Keystone 65 Rx HMO
Personal Choice℠ 65 Rx PPO
Select Option® Rx PDP
2025 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 **10/01/2024.** 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, 2026, and from time to time during the year.

Independence Blue Cross offers HMO and HMO-POS Medicare Advantage plans with a Medicare contract. Enrollment in Independence Blue Cross HMO and HMO-POS Medicare Advantage plans depends on contract renewal.

Independence Blue Cross offers products through its subsidiaries Independence Assurance Company, Independence Hospital Indemnity Plan, Keystone Health Plan East, and QCC Insurance Company — 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 *2025 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 *2025 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 321. 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 2025

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 2025

Products Affected

- *hydrocodone bitartrate er oral capsule extended release 12 hour*
- *hydrocodone bitartrate er oral tablet er 24 hour abuse-deterrent*
- HYSINGLA ER
- NUCYNTA ER
- OXYCONTIN ORAL TABLET ER 12 HOUR ABUSE-DETERRENT
- ROXYBOND
- 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 2025

Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	(PJIA, SJIA, RA, GCA, SSc-ILD): Concurrent therapy with other biologic disease modifying anti-rheumatic 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 (i.e. Humira, Adulimumab-ADBM), (b) etanercept (Enbrel), (c) Xeljanz, (d) Orencia, 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) Adalimumab (i.e., Humira, Adulimumab-ADBM), (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, 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

PA Criteria	Criteria Details
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ACTHAR HP 2025

Products Affected

- ACTHAR
- ACTHAR GEL
- 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.

PA Criteria	Criteria Details
Required Medical Information	Part D is medically necessary when ONE of the following is present: (1) Infantile Spasms (IS): (A) Diagnosis of IS. (B) Dosing for infantile spasms (West Syndrome) is in accordance with the United States Food and Drug Administration (FDA) approved labeling: not to exceed 150U/m2 daily (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) (D) Member is new to therapy with corticotropin OR member's multiple sclerosis exacerbations have been treated in the past with corticotropin AND member has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis AND medication is being used to treat a new exacerbation of multiple sclerosis. (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).
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
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

PA Criteria	Criteria Details
Other Criteria	Subject to Part B vs Part D review. (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. (E) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (F) Member does not have uremia of the idiopathic type (8) Systemic Lupus Erythematosus (SLE): (A) Diagnosis of SLE (B) Inadequate response or inability to tolerate two systemic steroids (e.g. prednisone, methylprednisolone). (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 such as Keratitis, Iritis, Iridocyclitis, Diffuse posterior uveitis and choroiditis, Optic neuritis, Chorioretinitis, Anterior segment inflammation, (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). (15) Edematous state: To induce a diuresis or a remission of proteinuria due to lupus erythematosus (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 2025 - Pending CMS Review

Products Affected

- BERINERT
- FIRAZYR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- *icatibant acetate subcutaneous solution prefilled syringe*
- RUCONEST
- 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, pulmonologist, or immunologist
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ACUTE SEIZURE ACTIVITY AGENTS 2025

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 NON-PREFERRED PRODUCTS 2025

Products Affected

- ABRILADA (1 PEN)
- ABRILADA (2 SYRINGE)
- *adalimumab-aacf (2 pen)*
- *adalimumab-aaty (1 pen) subcutaneous auto-injector kit 80 mg/0.8ml*
- *adalimumab-aaty (2 pen)*
- *adalimumab-aaty (2 syringe)*
- *adalimumab-adaz*
- *adalimumab-adbm (2 pen)*
- *adalimumab-adbm(cd/uc/hs strt)*
- *adalimumab-adbm(ps/uv starter)*
- *adalimumab-fkjp (2 pen)*
- *adalimumab-fkjp (2 syringe)*
- *adalimumab-ryvk (2 pen)*
- *adalimumab-ryvk (2 syringe)*
- AMJEVITA
- AMJEVITA-PED 10KG TO <15KG
- AMJEVITA-PED 15KG TO <30KG
- CYLTEZO (2 PEN)
- CYLTEZO (2 SYRINGE)
- CYLTEZO-CD/UC/HS STARTER
- CYLTEZO-PSORIASIS/UV STARTER
- HADLIMA
- HADLIMA PUSHTOUCH
- HULIO (2 PEN)
- HULIO (2 SYRINGE)
- HYRIMOZ
- HYRIMOZ-CROHNS/UC STARTER
- HYRIMOZ-PED<40KG CROHN STARTER
- HYRIMOZ-PED>/=40KG CROHN START
- HYRIMOZ-PLAQ PSOR/UVEIT START
- IDACIO (2 PEN)
- IDACIO (2 SYRINGE)
- IDACIO-CROHNS/UC STARTER
- IDACIO-PSORIASIS STARTER
- SIMLANDI (2 PEN)
- 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

