e.g. atorvastatin, rosuvastatin) OR (ii) Inability to tolerate statin therapy as determined by one of the following: (A) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (B) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN or (C) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (D) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks. (3) Inadequate response or inability to tolerate BOTH of the following: (a) Repatha and (b) Praluent.
Age Restrictions	
Prescriber Restrictions	(HoFH)(Initial, Reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	(Initial, Reauth): 6 months
Other Criteria	(HoFH)(REAUTH): (1) Documentation of reduction in LDL level since initiation of therapy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

JYNARQUE

Products Affected

- JYNARQUE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Initial): Baseline serum transaminases and bilirubin prior to initiation of therapy
Age Restrictions	(Initial and Reauth): Member is 18 years of age or older
Prescriber Restrictions	(Initial and Reauth): Prescribed by or in consultation with a nephrologist or kidney transplant specialist
Coverage Duration	(Initial): 3 months. (Reauth): 12 months.
Other Criteria	(REAUTH): (1) ONE of the following (a) decline in kidney function has slowed or (b) kidney pain has improved and (2) serum transaminase less than 3 times the upper limit of normal and (3) bilirubin less than 2 times upper limit of normal
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KALYDECO

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF): (1) Diagnosis of Cystic Fibrosis with documentation of one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data, (2) Mutation was documented by an FDA-cleared CF mutation test to detect the presence of the CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions.
Age Restrictions	(CF): Member is 1 month of age or older for granules. Member is 6 years of age or older for tablets
Prescriber Restrictions	(CF): Prescribed by or in consultation with is a pulmonologist or Specialist affiliated with a CF care center
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KERENDIA

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic kidney disease associated with type 2 diabetes (CKD with T2D): (1) Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D), (2) One of the following (a) Minimum 30-day trial of a maximally tolerated dose and member will continue therapy with ONE of the following (i) generic angiotensin-converting enzyme (ACE) inhibitor (e.g. benazepril, lisinopril), (ii) generic angiotensin II receptor blocker (ARB) (e.g. losartan, valsartan), (b) Member has contraindication or intolerance to ACE inhibitors or ARBs
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KEVEYIS

Products Affected

- KEVEYIS
- ORMALVI

PA Criteria	Criteria Details
Exclusion Criteria	(Initial, Reauth): Concomitant use of high dose Aspirin, severe pulmonary disease and hepatic insufficiency
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	(Initial, Reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	(Initial): 3 months (Reauth): Indefinite
Other Criteria	(Reauth): Member has had a positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KEVZARA

Products Affected

- KEVZARA

PA Criteria	Criteria Details
Exclusion Criteria	(RA, PMR, PJIA): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Rheumatoid arthritis (RA): (1) Diagnosis of RA. (2) Inadequate response or inability to tolerate TWO of the following: (a) adalimumab (Humira), (b) etanercept (Enbrel), (c) Rinvoq, (d)Xeljanz/Xeljanz XR, (e) Orencia, (f) adalimumab-adbm (Cyltezo), (g) adalimumab-aaty (Yuflyma) OR documentation demonstrating that a trial may be inappropriate. Polymyalgia Rheumatica (PMR): (1) Diagnosis of polymyalgia rheumatica (2) Inadequate response or inability to tolerate corticosteroids (e.g., prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA) (2) Member weighs at least 63 kg (3) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Xeljanz, (d) Orencia, (e) Cyltezo, (f) Yuflyma, (g) Rinvoq/Rinvoq LQ OR documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(RA, PMR): Member is 18 years of age or older
Prescriber Restrictions	(RA, PMR, PJIA): Prescribed by or in consultation with a rheumatologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KINERET

Products Affected

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	(RA, NOMID, DIRA): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Rheumatoid Arthritis (RA): (1) Diagnosis of RA. (2) Inadequate response or inability to tolerate TWO of the following: (a) adalimumab (Humira), (b) etanercept (Enbrel), (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, (f) adalimumab-adbm (Cyltezo), (g)adalimumab-aaty (Yuflyma) OR documentation demonstrating that a trial may be inappropriate. Neonatal-Onset Multisystem Inflammatory Disease (NOMID): (1) Diagnosis of NOMID. (2) Diagnosis has been confirmed by one of the following: (a) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation (b) Evidence of active inflammation including both of the following: (i) clinical symptoms (e.g. rash, fever, arthralgia) (ii) elevated acute phase reactants (e.g. ESR, CRP). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): (1) Diagnosis of DIRA.
Age Restrictions	
Prescriber Restrictions	(RA, NOMID, DIRA): Prescribed by or in consultation with a rheumatologist or pediatric specialist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KORLYM

Products Affected

- KORLYM
- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	(HCS): Pregnancy
Required Medical Information	Hyperglycemia in members with Cushing Syndrome (HCS): (1) Hyperglycemia secondary to hypercortisolism in adult member with endogenous Cushing syndrome, (2) member has type 2 diabetes mellitus or glucose intolerance, (3) member has failed surgery or is not a candidate for surgery.
Age Restrictions	
Prescriber Restrictions	(HCS): Prescribed by or in consultation with an endocrinologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LETAIRIS

Products Affected

- *ambrisentan*
- LETAIRIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH) (Initial): (1) Documentation of a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV. (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography. (3) Documentation of mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion. (4) Inadequate response or inability to tolerate ambrisentan (applies to brand Letairis only)
Age Restrictions	
Prescriber Restrictions	(PAH) (Initial): Prescribed by or in consultation with a Cardiologist or Pulmonologist.
Coverage Duration	(Initial): 6 months. (Continuation):12 months.
Other Criteria	(PAH)(Continuation): Stabilization or improvement as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LIDOCAINE TRANSDERMAL PATCH

Products Affected

- *lidocaine external patch 5 %*
- LIDOCAN
- TRIDACAINE II

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Post-Herpetic Neuralgia (PHN): (1) Diagnosis of post-herpetic neuralgia. Diabetic Peripheral Neuropathy (DPN): (1) Diagnosis of diabetic peripheral neuropathy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LIVMARLI

Products Affected

- LIVMARLI ORAL SOLUTION 9.5 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cholestatic Pruritus with Alagille Syndrome (CPALGS) (Initial): (1) Diagnosis of Cholestatic Pruritus with Alagille Syndrome. (2) Diagnosis of ALGS confirmed by one of the following: (A) liver histology showing bile duct scarcity, OR (B) THREE of the following clinical features (i) hepatic: cholestasis, jaundice, hepatomegaly (ii) Facial: high prominent forehead, pointed chin, deep-set eyes (iii) Ocular: posterior embryotoxon, optic disc drusen (iv) Cardiac: pulmonary stenosis, tetralogy of Fallot (v) Skeletal: butterfly vertebrae, pathological fractures (vi) Renal: renal dysplasia, renal tubular acidosis (vii) Vascular: intracranial bleeding, CNS/pulmonary vascular malformations, OR (C) genetic mutation in the JAG1 or NOTCH2 genes. (3) An inadequate response or inability to tolerate at least two of the following treatments used for the relief of pruritus: (a)Ursodeoxycholic acid (e.g. Ursodiol) (b) Antihistamines (e.g. diphenhydramine, hydroxyzine) (c) Rifampin (d) Bile acid sequestrants (e.g. Questran).
Age Restrictions	(CPALGS): Member is 3 months of age or older(PFIC): Member is 5 years of age or older
Prescriber Restrictions	(CPALGS, PFIC) (Initial, Reauth): Prescribed by or in consultation with a gastroenterologist or hepatologist.
Coverage Duration	(CPALGS, PFIC)(Initial): 6 months (CPALGS, PFIC)(Reauth): End of contract year
Other Criteria	Progressive Familial Intrahepatic Cholestasis (PFIC) (Initial): (1) BOTH of the following: (A) Diagnosis of Progressive familial intrahepatic cholestasis (PFIC) (B) Molecular genetic testing confirms mutations in the ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, or MYO5B gene (2) Member is experiencing moderate to severe cholestatic pruritus (3) Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: (i) Ursodeoxycholic acid (e.g., Ursodiol) (ii) Antihistamines (e.g., diphenhydramine, hydroxyzine) (iii) Rifampin (iv) Bile acid sequestrants (e.g., Questran) (CPALGS, PFIC) (Reauth): Positive clinical response to therapy (e.g. reduced bile acids, reduction in pruritis severity score).

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LIVTENCITY

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cytomegalovirus (CMV): (1) Diagnosis of cytomegalovirus (CMV) infection/disease, (2) Member is a recipient of one of the following (a) Hematopoietic stem cell transplant, (b) solid organ transplant, (3) Inadequate response to a minimum 2 weeks duration or inability to tolerate one of the following therapies at an appropriately indicated dose (a) intravenous (IV) ganciclovir, (b) oral valganciclovir, (c) intravenous (IV) foscarnet, (d) intravenous (IV) cidofovir, (4) Member weighs greater than or equal to 35kg
Age Restrictions	(CMV): Member is 12 years of age or older
Prescriber Restrictions	(CMV): Prescribed by or in consultation with a provider who specializes in one of the following areas (1) transplant, (2) infectious disease
Coverage Duration	8 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LUMRYZ

Products Affected

- LUMRYZ

PA Criteria	Criteria Details
Exclusion Criteria	CN, EDSN (Initial, Reauth): Concurrent use of sedative hypnotics and alcohol
Required Medical Information	Cataplexy in Narcolepsy (CN)(Initial): (1) Diagnosis of cataplexy in narcolepsy, (2) Diagnosis Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT) or prescriber provides justification that a sleep study is not feasible. Excessive Daytime Sleepiness in Narcolepsy (EDSN)(Initial): (1) Diagnosis of EDSN (Narcolepsy Type 2), (2) Diagnosis Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT) or prescriber provides justification that a sleep study is not feasible and (3) Inadequate response or inability to modafinil or armodafinil.
Age Restrictions	(CN, EDSN)(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(CN, EDSN)(Initial, Reauth): Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist.
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(CN, EDSN)(Reauth): (1) Documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale), (2) Member is re-evaluated every 12 months.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

METFORMIN IR

Products Affected

- *metformin hcl oral tablet 625 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(DM) (Initial): (1) Diagnosis of Type 2 Diabetes Mellitus (DM2) (2) Inadequate response to at least a 12-week trial of generic metformin 500mg, metformin 850mg, or metformin1000mg as evidenced by Hemoglobin A1C level above the member's goal, or inability to tolerate generic metformin 500mg, metformin 850mg, or metformin 1000mg.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(DM) (Reauth): (1) Member has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

METHOCARBAMOL 1000MG TAB

Products Affected

- *methocarbamol oral tablet 1000 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Inadequate response or inability to tolerate two generic skeletal muscle relaxants (e.g., tizanidine, chlorzoxazone 500mg, etc.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MODAFINIL

Products Affected

- *modafinil oral*
- PROVIGIL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	NARCOLEPSY: (1) Diagnosis of Narcolepsy confirmed by a sleep study (unless prescriber provides justification that a sleep study is not feasible). OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS): (1) Diagnosis confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). SHIFT WORK SLEEP DISORDER (SWSD): (1) One of the following: (a) Symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR (b) A sleep study demonstrating loss of a normal sleep-wake pattern (i.e., disturbed chronobiologic rhythmicity). (2) Documentation that the member has no other medical or mental disorder accounting for the symptoms. Multiple Sclerosis (MS) Related Fatigue: (1) Diagnosis of Multiple Sclerosis (MS) related fatigue, (2) Used in combination with standard educational therapies (e.g. psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc.) (All Indications): Inadequate response or inability to tolerate generic modafinil (applies to Brand Provigil)
Age Restrictions	
Prescriber Restrictions	(Narcolepsy, SWSD, OSAHS): Prescribed by or in consultation with a neurologist or sleep specialist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MULPLETA

Products Affected

- MULPLETA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Liver Disease (CLD): (1) Member is scheduled to undergo a procedure (2) Documentation of baseline platelet count less than 50,000/mcL
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MYALEPT

Products Affected

- MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Generalized Lipodystrophy (GL): (1) Diagnosis of congenital or acquired generalized lipodystrophy.
Age Restrictions	
Prescriber Restrictions	(GL): Prescribed by or in consultation with an endocrinologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MYCAPSSA

Products Affected

- MYCAPSSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Acromegaly)(Initial): (1) One of the following: (a) Inadequate response to surgical resection and/or pituitary irradiation, (b) member is not a candidate for surgical resection or pituitary irradiation (2) Inadequate response or inability to tolerate a dopamine agonist (e.g. bromocriptine or cabergoline) at maximally tolerated doses (3) Member has responded to and tolerated treatment with octreotide or lanreotide.
Age Restrictions	(Acromegaly): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(Acromegaly) (Reauth): Positive clinical response to therapy (e.g. reduction or normalization of IGF-1/GH level for same age and sex)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MYFEMBREE

Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Uterine Leiomyomas (UL)(Initial): (1) Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), (2) Member is premenopausal, (3) ONE of the following: (a) Inadequate response or inability to tolerate one of the following for no more than 30 days: combination (estrogen/progestin) contraceptive, progestins, tranexamic acid, OR (b) Member has had a previous interventional therapy to reduce bleeding (e.g. uterine-artery embolization and magnetic resonance-guided focused ultrasonography), (4) Treatment duration of therapy has not exceeded a total of 24 months. (Endometriosis)(Initial) (1) Diagnosis of moderate to severe pain associated with endometriosis (2) member is premenopausal (3) One of the following (a) Inadequate response or inability to tolerate one of the following for at least 3 months (danazol, combination (estrogen/progestin) contraceptive, progestins (b) member has had surgical ablation to prevent recurrence (4) Treatment duration of therapy has not exceeded a total of 24 months
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(UL) (Reauth): (1) Member has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g. significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.), (2) Treatment duration of therapy has not exceeded a total of 24 months. (Endometriosis)(Reauth) (1) Member has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain) (2) Treatment duration of therapy has not exceeded a total of 24 months
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