PA Criteria	Criteria Details
Required Medical Information	Rheumatoid Arthritis (RA): (1) Diagnosis of moderate to severe RA. (2) Inadequate response or inability to tolerate TWO of the following: (a) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, 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) Cosentyx, (b) Adalimumab (i.e. Humira, Adulimumab-ADBM), (c) Enbrel, (d) Xeljanz/Xeljanz XR, (e) Rinvoq, or documentation demonstrating that a trial may be inappropriate. Juvenile Idiopathic Arthritis (JIA): (1) Diagnosis of moderate to severe JIA (2) Inadequate response or inability to tolerate TWO of the following: (a) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Xeljanz, (d) Orencia, 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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Xeljanz/Xeljanz XR (d) Rinvoq, (e) Skyrizi, (f) Cosentyx, (g) Stelara, (h) Orencia, (i) Otezla, OR documentation demonstrating that a trial may be inappropriate. Plaque Psoriasis (PsO): (1) Diagnosis of moderate to severe chronic PsO. (2) Inadequate response or inability to tolerate TWO of the following: (a) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Skyrizi (d) Cosentyx, (e) Stelara, (f) Otezla, OR documentation demonstrating that a trial may be inappropriate.
Age Restrictions	
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 TWO of the following: (a) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Stelara, (c) Skyrizi, (d) Rinvoq or documentation demonstrating that a trial may be inappropriate. Ulcerative Colitis (UC): (1) Diagnosis of UC. (2) Inadequate response or inability to tolerate TWO of the following: (a) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Stelara, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, OR documentation demonstrating that a trial may be inappropriate. Hidradenitis Suppurativa (HS): (1) Diagnosis of HS (2) Inadequate response or inability to tolerate Cosentyx AND one of the following: (a) Adalimumab (i.e. Humira, Adulimumab-ADBM), OR documentation demonstrating that a trial may be inappropriate. Uveitis (UV) (1) Diagnosis of non-infectious intermediate, posterior, or pan- uveitis. (2) Inadequate response or inability to tolerate BOTH of the following: (a) corticosteroid or immunosuppressive drug (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate), AND (b) One of the following: (i) Adalimumab (i.e. Humira, Adulimumab-ADBM) OR documentation demonstrating that a trial may be inappropriate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ADALIMUMAB PREFERRED PRODUCTS 2025

Products Affected

- *adalimumab-adbm (2 pen)*
- *adalimumab-adbm (2 syringe)*
- *adalimumab-adbm(cd/uc/hs strt)*
- *adalimumab-adbm(ps/uv starter)*
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- YUFLYMA (2 SYRINGE)

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, leflunomide, 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): (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 2025

Products Affected

- ADBRY SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

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 TWO of the following: (a) one topical steroid (medium potency or higher) (b) topical tacrolimus (c) Eucrisa (crisaborole) ointment (d) Pimecrolimus cream
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

ADEMPAS 2025

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 as evaluated by a cardiologist or pulmonologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AFREZZA 2025

Products Affected

- AFREZZA INHALATION POWDER 12 UNIT, 4 UNIT, 60X4 &60X8 & 60X12 UNIT, 8 UNIT, 90 X 4 UNIT & 90X8 UNIT, 90 X 8 UNIT & 90X12 UNIT

PA Criteria	Criteria Details
Exclusion Criteria	(DM1, DM2) (Initial, Reauth): Member has chronic lung disease such as asthma or chronic obstructive pulmonary disease
Required Medical Information	Type 1 Diabetes Mellitus (DM1) (Initial): (1) Diagnosis of type 1 diabetes mellitus, (2) Used in combination with a long-acting insulin (e.g. Lantus), (3) Documented FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician, (4) Spirometry (FEV1) has been completed prior to initiation of therapy to identify potential lung disease (must provide the result). Type 2 Diabetes Mellitus (DM2) (Initial): (1) Diagnosis of type 2 diabetes mellitus, (2) Documented FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician, (3) Inadequate response or inability to tolerate one of the following: Novolin, Novolog, Humalog, Humulin, Insulin Lispro.
Age Restrictions	(DM1, DM2) (Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	(Initial): 6 months (Reauth): Indefinite
Other Criteria	(DM1, DM2)(Reauth): (1) Spirometry value (FEV1) that has not declined greater than or equal to 20% from baseline. (2) Documentation of positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AGAMREE 2025