NEXLETOL/NEXLIZET

Products Affected

- NEXLETOL
- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Heterozygous Familial Hypercholesterolemia (HeFH) OR Primary hyperlipidemia (PH). (Initial): (1) One of the following: (A) Diagnosis of HeFH, OR (B) Diagnosis of Primary hyperlipidemia (2) ONE of the following: (A) LDL-C 70 mg/dL or greater after at least 8 weeks of one low, moderate or high-intensity statin therapy and member will continue to receive statin therapy at maximally tolerated dose OR (B) Inability to tolerate statin therapy as documented by one of the following: (i) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (ii) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN or (iii) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (iv) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks. (3) One of the following: (A) Member has been receiving at least 8 weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy OR (B) Member has contraindication or intolerance to ezetimibe (Zetia).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(Initial): 6 months. (Continuation): 12 months

PA Criteria	Criteria Details
Other Criteria	Established cardiovascular disease (CVD) or high risk for a CVD event but without established CVD (Initial): (1) One of the following: (A) Diagnosis of established cardiovascular disease (CVD) (e.g., coronary artery disease, symptomatic peripheral arterial disease, cerebrovascular atherosclerotic disease) OR (B) Diagnosis of a high risk for a CVD event but without established CVD [e.g., diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age] (2) One of the following: (A) Member is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase) (B) Member has a contraindication to all statins (3) ONE of the following LDL-C values within the last 120 days (A) LDL-C greater than or equal to 55 mg/dL with ASCVD OR (B) LDL-C greater than or equal to 100 mg/dL without ASCVD (4) One of the following (A) For Nexletol, ONE of the following: (i) Member has been receiving at least 12 weeks of generic ezetimibe therapy (ii) Patient has a history of contraindication, or intolerance to ezetimibe OR (B) For Nexlizet, member has been receiving at least 12 weeks of generic ezetimibe therapy (HeFH, PH) (Continuation): (1) Positive Clinical response to therapy (e.g. reduction in LDL-C levels). (2) One of the following: (A) Member continues to receive other lipid-lowering therapy (e.g. statins, ezetimibe) at the maximally tolerated dose OR (B) Member has inability to tolerate other lipid-lowering therapy (e.g. statins, ezetimibe) (CVD) (Continuation): (1) Positive Clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NON-ORAL ANTIBIOTICS

Products Affected

- DALVANCE
- NUZYRA
- SIVEXTRO
- ZEMDRI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Initial): Part D is medically necessary when documentation of a current bacterial infection and an inadequate response or inability to tolerate at least TWO drugs to which the organism is susceptible OR the requested agent is the only antibiotic to which the organism is susceptible.
Age Restrictions	
Prescriber Restrictions	(Initial, Reauth): Prescribed by or in consultation with an infectious disease specialist OR oncologist
Coverage Duration	(Initial, Reauth): 1 month
Other Criteria	Subject to Part B vs Part D review. Subject to additional clinical review for ESRD-related use - if applicable. (REAUTH): Prescriber attests that an infectious disease consult determines that a longer duration of therapy is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NON-ORAL CHEMO AGENTS

Products Affected

- TRELSTAR MIXJECT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when ANY of the following inclusion criteria is met: (1) Drug is FDA approved for indication and regimen requested, (2) The indication and regimen is classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, (3) narrative text in The American Hospital Formulary Service-Drug Information (AHFS-DI) or Clinical Pharmacology Compendium is supportive for the specific condition(s) requested, (4) The Micromedex Compendium and the strength of recommendation is listed as Class I, Class IIa, or Class IIb for the specific condition(s) requested, (5) Indication is listed in Lexi-Drugs as "off label" with evidence level A, (6) supported by Peer-Reviewed Medical Literature as defined in Chapter 15 Section 50.4.5 of the Medicare Benefit Policy Manual
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy. Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NON-PREFERRED HEPATITIS C AGENTS

Products Affected

- SOVALDI
- VOSEVI
- ZEPATIER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) Documentation of member's Hepatitis C genotype. (2) Prescribed regimen is consistent with the current AASLD/ IDSA guidance. (3) Inability to tolerate ONE of the following when appropriate per the current AASLD/IDSA guidance: Harvoni, Epclusa, or Mavyret.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Duration will be applied consistent with AASLD/ IDSA guidance
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NOURIANZ

Products Affected

- NOURIANZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Parkinson's Disease (PD): (1) Diagnosis of Parkinson's disease. (2) concurrent use of carbidopa/levodopa containing product, (3) Member is experiencing intermittent OFF episodes, (4) member had inadequate response or inability to tolerate ONE of the following: (a) MAO-B inhibitor (e.g. rasagiline, selegiline), (b) Dopamine agonist (e.g. pramipexole, ropinirole), (c) COMT inhibitor (e.g. entacapone)
Age Restrictions	
Prescriber Restrictions	(PD): Prescribed by or in consultation with a neurologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NOXAFIL

Products Affected

- NOXAFIL ORAL SUSPENSION
- *posaconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of invasive aspergillosis (TAI): Diagnosis of TAI. Prophylaxis of Invasive Aspergillus Infections (AI): (1) For use in prophylaxis of invasive Aspergillus infection due to being severely immunocompromised after inadequate response or inability to tolerate voriconazole (Vfend). Prophylaxis of Invasive Candida Infections(CI): (1) For use in prophylaxis of invasive Candida infection due to being severely immunocompromised after inadequate response or inability to tolerate voriconazole (Vfend). Oropharyngeal Candidiasis (OC): (1) Diagnosis of oropharyngeal candidiasis or (2) Diagnosis of Oropharyngeal candidiasis refractory to itraconazole and /or fluconazole.
Age Restrictions	(TAI): Member is 13 years of age or older (OC): Member is 13 years of age or older. (AI, CI): Member is 2 years of age or older
Prescriber Restrictions	(All Indications): Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist, oncologist, OR prescribed as part of chemotherapy prophylaxis protocol
Coverage Duration	Remainder of contract year
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NOXAFIL 300MG PAK

Products Affected

- NOXAFIL ORAL PACKET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prophylaxis of Invasive Aspergillus Infections (AI): (1) For use in prophylaxis of invasive Aspergillus infection due to being severely immunocompromised after inadequate response or inability to tolerate voriconazole (Vfend). Prophylaxis of Invasive Candida Infections(CI): (1) For use in prophylaxis of invasive Candida infection due to being severely immunocompromised after inadequate response or inability to tolerate voriconazole (Vfend).
Age Restrictions	(AI, CI): Member is 2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist, oncologist, OR prescribed as part of chemotherapy prophylaxis protocol
Coverage Duration	Remainder of contract year
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NUCALA

Products Affected

- NUCALA

PA Criteria	Criteria Details
Exclusion Criteria	(SA, EGPA, CRSwNP) Will not be used in combination with other biologics for asthma/allergic conditions (e.g., benralizumab [Fasenra], dupilumab [Dupixent], omalizumab [Xolair], reslizumab [Cinqair])
Required Medical Information	Part D is medically necessary when there is documentation of ONE of the following: Severe Asthma with Eosinophilic Phenotype (SA) (Initial): (1) Diagnosis of severe asthma with eosinophilic phenotype as defined by one of the following: a) blood eosinophil levels are at least 150 cells/microliter at initiation of therapy (measured within 6 weeks of dosing), or b) blood eosinophil levels at least 300 cells/microliter within the past 12 months. (2) Member has had at least two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months OR member has had any prior intubation for an asthma exacerbation OR Member has had a prior asthma-related hospitalization within the past 12 months, AND (3) Member is currently treated with high-dose inhaled corticosteroids (ICS) (e.g. greater than or equal to 500 mcg fluticasone propionate equivalent/day) AND an additional controller medication (e.g. long-acting beta agonist such as salmeterol or formoterol, leukotriene inhibitor such as montelukast, theophylline), unless the individual is intolerant of or has a contraindication to two of the additional controller agents. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Initial): (1) Diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA), (2) Member's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy), and (3) Member is currently receiving corticosteroid therapy (e.g. prednisolone, prednisone). Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (Initial): (1) Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP). (2) Unless contraindicated, the member has had an inadequate response to at least a 2 month treatment with an intranasal corticosteroid (e.g. fluticasone, mometasone). (3) Used in combination with another agent for CRSwNP.
Age Restrictions	(SA) (Initial, Reauth): Member is 6 years of age or older. (HES) (Initial, Reauth): Member is 12 years of age or older. (CRSwNP, EGPA) (Initial, Reauth): Member is 18 years of age or older.

PA Criteria	Criteria Details
Prescriber Restrictions	(SA): Prescribed by or in consultation with pulmonologist or allergy/immunology specialist. (EGPA): Prescribed by or in consultation with a rheumatologist. (HES): Prescribed by or in consultation with either allergist/immunologist or hematologist. (CRSwNP): Prescribed by or in consultation with allergist, immunologist, otolaryngologist or pulmonologist.
Coverage Duration	(Initial): 12 months. (Reauth): 12 months.
Other Criteria	Subject to Part B vs Part D review. Hypereosinophilic Syndrome (HES) (Initial): (1) Diagnosis of HES. (2) All of the following: (a) Member has been diagnosed for at least 6 months, (b) Verification that other non-hematologic secondary causes have been ruled out (e.g. drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy), (c) member is FIP1-like1-platelet derived growth factor receptor alpha kinase (FIP1L1-PDGFRA kinase)-negative. (3) Member has uncontrolled HES defined by both of the following: (a) Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter, (b) Member has experienced 2 or more flares within the past 12 months. (4) Inadequate response or inability to tolerate one of the following: (a) corticosteroid therapy (e.g. prednisone), (b) cytotoxic/immunosuppressive therapy (e.g. hydroxyurea, cyclosporine, imatinib). (SA)(Reauth): (1) Member is currently treated with high-dose inhaled corticosteroids (ICS) (e.g. greater than or equal to 500mcg fluticasone propionate equivalent/day) AND an additional controller medication (e.g. long-acting beta agonist such as salmeterol or formoterol, leukotriene inhibitor such as montelukast, theophylline), unless the individual is intolerant of or has a contraindication to two of the additional controller agents. (EGPA) (Reauth): (1) Positive clinical response to therapy (e.g. increase in remission time). (HES) (Reauth): (1) Positive clinical response (e.g. reduction in corticosteroid use, reduction of blood eosinophil count, reduction in flares). (CRSwNP) (Reauth): (1) Documentation of positive clinical response to therapy (e.g. reduction of nasal polyps score [NPS: 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS: 0-10 scale]), (2) Used in combination with another agent for CRSwNP.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	(PBA): Presence of cardiac rhythm disorder documented by a cardiac test (e.g. electrocardiogram)
Required Medical Information	Pseudobulbar Affect (PBA): (1) Diagnosis of Pseudobulbar affect (2) Member has one of the following underlying conditions: (a) Amyotrophic lateral sclerosis (b) Multiple sclerosis (c) Alzheimer's disease (d) Parkinson's disease (e) Stroke (f) Traumatic brain injury
Age Restrictions	(PBA): Member is 18 years of age or older
Prescriber Restrictions	(PBA): Prescribed by or in consultation with a neurologist or psychiatrist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NUPLAZID

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hallucinations and Delusions Parkinson Disease Psychosis (HDPDP): Inadequate response or inability to tolerate ONE of the following (a) quetiapine or (b) clozapine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NURTEC

Products Affected

- NURTEC

PA Criteria	Criteria Details
Exclusion Criteria	(AM)(Initial, Reauth): Will be used for preventitive treatment of migraine. Medication will be used in combination with another oral CGRP inhibitor. (MP)(Initial, Reauth): Will be used for acute treatment of migraine. Medication used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Required Medical Information	Acute Treatment of Migraines (AM)(Initial): (1) Diagnosis of migraine with or without aura in adults. (2) Member has fewer than 15 headache days per month. (3) inadequate response or inability to tolerate ONE generic formulary triptan. Preventative Treatment of Migraines (MP) (Initial): (1) Diagnosis of episodic migraines defined as 4 to 18 migraine days per month AND inadequate response or inability to tolerate a 4 week trial of TWO of the following prophylactic medications (a) topiramate (b) divalproex sodium/ valproic acid (c) beta-blocker: metoprolol, propranolol, timolol, atenolol, nadolol (d) tricyclic antidepressants: amitriptyline, nortriptyline (e)SNRI antidepressants: venlafaxine, duloxetine
Age Restrictions	(AM)(MP)(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(AM)(MP)(Initial, Reauth): Prescribed by or in consultation with a neurologist or headache specialist certified by the United Council for Neurologic Subspecialties, or pain specialist.
Coverage Duration	(AM)(MP)(Initial): 6 months. (AM)(MP)(Reauth): 12 months
Other Criteria	(AM)(REAUTH): (1) Positive response to therapy (e.g. reduction in pain, photophobia, phonophobia, nausea). (MP)(Reauth): (1) Positive clinical response to therapy (e.g. reduction in headache frequency and/or intensity, use of acute migraine medications [e.g. nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g. ibuprofen, naproxen), triptans (e.g. eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

OCALIVA

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary biliary cholangitis (PBC): (1) Used in combination with ursodeoxycholic acid (e.g. Urso, Urso Forte, ursodiol), OR (2) inability to tolerate ursodeoxycholic acid. (2) Member has one of the following: (a) no cirrhosis or (b) compensated cirrhosis with no evidence of portal hypertension.
Age Restrictions	
Prescriber Restrictions	(PBC) (Initial, Reauth): Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	(Initial): 6 months. (Reauth): Indefinite
Other Criteria	(PCB)(Reauth): Positive clinical response to Ocaliva therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OFEV

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Idiopathic Pulmonary Fibrosis (IPF): (1) Diagnosis of IPF confirmed by high resolution CT scan or biopsy. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD): (1) Diagnosis of SSc-ILD confirmed by a high resolution CT scan or biopsy. Chronic Fibrosing Interstitial Lung Disease (ILDs) with progressive phenotype (Initial): (1) Confirmed by high resolution CT scan (HRCT) showing at least 10% of lung volume with fibrotic features, (2) Disease has a progressive phenotype as observed by one of the following: (a) decline of forced vital capacity (FVC), (b) worsening of respiratory symptoms, (c) increased extent of fibrosis seen on imaging.
Age Restrictions	
Prescriber Restrictions	(IPF, SSc-ILD, ILDs): Prescribed by or in consultation a pulmonologist or lung transplant specialist.
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(REAUTH) (IPF, ILDs, SSc-ILD): BOTH of the following (1) stabilization from baseline AND (2) no elevations in AST or ALT greater than 5 times upper limit of normal or greater than 3 times upper limit of normal with signs or symptoms of severe liver damage
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OLUMIANT

Products Affected

- OLUMIANT

PA Criteria	Criteria Details
Exclusion Criteria	(RA, COVID-19, Alopecia Areata): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g., tumor necrosis factor antagonists JAK inhibitors, or potent immunosuppressants such as azathioprine, cyclosporine
Required Medical Information	Rheumatoid arthritis (RA): (1) Diagnosis of RA. (2) Inadequate response or inability to tolerate two of the following: (a) Humira, (b) Enbrel (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, (f) Cyltezo, (g) Yuflyma OR documentation demonstrating that a trial may be inappropriate. (COVID-19): (1) Diagnosis of COVID-19 (2) Member is hospitalized (3) Member requires one of the following: (a) supplemental oxygen, (b) non-invasive mechanical ventilation, (c) invasive mechanical ventilation, (d) extracorporeal membrane oxygenation (ECMO). Alopecia Areata (AA): (1) Diagnosis of alopecia areata (2) Member has at least 50% scalp hair loss (3) Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, trichotillomania, tinea capitis, psoriasis) (4) Inadequate response or inability to tolerate one previous treatment for alopecia areata (e.g., topical, intralesional, or systemic corticosteroids, topical immunotherapy)
Age Restrictions	(RA, COVID-19, Alopecia Areata): Member is 18 years of age or older
Prescriber Restrictions	(RA): Prescribed by or in consultation with a rheumatologist (AA): Prescribed by or in consultation with a dermatologist
Coverage Duration	(RA, Alopecia Areata): Indefinite. (COVID-19): 14 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ONYCHOMYCOSIS AGENTS

Products Affected

- JUBLIA
- *tavaborole*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Onychomycosis: (1) Diagnosis of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes. (2) Diagnosis confirmed by one of the following: (a) positive potassium hydroxide (KOH) preparation, (b) culture, or (c) histology. (3) Condition is causing debility or a disruption in member's activities of daily living. (4) Inadequate response or inability to tolerate BOTH of the following: (a) oral generic terbinafine, AND (b) oral generic itraconazole OR topical generic ciclopirox.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OPZELURA

Products Affected

- OPZELURA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis (AD) (Initial): (1) For short-term, non-continuous treatment of chronic atopic dermatitis. (2) Inadequate response or inability to tolerate at least TWO of the following: (a) topical tacrolimus OR topical pimecrolimus, OR (b) generic, prescription medium potency or higher topical steroid, OR (c) Eucrisa. (3) Will not be used in combination with therapeutic biologics, other Janus kinase inhibitors, or potent immunosuppressants (e.g. azathioprine or cyclosporine). Nonsegmental Vitiligo (NV)(Initial): (1) Diagnosis of nonsegmental vitiligo (2) Inadequate response or inability to tolerate one of the following (a) medium or higher potency topical corticosteroid (b) pimecrolimus cream (c) tacrolimus ointment (3) Will not be used in combination with therapeutic biologics, other Janus kinase inhibitors, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
Age Restrictions	(AD, NV): Member is 12 years of age or older
Prescriber Restrictions	(AD) (Initial, Reauth): Prescribed by or in consultation with a dermatologist or allergist/immunologist (NV) (Initial, Reauth): Prescribed by or in consultation with a dermatologist.
Coverage Duration	(AD)(Initial): 8 Weeks, (Reauth): End of contract year (NV)(Initial): 6 months, (Reauth): 12 months
Other Criteria	(AD) (Reauth): Positive clinical response to therapy. (NV)(Reauth): (1) Documentation of positive clinical response to therapy (2) Will not be used in combination with therapeutic biologics, other Janus kinase inhibitors, or potent immunosuppressants (e.g., azathioprine or cyclosporine).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORAL ANTIBIOTICS

Products Affected

- NUZYRA
- SIVEXTRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Initial): Documentation of a current bacterial infection and an inadequate response or inability to tolerate TWO antibiotics to which the organism is susceptible OR the requested medication is the only antibiotic to which the organism is susceptible.
Age Restrictions	
Prescriber Restrictions	(Initial, Reauth): Prescribed by or in consultation with an infectious disease specialist OR oncologist
Coverage Duration	(Initial, Reauth): 1 month
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable. (REAUTH): Prescriber attests that an infectious disease consult determines that a longer duration of therapy is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORAL CHEMO AGENTS

Products Affected

- *abiraterone acetate*
- AFINITOR
- AFINITOR DISPERZ
- AKEEGA
- ALECENSA
- ALUNBRIG
- AUGTYRO ORAL CAPSULE 40 MG
- AYVAKIT
- BALVERSA
- *bexarotene*
- BOSULIF
- BRAFTOVI ORAL CAPSULE 75 MG
- BRUKINSA
- CABOMETYX
- CALQUENCE ORAL TABLET
- CAPRELSA
- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)
- COPIKTRA
- COTELLIC
- *dasatinib*
- DAURISMO
- ERIVEDGE
- ERLEADA
- *erlotinib hcl*
- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet soluble*
- FOTIVDA
- FRUZAQLA
- GAVRETO
- *gefitinib*
- GILOTRIF
- GLEEVEC
- GLEOSTINE ORAL CAPSULE 10 MG, 100 MG, 40 MG
- IBRANCE
- ICLUSIG
- IDHIFA
- *imatinib mesylate*
- IMBRUVICA ORAL CAPSULE
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG
- INLYTA
- INQOVI
- INREBIC
- IWILFIN
- JAKAFI
- JAYPIRCA
- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KOSELUGO
- 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)
- LONSURF
- LORBRENA
- LUMAKRAS ORAL TABLET 120 MG, 320 MG
- LYNPARZA ORAL TABLET
- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)
- MEKINIST
- MEKTOVI
- NERLYNX
- NEXAVAR
- NINLARO
- NUBEQA
- ODOMZO
- OGSIVEO
- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET 100 MG

- OJJAARA
- ONUREG
- ORGOVYX
- ORSERDU
- *pazopanib hcl*
- PEMAZYRE
- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)
- POMALYST
- QINLOCK
- RETEVMO ORAL TABLET
- REVLIMID
- REZLIDHIA
- ROZLYTREK
- RUBRACA
- RYDAPT
- SCEMBLIX
- *sorafenib tosylate*
- SPRYCEL
- STIVARGA
- *sunitinib malate*
- SUTENT
- TABRECTA
- TAFINLAR
- TAGRISSO
- TALZENNA
- TASIGNA
- TAZVERIK
- TEPMETKO
- THALOMID ORAL CAPSULE 100 MG, 50 MG
- TIBSOVO
- TRUQAP ORAL TABLET
- TUKYSA
- TURALIO ORAL CAPSULE 125 MG
- TYKERB
- VANFLYTA
- VENCLEXTA
- VENCLEXTA STARTING PACK
- VERZENIO
- VITRAKVI
- VIZIMPRO
- VONJO
- VORANIGO
- VOTRIENT
- WELIREG
- XALKORI
- XOSPATA
- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (80 MG TWICE WEEKLY)
- XTANDI
- YONSA
- ZEJULA ORAL TABLET
- ZELBORAF
- ZOLINZA
- ZYDELIG
- ZYKADIA ORAL TABLET
- ZYTIGA

PA Criteria	Criteria Details
Exclusion Criteria	

PA Criteria	Criteria Details
Required Medical Information	Approved when ANY of the following inclusion criteria is met: (1) Drug is FDA approved for indication and regimen requested, (2) The indication and regimen is classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, (3) narrative text in The American Hospital Formulary Service-Drug Information (AHFS-DI) or Clinical Pharmacology Compendium is supportive for the specific condition(s) requested, (4) The Micromedex Compendium and the strength of recommendation is listed as Class I, Class IIa, or Class IIb for the specific condition(s) requested, (5) Indication is listed in Lexi-Drugs as "off label" with evidence level A, (6) supported by Peer-Reviewed Medical Literature as defined in Chapter 15 Section 50.4.5 of the Medicare Benefit Policy Manual
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORAL PAH AGENTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH) (Initial): (1) Documentation of a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV. (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography. (3) Documentation of mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion.
Age Restrictions	
Prescriber Restrictions	(PAH) (Initial): Prescribed by or in consultation with a Cardiologist or Pulmonologist
Coverage Duration	(Initial): 6 months. (Continuation):12 months.
Other Criteria	(PAH)(Continuation): Stabilization or improvement as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORENCIA SQ

Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	(RA, PsA, pJIA): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Rheumatoid arthritis (RA): (1) Diagnosis of RA. (2) Inadequate response or inability to tolerate one DMARD: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Psoriatic arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least one DMARD: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Polyarticular Juvenile idiopathic arthritis (pJIA): (1) Diagnosis of JIA. (2) Inadequate response or inability to tolerate one of the following: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine.
Age Restrictions	(Pjia, PsA): Member is 2 years of age or older. (RA): member is 18 years of age or older
Prescriber Restrictions	(RA, pJIA): Prescribed by or inconsultation with a rheumatologist. (PsA): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORIAHNN

Products Affected

- ORIAHNN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Uterine Leiomyomas (UL)(Initial): (1) Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), (2) Member is premenopausal, (3) ONE of the following: (a) Inadequate response or inability to tolerate one of the following for no more than 30 days: combination (estrogen/progestin) contraceptive, progestins, tranexamic acid, OR (b) Member has had a previous interventional therapy to reduce bleeding (e.g. uterine-artery embolization and magnetic resonance-guided focused ultrasonography), (4) Treatment duration of therapy has not exceeded a total of 24 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(UL) (Reauth): (1) Member has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g. significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.), (2) Treatment duration of therapy has not exceeded a total of 24 months.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORILISSA

Products Affected

- ORILISSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pain Associated with Endometriosis (PAE): (1) Documentation of ONE of the following, (a) Inadequate response or inability to tolerate BOTH of the following (i) one nonsteroidal anti-inflammatory drug AND (ii) one contraceptive OR (b) Member has had surgical ablation to prevent recurrence. (2) Treatment duration does not exceed 24 months (150mg tablet) or 6 months (200mg tablet).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	24 months for 150mg tablet, 6 months for 200mg tablet
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORKAMBI

Products Affected

- ORKAMBI

PA Criteria	Criteria Details
Exclusion Criteria	(CF): Diagnosis of CF other than those homozygous for the F508del mutation
Required Medical Information	Cystic Fibrosis (CF): (1) Diagnosis of CF, (2) Member is homozygous for the F508del mutation in the CFTR gene (3) If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene
Age Restrictions	(CF): Member is 1 year of age or older
Prescriber Restrictions	(CF): Prescribed by or in consultation with pulmonologist or Specialist affiliated with a CF care center
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORLADEYO

Products Affected

- ORLADEYO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hereditary Angioedema (HAE): (1) Diagnosis of HAE, (2) For prophylaxis against HAE attacks.
Age Restrictions	(HAE): Member is 12 years of age or older
Prescriber Restrictions	(HAE): Prescribed by or in consultation with an immunologist, allergist or pulmonologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OTEZLA

Products Affected

- OTEZLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Oral Ulcers Associated with Behcet's Disease (OU-BD): (1) Diagnosis of OU-BD. (2) Inadequate response or inability to tolerate ONE topical corticosteroid (e.g. triamcinolone acetonide dental paste) AND ONE systemic corticosteroid. Psoriatic arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least one DMARD. Plaque psoriasis (PsO): (1) Diagnosis of PsO.
Age Restrictions	(PsA, OUBD): Member is 18 years of age or older. (PsO): Member is 6 years of age or older.
Prescriber Restrictions	(PsA, OU-BD): Prescribed by or in consultation with a Rheumatologist or Dermatologist. (PsO): Prescribed by or in consultation with dermatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OXERVATE