Products Affected

- AGAMREE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(DMD)(Initial): (1) Diagnosis of Duchenne muscular dystrophy (DMD) (2) Member has received genetic testing for a mutation of the dystrophin gene (3) One of the following: (a) Member has a confirmed mutation of the dystrophin gene (b) Muscle biopsy confirmed an absence of the dystrophin gene) (4) Inadequate response or inability to tolerate ONE of the following: (a) prednisone (b) prednisolone (5) One of the following: (a) for members less than or equal to 50kg, dose will not exceed 6mg/kg of body weight once daily (b) For members greater than 50kg, dose will not exceed 300mg/day
Age Restrictions	
Prescriber Restrictions	(DMD) (Initial, Reauth): Prescribed by or in consultation with a neurologist who has experience treating children with DMD.
Coverage Duration	(DMD) (Initial, Reauth): 12 months
Other Criteria	(DMD)(Reauth): (1) Member has experienced a benefit from therapy (e.g., improvement or preservation of muscle strength) (2) One of the following: (a) for members less than or equal to 50kg, dose will not exceed 6mg/kg of body weight once daily (b) For members greater than 50kg, dose will not exceed 300mg/day
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AIMOVIG 2025

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 or contraindication to 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, (f) candesartan 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 or contraindication to 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 (vi) candesartan.
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	

PA Criteria	Criteria Details
Part B Prerequisite	No

AJOVY 2025

Products Affected

- AJOVY

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 or contraindication to of Aimovig or Emgality. 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 or contraindication to Aimovig or Emgality.
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 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) 2025

Products Affected

- GRASTEK
- ODACTRA

PA Criteria	Criteria Details
Exclusion Criteria	(Initial): (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

ALVAIZ 2025

Products Affected

- ALVAIZ

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. 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, 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):12mo (RSAA)(Initial):6mo (HEPC-TP)(Initial):3mo (ITP,RSAA,HEPC-TP)(Continuation):12mo

PA Criteria	Criteria Details
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. 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 Alvaiz 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) documentation that member reached a threshold platelet count that allows initiation of antiviral interferon therapy with Alvaiz treatment by week 9. OR (B) For members that started treatment with Alviaz 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

AMBRISENTAN 2025

Products Affected

- *ambrisentan*

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

AMPYRA 2025

Products Affected

- AMPYRA

PA Criteria	Criteria Details
Exclusion Criteria	MS (Initial): 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): Documentation of positive clinical response as evidenced by improvement in walking speed
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ANTICHOLINERGIC HRM 2025

Products Affected

- *chlordiazepoxide-clidinium*
- LIBRAX
- *orphenadrine citrate er*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- *promethazine vc*
- 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 Poly-ACH DUR- 1 year
Other Criteria	Subject to additional clinical review for ESRD-related use - if applicable. Subject to additional clinical review for Poly-ACH cDUR related use - if applicable. (1) The drug is being prescribed for a medically accepted indication (2) The prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) (3) The prescriber will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the member
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ANTIDEPRESSANTS [SSRIS] ACH 2025

Products Affected

- PAXIL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Trial of three generic formulary selective serotonin reuptake inhibitors (SSRI). Applies to new starts.
Age Restrictions	POLY-ACH DUR: Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	PA: Indefinite Poly-ACH DUR: 1 year
Other Criteria	Subject to additional clinical review for Poly-ACH cDUR related use - if applicable. (1) The drug is being prescribed for a medically accepted indication (2) The prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) (3) The prescriber will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the member
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

APOKYN 2025

Products Affected

- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE
- *apomorphine hcl subcutaneous*

PA Criteria	Criteria Details
Exclusion Criteria	(PD): Member 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 2025

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 have not achieved 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 2025

Products Affected

- *armodafinil*
- NUVIGIL

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). (2) Both of the following (a): 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study is not feasible) AND (b) One of the following symptoms: Unintentional sleep episodes during wakefulness, or daytime sleepiness, or unrefreshing sleep, or fatigue, or insomnia, or waking up breath holding, gasping, or choking, or loud snoring, or breathing interruptions during sleep. 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	

PA Criteria	Criteria Details
Part B Prerequisite	No

AUSTEDO 2025

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

AUTHORIZED GENERICS-AUTHORIZED BRAND ALTERNATIVES 2025

Products Affected

- *dapagliflozin pro-metformin er*
- *dapagliflozin propanediol*
- *fluticasone furoate-vilanterol inhalation aerosol powder breath activated 100-25 mcg/act, 200-25 mcg/act*
- *fluticasone-salmeterol inhalation aerosol*
- *mirabegron er*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(1) At least 3 months of use of the brand product within the previous 365 days (document drug, duration, dose and date of use) (2) Both of the following: (a) Documentation provided stating that brand product has not been effective (b) Justification provided for why the target drug is expected to provide benefit when the brand product has not been shown to be effective. (3) One of the following: Requested drug is FDA-approved for the condition being treated OR if requested for an off-label indication, the off-label guideline approval criteria have been met
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Until end of the contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AUVELITY 2025