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neurotrophic keratitis (NK)(Initial): (1) Diagnosis of NK. (2) Submission of chart documentation indicating treatment of left eye, right eye, or both
Age Restrictions	
Prescriber Restrictions	(NK) (Initial, Reauth) Prescribed by or in consultation with an ophthalmologist or Optometrist.
Coverage Duration	8 weeks
Other Criteria	(NK)(Reauth): (1)Submission of chart documentation indicating treatment of left eye, right eye, or both, (2) Member has received less than or equal to 8 weeks of therapy (one course of therapy) per affected eye(s), (3) Documentation of clinical rational for treatment greater than 8 weeks (e.g. member has a recurrence of neurotrophic keratitis, or treatment of a different eye), (4) Documentation of clinical response to prior Oxervate therapy, (5) Member will not exceed a total of 16 weeks of Oxervate therapy per affected eye(s).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PALYNZIQ

Products Affected

- PALYNZIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Phenylketonuria (PK)(Initial): (1) Member has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, (2) Member will continue to have phenylalanine blood levels measured periodically during therapy.
Age Restrictions	(PK)(Initial, Continuation): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	(Initial): 6 months, (Continuation): Indefinite
Other Criteria	(PK)(CONTINUATION): (1) A positive clinical response to Palynziq therapy as determined by prescriber.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PART D VS EXCLUDED

Products Affected

- AURYXIA
- INTRAROSA
- OSPHENA
- *voriconazole intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PDE INHIBITOR AGENTS FOR PAH

Products Affected

- ADCIRCA
- ALYQ
- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH)(Initial): (1) Diagnosis of PAH WHO Group I with New York Heart Association (NYHA) Functional Class II to IV, (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography, (3) Mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion, (4) inadequate response or inability to tolerate generic tadalafil (Applies to Brand Adcirca only)
Age Restrictions	
Prescriber Restrictions	(PAH)(Initial): Prescribed by or in consultation with Cardiologist or Pulmonologist
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(PAH)(Reauth): (1) Stabilization or improvement as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PRALUENT

Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hyperlipidemia (HLA) (Initial): (1) Diagnosis of hyperlipidemia, (2) ONE of the following: (A) LDL-C 70 mg/dL or greater after a minimum 8-week trial of at least moderate-intensity statin therapy OR (B) Inability to tolerate statin therapy as documented by one of the following: (i) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (ii) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN or (iii) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (iv) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks Atherosclerotic cardiovascular disease (ASCVD) (Initial): (1) Diagnosis of atherosclerotic cardiovascular disease (ASCVD) as diagnosed by either stress test, angiography, atherosclerotic event (e.g. MI, angina, stroke, claudication, carotid stenosis) or arterial intervention for atherosclerotic disease (e.g. coronary, peripheral, carotid), (2) ONE of the following: (A) LDL-C 70 mg/dL or greater after a minimum 8-week trial of at least moderate-intensity statin therapy OR (B) Inability to tolerate statin therapy as documented by one of the following: (i) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (ii) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN or (iii) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (iv) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(Initial): 6 months (Continuation): 12 months

PA Criteria	Criteria Details
Other Criteria	Homozygous Familial Hypercholesterolemia (HoFH) (Initial): (1) Diagnosis of HoFH. (2) One of the following: (a) Untreated LDL-C greater than 500 mg/dL or (b) Treated LDL-C greater than 300 mg/dL. (3) Member is receiving other lipid-lowering therapy (e.g. statin, ezetimibe). (4) Not used in combination with Juxtapid (lomitapide). (HLA, ASVCD)(CONTINUATION): (1) Positive Clinical response to therapy (e.g. reduction in LDL-C levels). (HoFH)(Continuation): (1) Positive Clinical response to therapy (e.g. reduction in LDL-C levels). (2) Member continues to receive other lipid-lowering therapy (e.g. statin, ezetimibe). (3) Not used in combination with Juxtapid (lomitapide).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PREFERRED HEPATITIS C AGENTS

Products Affected

- EPCLUSA
- HARVONI ORAL PACKET
- HARVONI ORAL TABLET 90-400 MG
- *ledipasvir-sofosbuvir*
- MAVYRET
- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) Documentation of member's Hepatitis C Genotype. (2) Prescribed regimen is consistent with the current AASLD/IDSA guidance.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Duration will be applied consistent with AASLD/ IDSA guidance
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PRETOMANID

Products Affected

- *pretomanid*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multidrug Resistant Tuberculosis (MDRTB): (1) Diagnosis of pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive MDRTB. (2) Medication will be used as part of a combination regimen with bedaquiline (Sirturo) and linezolid.
Age Restrictions	(MDRTB): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	26 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PROCYSBI

Products Affected

- PROCYSBI ORAL PACKET

PA Criteria	Criteria Details
Exclusion Criteria	(NC) (Initial, Reauth): Hypersensitivity to penicillamine
Required Medical Information	Nephrotic Cystinosis (NC) (Initial): (1) Diagnosis of nephrotic cystinosis, (2) inadequate response or titration from cysteamine bitartrate immediate-release capsules (Cystagon), (3) documentation of baseline WBC and alkaline phosphatase levels.
Age Restrictions	(NC): Member is 1 year of age or older
Prescriber Restrictions	(NC)(Initial, Reauth): Prescribed by or in consultation with a nephrologist.
Coverage Duration	(Initial): 3 months. (Reauth): 6 months.
Other Criteria	(NCB)(REAUTH): The prescriber has evaluated all of the following since the initiation of treatment: (1) ONE of the following: (a) WBC cysteine level or (b) plasma cysteamine level, (2) WBC count, AND (3) alkaline phosphatase level.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PROLIA

Products Affected

- PROLIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when all of the following criteria are met: Osteoporosis (OS) (Initial): ALL of the following: (1) Diagnosis of osteoporosis confirmed by one of the following: (a) T-score less than or equal to -2.5 (b) history of osteoporotic fracture (e.g. vertebral, hip, non-vertebral) or (c) multiple risk factors for fracture. (2) ONE of the following: (a) inadequate response or inability to tolerate at least one other osteoporosis medicine (e.g. oral bisphosphonates, calcitonin, estrogens, selective estrogen receptor modulator (SERMs)) or (b) severely deteriorated condition indicating that the osteoporosis is so significant that a trial of oral bisphosphonates is not medically warranted or (c) documented moderate to severe renal insufficiency (glomerular filtration rate [GFR] 30 to 35 ml/min or less). Osteopenia (OPN) (Initial): BOTH of the following: (1) Diagnosis of osteopenia confirmed by a T-score less than -1.0, but greater than -2.5. (2) One of the following: (a) Member is receiving adjuvant aromatase inhibitor therapy for breast cancer (b) member is receiving androgen deprivation therapy for non-metastatic prostate cancer. Prophylaxis of Postmenopausal Osteoporosis (PO) (Initial): BOTH of the following: (1) BMD T score less than -1.0 and greater than -2.5. (2) ONE of the following: (a) Inadequate response or inability to tolerate an oral bisphosphonates or a selective estrogen receptor modulator (SERMs) or (b) documented moderate to severe renal insufficiency (glomerular filtration rate [GFR] 30 to 35 ml/min or less) not receiving dialysis or diagnosed with stage 5 kidney disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite

PA Criteria	Criteria Details
Other Criteria	Subject to Part B vs Part D review. Glucocorticoid Induced Osteoporosis (GCO)(Initial): ALL of the following: (1) Diagnosis of CGO in men or women. (2) Daily dose of prednisone is greater than or equal to 5mg for at least 3 months. (3) ONE of the following: (a)Inadequate response or inability to tolerate ONE of the following: (i) bisphosphonates, (ii) hormone replacement therapy, (iii) selective-estrogen receptor modulators (SERMs)., (b) severely deteriorated condition indicating that the osteoporosis is so significant that a trial of oral bisphosphonates is not medically warranted, (c) documented moderate to severe renal insufficiency (glomerular filtration rate [GFR] 30 to 35 ml/min or less)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PROMACTA

Products Affected

- PROMACTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Idiopathic Thrombocytopenic Purpura (ITP)(Initial): (1) Diagnosis of relapsed/refractory, persistent, or chronic ITP. (2) Baseline platelet count is less than 30,000/mcL. (3) Member's degree of thrombocytopenia and clinical condition increase the risk of bleeding. (4) Inadequate response or inability to tolerate ONE of the following: (a) corticosteroids, (b) immune globulin, (c) splenectomy. First-Line for Severe Aplastic Anemia(FLSAA): (1) Diagnosis of severe aplastic anemia. (2) Used for first-line treatment (i.e., member has not received prior immunosuppressive therapy). (3) Member meets at least TWO of the following: (a) absolute neutrophil count less than 500/mcL, (b) platelet count less than 20,000/mcL, (c) absolute reticulocyte count less than 60,000/mcL. (4) Used in combination with standard immunosuppressive therapy (e.g. Atgam [antithymocyte globulin equine] and cyclosporine). Refractory Severe Aplastic Anemia (RSAA)(Initial): (1) Diagnosis of refractory severe aplastic anemia. (2) Member has a platelet count less than 30,000/mcL. (3) Inadequate response or inability to tolerate immunosuppressive therapy with antithymocyte globulin and cyclosporine. Chronic Hepatitis C-Associated Thrombocytopenia (HEPC-TP): (1) Diagnosis of chronic hepatitis C-associated thrombocytopenia. (2) One of the following: (a) Planning to initiate and maintain interferon-based treatment, or (b) currently receiving interferon-based treatment.
Age Restrictions	
Prescriber Restrictions	(ITP, FLSAA, RSAA)(Initial, Continuation): Prescribed by or in consultation with hematologist/oncologist. (HEPC-TP)(Initial, Continuation): Prescribed by or in consultation with Hematologist/oncologist, Gastroenterologist, Hepatologist, Infectious disease specialist, HIV specialist.
Coverage Duration	(ITP)Initial,Cont.=12mo.(FLSAA)=6mo.(RSAA)Initial=6mo.(HEPC-TP)Initial=3mo.(RSAA,HEPC-TP)Cont.=12mo.

PA Criteria	Criteria Details
Other Criteria	(ITP, RSAA)(Continuation): (1) Positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. (HEPC-TP)(Continuation): (1) ONE of the following: (A) For members that started treatment with Promacta prior to initiation of treatment with interferon, both of the following: (i) Member is currently on antiviral interferon therapy for treatment of chronic hepatitis C, AND (ii) member reached a threshold platelet count that allows initiation of antiviral interferon therapy with Promacta treatment by week 9. (B) For members that started treatment with Promacta while on concomitant treatment with interferon, member is currently on antiviral interferon therapy for treatment of chronic hepatitis C.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PYRUKYND

Products Affected

- PYRUKYND
- PYRUKYND TAPER PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hemolytic anemia with pyruvate kinase deficiency (HAwPKD) (Initial): (1) Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count) (2) Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL of the following mutations on the PKLR gene: (a) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant, (b) Member is not homozygous for the c. 1436G A (p.R479H) variant, (c) Member does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene (3) Hemoglobin is less than or equal to 10g/dL (4) Member has symptomatic anemia or is transfusion dependent (5) Other causes of hemolytic anemia (e.g., infections, toxins, drugs) have been ruled out.
Age Restrictions	(HAwPKD) (Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(HAwPKD) (Initial, Reauth): Prescribed by or in consultation with a hematologist
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(HAwPKD)(Reauth): (1) Documentation of positive clinical response to therapy, improvement in markers of hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

QBREXZA

Products Affected

- QBREXZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hyperhidrosis: (1) Hyperhidrosis Disease Severity Scale grade 3 or 4.
Age Restrictions	(Hyperhidrosis): Member is 9 years of age or older
Prescriber Restrictions	(Hyperhidrosis): Prescribed by or in consultation with a dermatologist, primary care physician, internist, or pediatrician.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

QUALAQUIN

Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Uncomplicated Malaria: (1) Diagnosis of uncomplicated malaria due to (a) plasmodium falciparum malaria or (b) plasmodium vivax . (2) One of the following: (a) Both of the following: (i) treatment in areas of chloroquine-sensitive malaria (ii) Inadequate response or inability to tolerate chloroquine or hydroxychloroquine, or (b)treatment in areas of chloroquine-resistant malaria. Babesiosis: (1) Diagnosis of babesiosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Babesiosis: 10 days Uncomplicated Malaria: 14 Days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RADICAVA

Products Affected

- RADICAVA ORS STARTER KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Amyotrophic Lateral Sclerosis (ALS)(Initial): (1) Diagnosis of definite or probable ALS per the revised El Escorial World Federation of Neurology criteria. (2) Time from symptom onset is 2 years or less. (3) Normal respiratory function defined as forced vital capacity (FVC) of greater than or equal to 80% at the start of treatment. (4) Scores of 2 points or greater on each individual item of the ALS Functional Rating Scale-revised (ALSFRS-R).
Age Restrictions	
Prescriber Restrictions	(ALS)(Initial and Reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	(Initial, Reauth): 6 months.
Other Criteria	(ALS)(Reauth): (1) Member shows benefit from therapy (e.g. slowing of decline of functional abilities).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RAVICTI

Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	(UCD): Acute hyperammonemia. N-acetylglutamate synthase (NAGS) deficiency
Required Medical Information	Urea Cycle Disorder (UCD): (1) Diagnosis of urea cycle disorder involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamoylase (OTC), or argininosuccinic acid synthetase (AAS) confirmed via enzymatic, biochemical, or genetic testing. (2) Inadequate response or inability to tolerate sodium phenylbutyrate.
Age Restrictions	(UCD): Member is 2 months of age or older
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RECORLEV

Products Affected

- RECORLEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cushing's Syndrome (CS) (Initial): (1) Diagnosis of Cushing's syndrome (2) Member is being treated for endogenous hypercortisolemia (e.g., pituitary adenoma, ectopic tumor, adrenal adenoma) (3) One of the following: (a) Member is not a candidate for surgery, (b) surgery has not been curative (4) Inadequate response or inability to tolerate oral ketoconazole
Age Restrictions	(CS) (Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(CS) (Initial) (Reauth): Prescribed by or in consultation with an endocrinologist
Coverage Duration	(Initial) (Reauth): 12 months
Other Criteria	(CS) (Reauth): (1) Documentation of positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

REPATHA

Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hyperlipidemia (HLA) (Initial): (1) Diagnosis of hyperlipidemia. Atherosclerotic cardiovascular disease (ASCVD)(Initial): (1) Diagnosis of ASCVD confirmed by either stress test, angiography, atherosclerotic event (e.g. MI, angina, stroke, claudication, carotid stenosis) or arterial intervention for atherosclerotic disease (e.g. coronary, peripheral, carotid). (HLA, ASCVD) (Initial): ONE of the following: (A) LDL-C 70 mg/dL or greater after a minimum 8-week trial of at least moderate-intensity statin therapy OR (B) Inability to tolerate statin therapy as documented by one of the following: (i) member had rhabdomyolysis or symptoms with creatine kinase (CK) exceeding 10 times the upper limit of normal (ULN) or (ii) either of the following with TWO statins: myalgia (no CK elevation) or myositis (CK less than 10 times ULN or (iii) hepatotoxicity from statin use (increased AST/ALT exceeding 3 times ULN) or (iv) liver disease documented by Child Pugh A or worse OR AST/ALT exceeding 3 times ULN for at least 6 weeks
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(Initial): 6 months. (Continuation): 12 months.
Other Criteria	Homozygous Familial Hypercholesterolemia (HoFH) (Initial): (1) Diagnosis of HoFH. (2) One of the following: (a) Untreated LDL-C greater than 500 mg/dL or (b) Treated LDL-C greater than 300 mg/dL. (3) Member is receiving other lipid-lowering therapy (e.g. statin, ezetimibe). (4) Not used in combination with Juxtapid (lomitapide). (HLA, ASCVD)(Continuation): (1) Positive Clinical response to therapy (e.g. reduction in LDL-C levels). (HoFH)(Continuation): (1) Positive Clinical response to therapy (e.g. reduction in LDL-C levels). (2) Member continues to receive other lipid-lowering therapy (e.g. statin, ezetimibe). (3) Not used in combination with Juxtapid (lomitapide).
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

RESPIRATORY ENZYMES

Products Affected

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION
- ZEMAIRA INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG

PA Criteria	Criteria Details
Exclusion Criteria	(ATT): (1) IgA deficiency with known anti-IgA antibody.
Required Medical Information	Part D is medically necessary when ALL of the following are met: Congenital Alpha-1 Antitrypsin Deficiency (ATT): (1) Diagnosis of congenital alpha1-antitrypsin deficiency confirmed by one of the following: (a) PiZZ, PiZ(null) or Pi(null)(null) protein phenotypes (homozygous) or (b) Other rare AAT disease-causing alleles associated with serum alpha1-antitrypsin (AAT) level less than 11?mol/L. (2) Low serum concentration of alpha-1 antitrypsin defined as less than 35 percent of normal (less than 80 mg/dL or less than 11 uM/L or less than 0.8 g/L). (3) the member has progressive panacinar emphysema with a documented rate of decline in forced expiratory volume in 1 second (FEV 1)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

REZUROCK

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic graft-versus-host disease (cGVHD) (Initial): (1) Diagnosis of chronic graft-versus-host disease, (2) Inadequate response or inability to tolerate two or more lines of systemic therapy (e.g. corticosteroids, mycophenolate, etc.)
Age Restrictions	
Prescriber Restrictions	(cGVHD) (Initial/Reauth): Prescribed by or in consultation with one of the following (1) Hematologist, (2) Oncologist, (3) physician experienced in the management of transplant patients
Coverage Duration	(Initial/Reauth): 12 months
Other Criteria	(cGVHD) (Reauth): (1) Member does not show evidence of progressive disease while on therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RINVOQ

Products Affected

- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	(RA, PsA, AD, UC, AS, nr-AxSPA, CD, PJIA): Concurrent use with any other biologic disease modifying antirheumatic drug (DMARD), other JAK inhibitors, or potent immunosuppressants (e.g. azathioprine, cyclosporine).
Required Medical Information	Rheumatoid Arthritis (RA): (1) Diagnosis of moderate to severely active RA. (2) Member has inadequate response or inability to tolerate one DMARD: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine (3) Member had inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Enbrel, Humira, Cyltezo, Yuflyma) OR documentation demonstrating that a trial may be inappropriate. Psoriatic Arthritis (PsA): (1) Diagnosis of PsA, (2) Inadequate response or inability to tolerate at least one DMARD (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine) (3) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Enbrel, Humira, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate. Atopic Dermatitis (AD): (1) Diagnosis of moderate to severe atopic dermatitis, (2) Inadequate response of inability to tolerate at least one of the following: (a) medium or higher potency topical corticosteroid, (b) pimecrolimus cream, (c) tacrolimus cream, (d) Eucrisa (crisaborole) ointment (3) Inadequate response or inability to tolerate at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to Dupixent, Adbry or documentation that a trial may be inappropriate. Ulcerative Colitis (UC): (1) Diagnosis of Ulcerative Colitis (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g. corticosteroid, Aminosalicylate, azathioprine or 6-mercaptopurine). (3) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Humira, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(RA, UC, AS, nr-AxSPA, CD): Member is 18 years of age or older (AD): Member is 12 years of age or older. (PsA, PJIA): Member is 2 years of age or older.
Prescriber Restrictions	(RA, AS, nr-AxSPA, PJIA): Prescribed by or in consultation with a rheumatologist. (PsA): Prescribed by or in consultation with a rheumatologist or dermatologist. (AD): Prescribed by or in consultation with a dermatologist, allergist, immunologist. (UC, CD): Prescribed by or in consultation with a gastroenterologist.

PA Criteria	Criteria Details
Coverage Duration	Indefinite
Other Criteria	Ankylosing Spondylitis (AS): (1) Diagnosis of active ankylosing spondylitis. (2) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g., Enbrel, Humira, Cyltezo, Yuflyma) OR documentation demonstrating that a trial may be inappropriate. Non-radiographic axial spondyloarthritis (nr-AxSPA): (1) Diagnosis of nr-AxSPA (2) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g., Enbrel, Humira, Cimzia, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate (3) Inadequate response or inability to tolerate one NSAID. Crohn's Disease (CD): (1) Diagnosis of CD. (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g., corticosteroid, methotrexate, azathioprine or 6-mercaptopurine) (3) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g., Enbrel, Humira, Cyltezo, Yuflyma) OR documentation demonstrating that a trial may be inappropriate. Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Diagnosis of active PJIA, (2) Inadequate response or inability to tolerate ONE of the following: Methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine (3) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Enbrel, Humira, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RINVOQ LQ 2024

Products Affected

- RINVOQ LQ

PA Criteria	Criteria Details
Exclusion Criteria	(PsA, pJIA): Concurrent use with any other biologic disease modifying antirheumatic drug (DMARD), other JAK inhibitors, or potent immunosuppressants (e.g. azathioprine, cyclosporine).
Required Medical Information	Psoriatic Arthritis (PsA): (1) Diagnosis of PsA, (2) Inadequate response or inability to tolerate at least one DMARD (3) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Enbrel, Humira, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate. Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Diagnosis of active PJIA, (2) Inadequate response or inability to tolerate ONE of the following: Methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine (3) Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Enbrel, Humira, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(PsA, pJIA): Member is 2 years of age or older
Prescriber Restrictions	(PsA): Prescribed by or in consultation with a rheumatologist or dermatologist. (pJIA): Prescribed by or in consultation with a rheumatologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SAMSCA

Products Affected

- SAMSCA
- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Hyponatremia: (1) Members who are unable to sense or appropriately respond to thirst, (2) hypovolemic hyponatremia, (3) concomitant use of strong CYP3A inhibitors
Required Medical Information	Hyponatremia: (1) Diagnosis of clinically significant hypervolemic or euvolemic hyponatremia.
Age Restrictions	Hyponatremia: Member is 18 years of age or older.
Prescriber Restrictions	Hyponatremia: Prescribed by or in consultation with a cardiologist, endocrinologist or nephrologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SEROSTIM

Products Affected

- SEROSTIM SUBCUTANEOUS SOLUTION RECONSTITUTED 4 MG, 5 MG, 6 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Wasting or Cachexia Associated with HIV (WC-HIV): (1) Diagnosis of wasting or cachexia associated with HIV. (2) Member is receiving concomitant antiretroviral therapy. (3) Nutritional evaluation since onset of wasting first occurred
Age Restrictions	
Prescriber Restrictions	(WC-HIV): Prescribed by or in consultation with a HIV specialist or infectious disease specialist
Coverage Duration	48 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cushing's disease (CD)(Initial): (1) Diagnosis of (pituitary) Cushing's disease. (2) Pituitary surgery is not an option or has not been curative
Age Restrictions	(CD)(Initial): Member is 18 years of age or older
Prescriber Restrictions	(CD)(Initial, Reauth): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(CD)(Reauth): Documentation of positive clinical response (e.g. clinically meaningful reduction in 24- hour urinary free cortisol levels, improvement in signs or symptoms of the disease)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SILDENAFIL

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	(PAH, RP): Documentation of concomitant nitrate use
Required Medical Information	Pulmonary Arterial Hypertension (PAH): (1) Diagnosis of PAH WHO Group I with New York Heart Association (NYHA) Functional Class II to IV (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography (3) Mean pulmonary artery pressure greater than or equal 25 mm Hg at rest or greater than 30 mm Hg with exertion. Raynaud's Phenomenon (RP): (1) Diagnosis of secondary Raynaud's phenomenon. (2) Inadequate response or inability to tolerate a calcium channel blocker.
Age Restrictions	
Prescriber Restrictions	(PAH, RP): Prescribed by or in consultation with a Cardiologist or Pulmonologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SILIQ

Products Affected

- SILIQ

PA Criteria	Criteria Details
Exclusion Criteria	(PsO)(Initial, Reauth): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Plaque psoriasis (PsO)(Initial): (1) Diagnosis of moderate to severe PsO. (2) Inadequate response or inability to tolerate TWO of the following: (a) adalimumab (Humira), (b) etanercept (Enbrel), (c) Skyrizi, (d) Cosentyx, (e) Stelara, (f) Otezla, (g) Cyltezo, (h) Yuflyma OR documentation demonstrating that a trial may be inappropriate. (3) Member has been evaluated for depression and suicidal ideations using the PHQ-9.
Age Restrictions	(PsO)(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(PsO)(Initial, Reauth): Prescribed by or in consultation with a dermatologist
Coverage Duration	(Initial): 16 weeks (Reauth) 1 year
Other Criteria	(PsO) (Reauth): (1) Member has positive response to therapy as evidenced by one of the following: (i) Reduction in the body surface area (BSA) involvement from baseline, (ii) Improvement in symptoms (e.g. pruritus, inflammation) from baseline , (2) Member has been evaluated for depression and suicidal ideations using the PHQ-9
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SIMPONI

Products Affected

- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	(AS, PsA, RA, UC): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Ankylosing Spondylitis (AS): (1) Diagnosis of AS. (2) Inadequate response or inability to tolerate two of the following: (a) adalimumab (Humira), (b) etanercept (Enbrel), (c) secukinumab (Cosentyx), (d) tofacitinib (Xeljanz/Xeljanz XR), (e) upadacitinib (Rinvoq), (f) adalimumab-adbm (Cyltezo), (g) adalimumab-aaty (Yuflyma) or documentation demonstrating that a trial may be inappropriate. Psoriatic Arthritis (PsA): (1) Diagnosis of active PsA. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Xeljanz/Xeljanz XR, (d) Rinvoq/Rinvoq LQ, (e) Skyrizi, (f) Cosentyx, (g) Stelara, (h) Orencia, (i) Otezla, (j) Cyltezo, (k) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Rheumatoid arthritis (RA): (1) Diagnosis of moderate to severe RA. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, (f) Cyltezo, (g) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Ulcerative Colitis (UC): (1) Diagnosis of moderate to severe UC. (2) Inadequate response or inability to tolerate two of the following: (a) Humira, and (b) Xeljanz/Xeljanz XR, (c) Stelara, (d) Rinvoq, (e) Cyltezo, (f) Yuflyma, (g) Skyrizi OR documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(AS, PsA, RA, UC): Member is 18 years of age or older
Prescriber Restrictions	(RA, AS): Prescribed by or in consultation with a rheumatologist. (PsA): Prescribed by or in consultation with a rheumatologist or dermatologist. (UC): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