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 2025

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 2025

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

BIMZELX 2025

Products Affected

- BIMZELX

PA Criteria	Criteria Details
Exclusion Criteria	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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Skyrizi (d) Cosentyx, (e) Stelara, (f) Otezla, 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 or rheumatologist.
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BRAND ANTIPSYCHOTICS ACH 2025 - Pending CMS Review

Products Affected

- LYBALVI
- ZYPREXA ORAL
- ZYPREXA ZYDIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Trial of two generic formulary antipsychotics. Applies to new starts.
Age Restrictions	POLY-ACH DUR: Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	PA: Indefinite Poly-ACH DUR: 1 year
Other Criteria	Subject to additional clinical review for Poly-ACH cDUR related use - if applicable. (1) The drug is being prescribed for a medically accepted indication (2) The prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) (3) The prescriber will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the member
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BRAND ORAL FENTANYL 2025

Products Affected

- *fentanyl citrate buccal tablet 200 mcg, 400 mcg, 600 mcg, 800 mcg*
- FENTORA BUCCAL TABLET 100 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cancer Pain (CP): (1) Pain associated with cancer, (2) long-acting pain medication regimen, (3) member is opioid tolerant (e.g. at least one week where total daily dose is at least one of the following: 25mcg of transdermal fentanyl hourly, 30mg of oxycodone daily, 60mg of oral morphine daily, 8mg of oral hydromorphone daily, 25mg of oral oxymorphone daily or an equianalgesic dose of another opioid), AND (4) inadequate response to a generic oral transmucosal fentanyl citrate product for brand oral fentanyl
Age Restrictions	
Prescriber Restrictions	(CP): Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BYLVAY 2025

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 (4) An inadequate response or inability to tolerate at least ONE 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). 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	(PPFIC, CPALGS)(Initial): 6mo (PPFIC)(Reauth): Indefinite (CPALGS)(Reauth): End of contract year

PA Criteria	Criteria Details
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	
Part B Prerequisite	No

CAMZYOS 2025

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 2025

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 2025

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	Prescribed by or in consultation with a provider who specializes in the treatment of metabolic disorders
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CAYSTON 2025

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	Reauth: (1) Evidence of Pseudomonas aeruginosa in the lungs (2) Documentation of positive clinical response to therapy (e.g. improvement in lung function demonstrated by improved FEV1)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CERDELGA 2025

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 2025

Products Affected

- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	(BASD, PD)(Initial, Reauth): 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 2025

Products Affected

- CIALIS ORAL TABLET 5 MG
- *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 2025

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 member has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies: Adbry (tralokinumab-ldrm) AND Dupixent (dupilumab) 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 2025

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 (i.e., Humira, Adulimumab-ADBM), (c) etanercept (Enbrel), (d) tofacitinib (Xeljanz/Xeljanz XR), (e) upadacitinib (Rinvoq), 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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (, (b) Enbrel, (c) Xeljanz/Xeljanz XR (d) Rinvoq, (e) Skyrizi, (f) Cosentyx, (g) Stelara, (h) Orencia, (i) Otezla 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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Skyrizi (d) Cosentyx, (e) Stelara, (f) Otezla 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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia 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 (i.e., Humira, Adulimumab-ADBM), (b) ustekinumab (Stelara), (c) risankizumab (Skyrizi), (d) upadacitinib (Rinvoq) 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 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, nr-axSpA): Member is 18 years of age or older

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

CINRYZE 2025

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 2025

Products Affected

- *ibuprofen-famotidine*
- *naproxen-esomeprazole mg*
- VIMOVO

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 2025 - Pending CMS Review

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 2 of the following therapies: (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. (c) maximally tolerated doses of Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g. Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)] (d) maximally tolerated doses of mineralocorticoid receptor antagonist (MRA) [e.g. eplerenone, spironolactone] 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 SQ 2025 - Pending CMS Review

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 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	

PA Criteria	Criteria Details
Part B Prerequisite	No

CRESEMBA [ORAL] 2025

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 2025

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	Prescribed by or in consultation with an ophthalmologist or a specialist with experience in treating cystinosis with corneal cystine crystal accumulation
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DALFAMPRIDINE 2025