SIRTURO

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary Multi-Drug Resistant Tuberculosis (MDR-TB): (1) Diagnosis of MDR-TB. (2) Member weighs at least 15kg (applies to members 5 to less than 18 years of age). (3) One of the following: (a) Medication will be used in combination with at least 3 other drugs to which the member's MDR-TB isolate has been shown to be susceptible in vitro OR (b) If in vitro testing results are unavailable, treatment will be initiated in combination with at least 4 other drugs to which the member's MDR-TB isolate is likely to be susceptible. (4) Sirturo (bedaquiline) will be administered by directly observed therapy (DOT).
Age Restrictions	(MDR-TB): Member is 5 years of age or older.
Prescriber Restrictions	(MDR-TB): Prescribed by or in consultation with infectious disease specialist or pulmonologist
Coverage Duration	24 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SKYCLARYS

Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Friedreich Ataxia (FA)(Initial): (1) Diagnosis of Friedreich Ataxia (FA) confirmed by genetic testing demonstrating mutation in the FXN gene (2) Member has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80 (3) Member has B-type natriuretic peptide value less than or equal to 200 pg/ml
Age Restrictions	(FA)(Initial)(Reauth): member is 16 years of age or older
Prescriber Restrictions	(FA)(Initial)(Reauth): Prescribed by or in consultation with one of the following specialists: neurologist, neurogeneticist, Physiatrist (Physical Medicine and Rehabilitation Specialist)
Coverage Duration	(Initial): 12 months (Reauth): 12 months
Other Criteria	(FA)(Reauth): (1) Documentation of positive clinical response to therapy as evidenced by one of the following: (a) an increase in peak work (in Watts/kg) during exercise testing from baseline (b) a decrease in the rate of progression of Modified Friedreich's Ataxia Rating Scale (mFARS)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SKYRIZI SC

Products Affected

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	(PsO, PsA, CD, UC): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Plaque psoriasis (PsO):Diagnosis of moderate to severe PsO. Psoriatic Arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least ONE DMARD. Crohn's Disease (CD): (1) Diagnosis of CD. (2) One of the following: (a) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g., corticosteroid, methotrexate, azathioprine or 6-mercaptopurine). (b) Will be used as a maintenance dose following the intravenous induction doses. Ulcerative Colitis (UC): (1) Diagnosis of moderately to severely active UC. (2) One of the following: (a) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g. prednisone, mesalamine) (b) will be used as a maintenance dose following the intravenous induction doses.
Age Restrictions	(PsO, PsA, CD, UC): Member is 18 years of age or older
Prescriber Restrictions	(PsO): Prescribed by or in consultation with a dermatologist (PsA): Prescribed by or consultation with a rheumatologist or dermatologist (CD, UC): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite
Other Criteria	Part B drug applies only to beneficiaries enrolled in an MA-PD plan.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SKYTROFA

Products Affected

- SKYTROFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Growth Failure in Children (GFC)(Initial): (1) Diagnosis of growth hormone deficiency confirmed by one of the following: (a) Height is documented by one of the following (utilizing age and gender growth charts related to height): (i) Height is greater than 2.0 standard deviations [SD] below midparental height (ii) Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender). (2) Growth velocity is greater than 2 SD below mean for age and gender. (3) Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g. delayed is greater than 2 years compared with chronological age). (4) documentation of bone age, abnormal response from provocative testing, such as insulin-induced hypoglycemia test, levodopa, or clonidine.
Age Restrictions	(GFC) (Initial, Reauth): Member is 1 years of age or greater
Prescriber Restrictions	(GFC)(Initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	(Initial, Continuation): 12 months
Other Criteria	(GFC) (Continuation): (1) Annual clinical re-evaluation by the treating endocrinologist
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SOTYKTU

Products Affected

- SOTYKTU

PA Criteria	Criteria Details
Exclusion Criteria	Plaque Psoriasis (PsO): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	(PsO): (1) Diagnosis of moderate to severe PsO. (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira, (b) Enbrel, (c) Skyrizi (d) Cosentyx, (e) Stelara, (f) Otezla, (g) Cyltezo, (h) Yuflyma OR documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(PsO): Member is 18 years of age or older
Prescriber Restrictions	(PsO): Prescribed by or in consultation with a dermatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

STELARA SQ

Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	(CD, UC, PsA, PsO):Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Part D is medically necessary when: Plaque psoriasis (PsO): Diagnosis of moderate to severe PsO. Psoriatic arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least one DMARD: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). Crohn's Disease (CD): (1) Diagnosis of moderate to severe CD. (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g. corticosteroid, Aminosalicylate, azathioprine or 6-mercaptopurine). Ulcerative Colitis (UC): (1) Diagnosis of moderate to severe UC. (2) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g. corticosteroid, Aminosalicylate, azathioprine or 6-mercaptopurine).
Age Restrictions	(CD, UC): Member is 18 years of age or older. (PsO, PsA): Member is 6 years of age or older.
Prescriber Restrictions	(CD, UC): prescribed by or in consultation with a Gastroenterologist. (PsO): prescribed by or in consultation with a Dermatologist. (PsA): prescribed by or in consultation with a Dermatologist or Rheumatologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF): (1) Diagnosis of Cystic Fibrosis. (2) One of the following: a) Member is homozygous for the F508del mutation, or b) Member has at least one tezacaftor/ivacaftor responsive mutation in the CFTR gene. (3) If the member's genotype is unknown, an FDA-cleared test must be used to detect the presence of CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test
Age Restrictions	(CF): Member is 6 years of age or older
Prescriber Restrictions	(CF): Prescribed by or in consultation with a pulmonologist or Specialist affiliated with a CF care center
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SYMLIN

Products Affected

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	(DM): Gastroparesis.
Required Medical Information	Diabetes Mellitus (DM): (1) Diagnosis of diabetes (Type 1 or Type 2). (2) inadequate response to optimal insulin monotherapy. (3) concurrent use of mealtime insulin.
Age Restrictions	(DM): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TADLIQ

Products Affected

- TADLIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH)(Initial): (1) Diagnosis of PAH WHO Group I with New York Heart Association (NYHA) Functional Class II to IV, (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography, (3) Mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion, (4) inadequate response or inability to tolerate generic tadalafil
Age Restrictions	
Prescriber Restrictions	(PAH)(Initial): Prescribed by or in consultation with Cardiologist or Pulmonologist
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(PAH)(Reauth): (1) Stabilization or improvement as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TAFAMIDIS

Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM)(Initial): (1) Diagnosis of ATTR-CM confirmed by one of the following: (a) Member has a transthyretin (TTR) mutation (e.g. V122I), (b) cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, or (c) all of the following: echocardiogram or cardiac magnetic resonance image suggestive of amyloidosis, scintigraphy scan suggestive of cardiac TTR amyloidosis, and absence of light-chain amyloidosis, (2) One of the following: (a) History of heart failure (HF), with at least one prior hospitalization for HF, or (b) presence of clinical signs and symptoms of HF (e.g. dyspnea, edema), (3) Member has New York Heart Association (NYHA) Functional Class I, II, or III heart failure
Age Restrictions	(ATTR-CM) (Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(ATTR-CM) (Initial, Reauth): Prescribed by or in consultation with a cardiologist
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(ATTR-CM)(Reauth): (1) Positive clinical response to therapy, (2) Member continues to have NYHA Functional Class I, II, or III heart failure.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TAKHZYRO

Products Affected

- TAKHZYRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when: Hereditary Angioedema (HAE): (1) Diagnosis of HAE. (2) For prophylaxis against HAE attacks.
Age Restrictions	
Prescriber Restrictions	(HAE): Prescribed by or in consultation with an allergist, immunologist, pulmonologist
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TALTZ

Products Affected

- TALTZ

PA Criteria	Criteria Details
Exclusion Criteria	(PsO, PsA, AS, nr-axSpA): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe PsO. (2) ONE of the following: (A) For members 6 to 17 years of age: an inadequate response or inability to tolerate two of the following: (a) Enbrel, (b) Cosentyx, (c) Stelara or documentation demonstrating that a trial may be inappropriate, OR (B) For members 18 years of age or older: an inadequate response or inability to tolerate two of the following: (a)Cosentyx (b) Enbrel (c) Humira (d) Skyrizi, (e) Stelara, (f) Otezla, (g) Cyltezo, (h) Yuflyma or documentation demonstrating that a trial may be inappropriate. Psoriatic arthritis (PsA): (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate TWO of the following: (a) Enbrel (b) Humira (c) Cosentyx (d) Rinvoq/Rinvoq LQ (e) Skyrizi (f) Stelara (g) Xeljanz/Xeljanz XR, (h) Orencia, (i) Otezla, (j) Cyltezo, (k) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Ankylosing spondylitis (AS): (1) Diagnosis of AS. (2) Inadequate response or inability to tolerate TWO of the following: (a) adalimumab (Humira), (b) etanercept (Enbrel), (c) secukinumab (Cosentyx), (d) upadacitinib (Rinvoq), (e) tofacitinib (Xeljanz/Xeljanz XR), (f) adalimumab-adbm (Cyltezo), (g) adalimumab-aaty (Yuflyma) OR documentation demonstrating that a trial may be inappropriate. Non-Radiographic Axial Spondyloarthritis (nr-axSpA): (1) Diagnosis of nr-axSpA. (2) Inadequate response or inability to tolerate Rinvoq OR Cosentyx OR documentation demonstrating that a trial may be inappropriate (3) Inadequate response or inability to tolerate one NSAID (e.g. ibuprofen, meloxicam, naproxen).
Age Restrictions	(PsA, AS, nraxSpA): Member is 18 years of age or older. (PsO): Member is 6 years of age or older.
Prescriber Restrictions	(PsO): Prescribed by or in consultation with a dermatologist. (PsA): Prescribed by or in consultation with a dermatologist or rheumatologist. (AS, nr-axSpA): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Indefinite

PA Criteria	Criteria Details
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TARPEYO

Products Affected

- TARPEYO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Immunoglobulin A nephropathy (IgAN): (1) Diagnosis of primary immunoglobulin A nephropathy (IgAN) (2) Member is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the international IgAN Prediction Tool] (3) Used to reduce proteinuria (4) Estimated glomerular filtration rate (eGFR) greater than or equal to 35 ml/min/1.73 m2 (5) One of the following: (a) Member has been on a minimum 90-day trial of maximally tolerated dose and will continue to receive therapy with one of the following: (i) an angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), (ii) An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), (b) Member is unable to tolerate both ACE inhibitors and ARBs (6) Inadequate response or inability to tolerate another glucocorticoid (e.g., prednisone, methylprednisolone)
Age Restrictions	(IgAN): Member is 18 years of age or older
Prescriber Restrictions	(IgAN): Prescribed by or in consultation with a nephrologist
Coverage Duration	9 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TAVALISSE

Products Affected

- TAVALISSE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Immune Thrombocytopenia (ITP)(Initial): (1) Documentation of baseline platelet count less than 30,000/mcL, (2) Inadequate response or inability to tolerate ONE of the following: (a) Corticosteroids, (b) Immunoglobulins, (c) Splenectomy, (d) Thrombopoietin receptor agonists (e.g. Nplate, Promacta), or (e) rituximab (Rituxan).
Age Restrictions	(ITP)(Initial, Continuation): Member is 18 years of age or older
Prescriber Restrictions	(ITP)(Initial, Continuation): Prescribed by or in consultation with hematologist/oncologist
Coverage Duration	(Initial, Continuation): 12 months
Other Criteria	(ITP)(Continuation): (1) Positive clinical response to Tavalisse therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes

TAVNEOS

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) (ANCA-V(GPA)(MPA))(Initial): (1) Diagnosis of Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) AND 2) Used as adjunct to standard therapy, and glucocorticoids
Age Restrictions	(ANCA-V(GPA)(MPA))(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(ANCA-V(GPA)(MPA))(Initial, Reauth): Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.
Coverage Duration	(Initial): 6 Months (Reauth): 1 year
Other Criteria	(ANCA-V(GPA)(MPA))(Reauth): (1) Positive clinical response to therapy defined as sustained remission as assessed by the Birmingham Vasculitis Activity Score (BVAS). (2) Used as adjunct to standard therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TERIPARATIDE

Products Affected

- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR 600 MCG/2.4ML
- *teriparatide subcutaneous solution pen-injector 620 mcg/2.48ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary or Hypogonadal Osteoporosis (HGO)(Initial): (1) Diagnosis of HGO in men. (2) Member has severe osteoporosis or is at a high to very high risk for fracture as defined by ONE of the following: (a) Member has a history of multiple vertebral fractures, (b) T-score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR (c) history of osteoporotic fracture (i.e. hip, spine, etc.). (3) Inadequate response or inability to tolerate (a) bisphosphonates or (b) hormone replacement therapy. Postmenopausal Osteoporosis (PMO) (Initial): (1) Diagnosis of PMO. (2) Member has severe osteoporosis or is at a high to very high risk for fracture as defined by ONE of the following: (a) Member has a history of multiple vertebral fractures, (b) T score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR (c) history of osteoporotic fracture (i.e. hip, spine, etc.). (3) Inadequate response or inability to tolerate ONE of the following: (a) bisphosphonates, (b) hormone replacement therapy, (c) selective-estrogen receptor modulators (SERMs), OR (d) Denosumab (Prolia). Glucocorticoid Induced Osteoporosis (GCO)(Initial): (1) Diagnosis of CGO in men or women. (2) Daily dose of prednisone is greater than or equal to 5mg for at least 3 months. (3) Inadequate response or inability to tolerate ONE of the following: (a) bisphosphonates, (b) hormone replacement therapy, (c) selective-estrogen receptor modulators (SERMs), or (d) Denosumab (Prolia).
Age Restrictions	(HGO, PMO, GCO) (Initial and Reauth): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	(Initial and Reauth): Remainder of contract year
Other Criteria	(HGO, PMO, GCO) (Reauth): One of the following: (1) Cumulative lifetime therapy does not exceed 2 years [applies to Teriparatide and Forteo], OR (2) member remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [applies to Forteo only].

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TESTOSTERONE PRODUCTS

Products Affected

- JATENZO
- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml*
- *testosterone enanthate intramuscular solution*
- *testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)*
- *testosterone transdermal solution*
- TLANDO
- XYOSTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Delayed Puberty (DP): (1) Diagnosis of delayed puberty in male members (Applies to Testosterone Enanthate only). Breast Cancer (BC): (1) Diagnosis of inoperable breast cancer in female members (Applies to Testosterone Enanthate only). Hypogonadism (HG)(New starts only): (1) Attestation that diagnosis was initially confirmed by ALL of the following: (A) Two early morning total testosterone levels below 300 ng/dL measured on separate occasions, (B) Normal Prolactin Level, and (C) Physical or cognitive symptoms of testosterone deficiency (e.g. physical: fatigue, sleep disturbances, decreased activity, cognitive: depressive symptoms, cognitive dysfunction, loss of concentration, poor memory, irritability), (2) ONE of the following (A) negative history of prostate and breast cancer OR (B) Both of the following (i) history of prostate cancer with stable PSA less than or equal to 4ng/dL for 2 years and (ii) documentation that the risk versus benefit has been assessed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(DP, BC): Indefinite (HG)(New Starts, Continuation): Indefinite
Other Criteria	(HG)(Continuation): ONE of the following (1) negative history of prostate and breast cancer OR (2) Both of the following (a) history of prostate cancer with stable PSA less than or equal to 4ng/dL for 2 years and (b) documentation that the risk versus benefit has been assessed.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TOPICAL CHEMO AGENTS

Products Affected

- *bexarotene*
- TARGRETIN EXTERNAL
- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Approved when ANY of the following inclusion criteria is met: (1) Drug is FDA approved for indication and regimen requested, (2) The indication and regimen is classified as Category 1 or 2A by National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, (3) narrative text in The American Hospital Formulary Service-Drug Information (AHFS-DI) or Clinical Pharmacology Compendium is supportive for the specific condition(s) requested, (4) The Micromedex Compendium and the strength of recommendation is listed as Class I, Class IIa, or Class IIb for the specific condition(s) requested, (5) Indication is listed in Lexi-Drugs as "off label" with evidence level A, (6) supported by Peer-Reviewed Medical Literature as defined in Chapter 15 Section 50.4.5 of the Medicare Benefit Policy Manual
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	Indefinite
Other Criteria	(All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TOPICAL RETINOID PRODUCTS

Products Affected

- *adapalene external cream*
- *adapalene external gel 0.3 %*
- *adapalene external pad*
- *adapalene-benzoyl peroxide external gel*
- *clindamycin-tretinoin*
- *tretinoin external*

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic use
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TRACLEER

Products Affected

- *bosentan*
- TRACLEER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH) (Initial): (1) Documentation of a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV. (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography. (3) Documentation of mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion. (4) Inadequate response or inability to tolerate bosentan (applies to brand Tracleer only)
Age Restrictions	
Prescriber Restrictions	(PAH) (Initial): Prescribed by or in consultation with a Cardiologist or Pulmonologist.
Coverage Duration	(Initial): 6 months. (Continuation):12 months.
Other Criteria	(PAH)(Continuation): Stabilization or improvement as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TREMFYA

Products Affected

- TREMFYA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	(PsO, PsA): Concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
Required Medical Information	Plaque psoriasis (PsO): (1) Diagnosis or moderate to severe PsO. (2) Inadequate response or inability to tolerate two of the following: (a) Cosentyx, (b) Enbrel, (c) Humira, (d) Skyrizi, (e) Stelara, (f) Otezla, (g) Cyltezo, (h) Yuflyma OR documentation demonstrating that a trial may be inappropriate. Psoriatic arthritis (PsA): (1) Diagnosis of PsA, (2) Inadequate response or inability to tolerate TWO of the following: (a) Humira (b) Enbrel (c) Cosentyx (d) Rinvoq/Rinvoq LQ (e) Skyrizi (f) Stelara (g) Xeljanz/Xeljanz XR, (h) Orencia, (i) Otezla, (j) Cyltezo, (k) Yuflyma or documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(PsO, PsA): Member is 18 years of age or older
Prescriber Restrictions	(PsO): Prescribed by or in consultation with a dermatologist. (PsA): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TRIKAFTA

Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF): (1) Member has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test OR a mutation in the CFTR gene that is responsive based on in vitro data.
Age Restrictions	(CF): Member is 2 years of age or older
Prescriber Restrictions	(CF): Prescribed by or in consultation with a pulmonologist or Specialist affiliated with a CF care center
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TYMLOS

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Postmenopausal Osteoporosis (PMO) (Initial): (1) Diagnosis of PMO. (2) Member has severe osteoporosis or is at a high to very high risk for fracture as defined by ONE of the following: (a) Member has a history of multiple vertebral fractures, (b) T score of the individual's bone mineral density (BMD) is at least -2.5 standard deviations below the young adult mean OR (c) history of osteoporotic fracture (i.e. hip, spine, etc.). (3) Inadequate response or inability to tolerate ONE of the following: (a) bisphosphonates, (b) hormone replacement therapy, (c) selective-estrogen receptor modulators (SERMs), OR (d) Denosumab (Prolia). Osteoporosis at high risk for fracture in men (OSTm) (Initial): (1) Diagnosis of primary or hypogonadal osteoporosis (2) Both of the following: (a) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) (b) One of the following (i) History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm (ii) inadequate response or inability to tolerate at least one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])
Age Restrictions	(PMO, OSTm) (Initial and Reauth): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	(Initial and Reauth): Remainder of contract year
Other Criteria	(PMO, OSTm)(Reauth): Cumulative lifetime therapy does not exceed 2 years
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TYVASO DPI

Products Affected

- TYVASO DPI MAINTENANCE KIT INHALATION POWDER 16 MCG, 32 MCG, 48 MCG, 64 MCG
- TYVASO DPI TITRATION KIT INHALATION POWDER 16 & 32 & 48 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH) (Initial): (1) Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV. (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography. (3) Mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion. Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD) (Initial): (1) Diagnosis of pulmonary hypertension associated with interstitial lung disease (PHILD) WHO Group 3. (2) Diagnosis confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging)
Age Restrictions	
Prescriber Restrictions	(PAH)(PH-ILD)(Initial): Prescribed by or in consultation with a Cardiologist or Pulmonologist
Coverage Duration	(Initial): 6 months. (Continuation): 12 months.
Other Criteria	(PAH)(PH-ILD)(CONTINUATION): Stabilization or improvement as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

UBRELVY

Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	(AM)(Initial, Reauth): Will be used for preventative treatment of migraine. Medication will be used in combination with another oral CGRP inhibitor.
Required Medical Information	Acute Treatment of Migraines (AM)(Initial): (1) Diagnosis of migraine with or without aura in adults. (2) Member has fewer than 15 headache days per month. (3) inadequate response or inability to tolerate ONE generic formulary triptan.
Age Restrictions	(AM)(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(AM)(Initial, Reauth): Prescribed by or in consultation with a neurologist or headache specialist certified by the United Council for Neurologic Subspecialties, or pain specialist.
Coverage Duration	(AM)(Initial): 6 months. (AM)(Reauth): 12 months
Other Criteria	(AM)(REAUTH): (1) Positive response to therapy (e.g. reduction in pain, photophobia, phonophobia, nausea)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

UPTRAVI

Products Affected

- UPTRAVI ORAL
- UPTRAVI TITRATION

PA Criteria	Criteria Details
Exclusion Criteria	(PAH)(Initial, Reauth): Taken in combination with a prostanoid/prostacyclin analogue (e.g. epoprostenol, iloprost, treprostinil)
Required Medical Information	Pulmonary Arterial Hypertension (PAH)(Initial): (1) Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II to IV AND (2) Diagnosis confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography AND (3) Documentation of mean pulmonary artery pressure greater than or equal to 25 mm Hg at rest or greater than 30 mm Hg with exertion AND (4) inadequate response or inability to tolerate TWO of the following (a) an endothelin receptor antagonist (Tracleer if naive to the class) (b) a phosphodiesterase inhibitor (sildenafil if naive to the class) (c) riociguat (Adempas).
Age Restrictions	
Prescriber Restrictions	(PAH)(Initial): Prescribed by or in consultation with a Cardiologist or Pulmonologist
Coverage Duration	(Initial): 6 months. (Reauth): 12 months.
Other Criteria	(PAH)(REAUTH): Stabilization or improvement as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VECAMYL

Products Affected

- VECAMYL

PA Criteria	Criteria Details
Exclusion Criteria	(EHTN, MHTN): Uremia, glaucoma, organic pyloric stenosis, coronary insufficiency, recent myocardial infarction
Required Medical Information	Essential Hypertension (EHTN): (1) Diagnosis of moderately severe to severe essential hypertension (2) an inadequate response or inability to tolerate at least two antihypertensive medications in different classes. Malignant Hypertension (MHTN): (1) Diagnosis of malignant hypertension, (2) An inadequate response or inability to tolerate at least two antihypertensive medications in different classes.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VIJOICE

Products Affected

- VIJOICE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(PROS) (Initial): (1) Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) (2) Documentation of mutation in the PIK3CA gene (3) Documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])
Age Restrictions	(PROS) (Initial, Reauth): member is 2 years of age or older
Prescriber Restrictions	(PROS) (Initial, Reauth): Prescribed by or in consultation with a physician who specializes in the treatment of PROS
Coverage Duration	Initial: 6 months. Reauthorization: 12 months
Other Criteria	(PROS) (Reauth): (1) Documentation of positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOXZOGO

Products Affected

- VOXZOGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Achondroplasia) (Initial): (1) Member has open epiphyses, (2) Diagnosis of achondroplasia as confirmed by both of the following, (i) Member has clinical manifestations characteristic of achondroplasia (e.g. macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis), (ii) Member has radiographic findings characteristic of achondroplasia (e.g. large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosciatic notches, proximal scooping of the femoral metaphysis, and short and narrow chest)
Age Restrictions	
Prescriber Restrictions	(Achondroplasia) (Initial) (Reauth): Prescribed by or in consultation with one of the following: (1) clinical geneticist, (2)endocrinologist, (3) a physician who has specialized expertise in the management of achondroplasia
Coverage Duration	(Initial) (Reauth): 12 months
Other Criteria	(Achondroplasia) (Reauth): (1) member has open epiphyses, (2) Documentation of positive clinical response to therapy [e.g. improvement in annualized growth velocity (AGV) compared to baseline].
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VUITY

Products Affected

- VUITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Presbyopia) (Initial): (1) Diagnosis of presbyopia (2) Provider confirms valid clinical rationale, which excludes lifestyle choice, as to why patient is unable to use corrective lenses (e.g., eyeglasses or contact lenses)
Age Restrictions	
Prescriber Restrictions	(Presbyopia) (Initial) (Reauth): prescribed by or in consultation with one of the following (1) Ophthalmologist, (2) Optometrist
Coverage Duration	(Initial): 3 months, (Reauth): 6 months
Other Criteria	(Presbyopia) (Reauth): (1) Documentation of positive clinical response to therapy (e.g. improvement in near vision in low light conditions without loss of distance vision)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

WAKIX

Products Affected

- WAKIX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Narcolepsy type 1: (1) Diagnosis of cataplexy with narcolepsy (Type 1). (2) ONE of the following: (a) Diagnosis Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT), (b) prescriber provides justification confirming that a sleep study would not be feasible and (3) Symptoms of cataplexy are present. Narcolepsy (Type 2): (1) Diagnosis of excessive daytime sleepiness in Narcolepsy (Type 2). (2) ONE of the following: (a) Diagnosis Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT), (b) prescriber provides justification confirming that a sleep study would not be feasible and (3) Inadequate response or inability to tolerate modafinil or armodafinil.
Age Restrictions	
Prescriber Restrictions	(Narcolepsy): Prescribed by or in consultation with a neurologist or sleep specialist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XELJANZ

Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	(RA, PsA, UC, PJIA, AS): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), Janus kinase (JAK) inhibitors or potent immunosuppressants (e.g. azathioprine, cyclosporine)
Required Medical Information	Rheumatoid arthritis (RA) [applies to Xeljanz/Xeljanz XR tablets]: (1) Diagnosis of moderate to severe RA. (2) Inadequate response or inability to tolerate one DMARD: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine), (3) Member had inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Enbrel, Humira, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate. Psoriatic Arthritis (PsA) [applies to Xeljanz/Xeljanz XR tablets]: (1) Diagnosis of PsA. (2) Inadequate response or inability to tolerate at least ONE DMARD: (e.g. Methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine) (3) Inadequate response or inability to tolerate one or more TNF inhibitors (e.g. Enbrel, Humira, Cyltezo, Yuflyma) or documentation demonstrating that a trial may be inappropriate. Ulcerative Colitis (UC) [applies to Xeljanz/Xeljanz XR tablets]: (1) Diagnosis of moderate to severe UC. (2) Inadequate response or inability to tolerate at least ONE conventional therapy (e.g. corticosteroid, aminosalicylate, azathioprine or 6-mercaptopurine) (3) Inadequate response or inability to tolerate one or more TNF inhibitors (e.g. adalimumab (Humira), adalimumab-adbm (Cyltezo, adalimumab-aaty (Yuflyma)) or documentation demonstrating that a trial may be inappropriate. Polyarticular Juvenile Idiopathic Arthritis (PJIA) [applies to Xeljanz tablets/oral solution]: (1) Diagnosis of PJIA. (2) Inadequate response or inability to tolerate one or more TNF inhibitors (e.g. adalimumab (Humira), etanercept (Enbrel), adalimumab-adbm (Cyltezo), adalimumab-aaty (Yuflyma)) OR documentation demonstrating that a trial may be inappropriate. (3) Inadequate response or inability to tolerate ONE of the following: Methotrexate, Hydroxychloroquine, Leflunomide, Azathioprine, Sulfasalazine.
Age Restrictions	(RA, PsA, UC, AS): Member is 18 years of age or older. (PJIA): Member is 2 years of age or older.
Prescriber Restrictions	(RA, PJIA, AS): Prescribed by or in consultation with a rheumatologist. (PsA): Prescribed by or in consultation with a dermatologist or rheumatologist. (UC): Prescribed by or in consultation with a gastroenterologist.

PA Criteria	Criteria Details
Coverage Duration	Indefinite
Other Criteria	Ankylosing Spondylitis (AS): (1) Diagnosis of ankylosing spondylitis. (2) Inadequate response or inability to tolerate one or more TNF inhibitors (e.g. adalimumab (Humira), adalimumab-adbm (Cyltezo), adalimumab-aaty (Yuflyma), etanercept (Enbrel)) OR documentation that a trial may be inappropriate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XENAZINE

Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tardive Dyskinesia (TD)(Initial): (1) Diagnosis of TD, (2) Documentation is provided of ONE of the following: (a) Persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering or discontinuation of the offending medication, or (b) Member is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's Syndrome (TS): (1) Diagnosis of TS, (2) Member has tics associated with Tourette's syndrome, (3) Inadequate response or inability to tolerate haloperidol or risperidone. Chorea- Huntington's Disease (CHD): (1) Diagnosis of chorea associated with Huntington's disease
Age Restrictions	
Prescriber Restrictions	(TS, CHD): Prescribed by or in consultation with a neurologist or a psychiatrist. (TD)(Initial, Reauth): Prescribed by or in consultation with a neurologist or a psychiatrist.
Coverage Duration	(TD)(Initial): 3 months. (TD)(Reauth): Indefinite. (TS, CHD): Indefinite.
Other Criteria	(TD)(Reauth): Positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XERMELO

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Carcinoid Syndrome Diarrhea (CSD)(Initial): (1) Diagnosis of carcinoid syndrome diarrhea, (2) Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g. octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months, (3) Used in combination with SSA therapy
Age Restrictions	(CSD)(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	(CSD)(Initial, Reauth): Prescribed by or in consultation with an Oncologist, Endocrinologist, or Gastroenterologist
Coverage Duration	(Initial): 12 months (Reauth): Indefinite
Other Criteria	(CSD)(Reauth): (1) Positive clinical response to Xermelo therapy, (2) Xermelo will continue to be used in combination with SSA therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XGEVA

Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary when: Prevention of Skeletal Related Events in Multiple Myeloma or Bone Metastases from Solid Tumors (MM-BMST) : (1) For prevention of skeletal related events in multiple myeloma or bone metastases from solid tumors. Giant Cell Tumor of the Bone (GCTB): (1) Diagnosis of GCTB. (2) Member is (a) adult or (b) adolescent that is skeletally mature. (3) Tumor is unresectable or surgical resection is likely to result in severe morbidity. Hypercalcemia of Malignancy Refractory to Bisphosphonates (HCMRB): (1) Diagnosis of HCMRB.
Age Restrictions	
Prescriber Restrictions	(GCTB, HCMRB): Prescribed by or in consultation with an urologist, oncologist or hematologist.
Coverage Duration	Indefinite
Other Criteria	Subject to Part B vs Part D review. (All Indications): Approve if for continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prophylaxis for Hepatic Encephalopathy (HE): (1) Diagnosis of hepatic disease with risk for hepatic encephalopathy (i.e., previous episode of hepatic encephalopathy, advanced liver disease, hepatocellular carcinoma), (2) Inadequate response or inability to tolerate lactulose. Irritable Bowel Syndrome (IBS): (1) Diagnosis of irritable bowels syndrome- diarrhea, (2) Inadequate response or inability to tolerate BOTH of the following: (A) ONE of the following: (i) ONE Tricyclic antidepressant or (ii)selective serotonin reuptake inhibitor and (B) dicyclomine (3): BOTH of the following: (A) Member does not exceed 3 total courses (42 days in total) of therapy, (B) Member experiences irritable bowel syndrome with diarrhea (IBS-D) symptoms. Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (Initial): (1) Diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(HE): Indefinite. (IBS): 2 weeks. (SBBO/SIBO): Initial and Reauth: 2 weeks.
Other Criteria	(SBBO/SIBO) (Reauth): (1) Documentation of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) recurrence following successful initial treatment
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XOLAIR

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Part D is medically necessary for: Moderate to Severe Persistent Allergic Asthma (PAA)(Initial): (1) DIAGNOSIS OF MODERATE TO SEVERE PERSISTENT ALLERGIC ASTHMA, (2) The individual has a positive skin test or in vitro reactivity to a perennial aeroallergen, (3) The individual has a baseline serum IgE level of between 30 IU/mL and 1300 IU/mL, (4) Inadequate response or inability to tolerate a combination of high-dose inhaled corticosteroids (ICS)with a long-acting beta-agonist (LABA). Chronic Urticaria (CU)(Initial): (1) DIAGNOSIS OF CHRONIC URTICARIA, (2) an inadequate response, contraindication or inability to tolerate ONE second- generation H1 antihistamine at the maximally tolerated dose in addition to ANY of the following: (a) leukotriene receptor antagonist (e.g. montelukast) (b) histamine H2-receptor antagonist (e.g. ranitidine, cimetidine, famotidine), (c) substituting to a different second- generation antihistamine, (d) systemic glucocorticosteroids or (e) cyclosporine, (3) will be used concurrently with an h1 antihistamine, unless there is contraindication or intolerance to H1 antihistamines. Nasal Polyps (NP)(Initial): (1) Diagnosis of nasal polyps. (2) Member will use concurrently with nasal corticosteroid. (3) Member had inadequate response or inability to tolerate an intranasal corticosteroid. (4) Member has a baseline serum IgE level of between 30 IU/mL and 1500 IU/mL
Age Restrictions	(PAA)(Initial, Reauth): Member is 6 years of age or older (CU)(Initial, Reauth): Member is 12 years of age and older (NP)(Initial, Reauth): Member is 18 years of age and older (IMFA)(Initial, Reauth): Member is 1 year of age and older
Prescriber Restrictions	(PAA)(Initial, Reauth): Prescribed by or in consultation with an Allergist, Immunologist, or Pulmonologist. (CU)(Initial, Reauth): Prescribed by or in consultation with allergist/immunologist, dermatologist. (NP)(Initial, Reauth): Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or ENT specialist. (IMFA)(Initial, Reauth): Prescribed by or in consultation with an Allergist or Immunologist
Coverage Duration	(Initial): 12 months. (Reauth): 12 months.

PA Criteria	Criteria Details
Other Criteria	Subject to Part B vs Part D review. IgE-Mediated Food Allergy (IMFA) (Initial): (1) One of the following: (A) Both of the following (i) Diagnosis of IgE-Mediated Food Allergy (ii) Clinical history of IgE Mediated Food Allergy (B) Documentation that the member has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods (2) Used in conjunction with food allergen avoidance (3) Both of the following (A) Baseline (pre- Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL (B) Dosing is according to serum total IgE levels and body weight (PAA)(Reauth): (1) Documentation of positive clinical response to therapy (e.g. reduction in number of asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), or decreased use of rescue medications). (CU)(Reauth): (1) Member's disease status has been re- evaluated since the last authorization to confirm the member's condition warrants continued treatment (2) member has experienced one or both of the following: (a) Reduction in itching severity from baseline (b) Reduction in number of hives from baseline. (NP)(Reauth): (1) Documentation of positive clinical response to therapy (e.g. reduction in nasal polyps score [NPS: 0-8 scale], improvement in nasal congestion/obstruction score [NCS: 0-3 scale]) (2) Used in combination with another agent for nasal polyps. (IMFA)(Reauth) (1) Documentation of positive clinical response to therapy (2) Used in conjunction with food allergen avoidance. (3) Dosing will continue to be based on body weight and pretreatment total IgE serum levels
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XYREM

Products Affected

- *sodium oxybate*
- XYREM

PA Criteria	Criteria Details
Exclusion Criteria	CN, EDSN (Initial, Reauth): Concurrent use of sedative hypnotics and alcohol
Required Medical Information	Cataplexy in Narcolepsy (CN)(Initial): (1) Diagnosis of cataplexy in narcolepsy, (2) Diagnosis Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT) or prescriber provides justification that a sleep study is not feasible. Excessive Daytime Sleepiness in Narcolepsy (EDSN)(Initial): (1) Diagnosis of EDSN (Narcolepsy Type 2), (2) Diagnosis Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT) or prescriber provides justification that a sleep study is not feasible and (3) Inadequate response or inability to modafinil or armodafinil. (adult use only)
Age Restrictions	
Prescriber Restrictions	(CN, EDSN)(Initial, Reauth): Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist.
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(CN, EDSN)(Reauth): (1) Documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale), (2) Member is re-evaluated every 12 months.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XYWAV

Products Affected

- XYWAV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cataplexy in Narcolepsy (CN)(Initial): (1) Diagnosis of cataplexy in narcolepsy. Excessive Daytime Sleepiness in Narcolepsy (EDSN)(Initial): (1) Diagnosis of EDSN (Narcolepsy Type 2), (2) Inadequate response or inability to modafinil. Idiopathic Hypersomnia (IH) (Initial): (1) Diagnosis of Idiopathic Hypersomnia as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), (2) Symptoms of excessive daytime sleepiness (e.g. nap duration of longer than 60 minutes) are present
Age Restrictions	
Prescriber Restrictions	(CN, EDSN, IH)(Initial, Reauth): Prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist.
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(CN, EDSN)(Reauth): (1) Documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale), (2) Member is re-evaluated every 12 months. (IH) (Reauth): (1) Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZAVESCA

Products Affected

- *miglustat*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Type 1 Gaucher's Disease (T1GD): (1) Diagnosis of mild to moderate T1GD, (2) enzyme replacement therapy is not a therapeutic option (e.g. because of allergy, hypersensitivity, or poor venous access).
Age Restrictions	(T1GD): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZEPOSIA

Products Affected

- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- ZEPOSIA STARTER KIT ORAL CAPSULE THERAPY PACK 0.23MG &0.46MG 0.92MG(21)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS): (1) Diagnosis of relapsing form of multiple sclerosis (MS) (e.g. clinically isolated syndrome, relapsingremitting disease, secondary progressive disease, including active disease with new brain lesions) and inadequate response or inability to tolerate two of the following medications: (a) Avonex (interferon beta-1a), (b) Plegridy (peginterferon beta-1a), (c) Betaseron (interferon beta-1b), (d) Glatopa (glatiramer acetate), (e) Tecfidera (Dimethyl Fumarate), (f) Gilenya (fingolimod), (g) Aubagio (teriflunomide), or (h) Rebif (interferon beta 1a), OR documentation demonstrating that a trial may be inappropriate. Ulcerative Colitis (UC): (1) Diagnosis of ulcerative colitis, (2) Inadequate response or inability to tolerate TWO of the following (a) Humira (b) Xeljanz/Xeljanz XR (c) Stelara (d) Rinvoq (e) Cyltezo, (f) Yuflyma, (g) Skyrizi OR documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(MS) (UC): Member is 18 years of age or older
Prescriber Restrictions	UC): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZOKINVY

Products Affected

- ZOKINVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hutchinson-Gilford Progeria Syndrome (HGPS): (1) Diagnosis of Hutchinson-Gilford Progeria Syndrome. (2) Member has a body surface are of 0.39 m2 or above. Processing-deficient Progeroid Laminopathies (PDPL): (1) For treatment of processing-deficient Progeroid Laminopathies. (2) One of the following: (a) Heterozygous LMNA mutation with progerin-like protein accumulation (b) Homozygous or compound heterozygous ZMPSTE24 mutations. (3) Member has a body surface are of 0.39 m2 or above
Age Restrictions	(HGPS, PDPL): Member is 12 months of age or older
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZTALMY

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(CDKL5): (1) Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (2) Documentation of mutation in the CDKL5 gene (3) member is experiencing motor seizures (e.g., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal, or bilateral tonic-clonic) (4) Inadequate response or inability to tolerate two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine)
Age Restrictions	(CDKL5): Member is 2 years of age or older
Prescriber Restrictions	(CDKL5): Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	Approve if for continuation of therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZURZUVAE

Products Affected

- ZURZUVAE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(PPD): (1) Diagnosis of Postpartum depression (PPD) (2) Inadequate response or inability to tolerate (a) one generic Selective serotonin reuptake inhibitor (SSRI) (b) One generic Serotonin-Norepinephrine reuptake inhibitor (SNRI) (3) Medication will not be used for greater than 14 days
Age Restrictions	(PPD): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	14 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Index