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	MS (Initial): 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.
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): Documentation of positive clinical response as evidenced by improvement in walking speed
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DAYBUE 2025

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 2025

Products Affected

- DAYVIGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Insomnia: (1) Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. (2) Inadequate response or inability to tolerate generic ramelteon (Rozerem) AND Belsomra (suvorexant).
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 2025 - Pending CMS Review

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	(NTDT, CIO-BT)(Initial, Continuation): GFR is less than 40mL/min/1.73m, platelet counts less than 50,000/mcL
Required Medical Information	Chronic Iron Overload in Non transfusion-dependent thalassemia (NTDT) (Initial): (1) Diagnosis of Chronic iron overload in Non transfusion-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	

PA Criteria	Criteria Details
Part B Prerequisite	No

DIACOMIT 2025

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

DICHLORPHENAMIDE 2025

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	One of the following (1) Diagnosis of Primary hyperkalemic periodic paralysis, (2) Diagnosis of Primary hypokalemic periodic paralysis (3) Diagnosis of Paramyotonia Congenita with periodic paralysis
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

DICLOFENAC 3% PRODUCTS 2025

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 2025

Products Affected

- *diclofenac epolamine external*
- FLECTOR EXTERNAL
- LICART 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 2025

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 (3) Not used with any other medium-chain triglyceride (MCT) product (4) Disease has been confirmed by at least two of the following: Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma, Low enzyme activity in cultured fibroblasts, one or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g. geneticist, cardiologist, gastroenterologist, etc.)
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DOPTELET 2025

Products Affected

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Liver Disease (CLD): (1) Diagnosis of Chronic Liver Disease (CLD) (2) 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 2025

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent therapy with any other biologic agents
Required Medical Information	Atopic Dermatitis (AD): (1) Diagnosis of moderate-severe atopic dermatitis. (2) inadequate response or inability to tolerate TWO 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) 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, (3) 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 (b) (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).
Age Restrictions	(Asthma)(Initial, Reauth): Member is 6 years old or older. (AD): Member is 6 months of age or older. (CRSwNP)(PN)(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	(AD): Prescribed by/in consultation with a dermatologist, allergist, immunologist (Asthma)(Initial, Reauth): Prescribed by/in consultation with an allergist, immunologist or pulmonologist (CRSwNP)(Initial, Reauth): Prescribed by/in consultation with an allergist, immunologist or ENT specialist (EoE)(Initial, Reauth): Prescribed by/in consultation with gastroenterologist, allergist, or immunologist (PN)(Initial, Reauth): Prescribed by/in consultation with allergists/immunologist or dermatologist
Coverage Duration	(AD): Indefinite (Asthma, CRSwNP, EoE, PN) (Initial): 12 months (Reauth): 12 months
Other Criteria	Prurigo Nodularis (PN)(Initial): (1) Diagnosis of Prurigo Nodularis (PN) (2) inadequate response or inability to tolerate one medium or higher potency topical corticosteroid. (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)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DUVYZAT 2025

Products Affected

- DUVYZAT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Duchenne muscular dystrophy (DMD) (Initial): (1) Diagnosis of Duchenne muscular dystrophy (DMD) (2) Diagnosis confirmed by ONE of the following: (a) Mutation of the dystrophin gene (b) Absence of the dystrophin protein confirmed by muscle biopsy (3) Member is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to initiating Duvyzat (4) Duvyzat will be used concomitantly with a corticosteroid regimen
Age Restrictions	
Prescriber Restrictions	(DMD) (Initial) (Reauth): Prescribed by or in consultation with a neurologist who has experience treating children with Duchenne Muscular Dystrophy (DMD)
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(DMD) (Reauth): (1) Member has experienced a benefit from therapy (e.g., improvement in preservation of muscle strength) (2) Member is maintaining ambulatory status without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) (3) Member continues to receive concomitant corticosteroid regimen.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EGRIFTA 2025

Products Affected

- EGRIFTA SV

PA Criteria	Criteria Details
Exclusion Criteria	(HIV-L): (1) hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, or head irradiation or trauma, (2)hypersensitivity to tesamorelin and/or mannitol, (3)malignancy, active (either newly diagnosed or recurrent) malignancies should be inactive and completely treated prior to initiating therapy, (4)pregnancy.
Required Medical Information	HIV-Associated Lipodystrophy (HIV-L): (1) Diagnosis of HIV-associated lipodystrophy, (2) one of the following: (a) waist-circumference of greater than or equal to 95 cm (37.4 inches) in men, OR (b) waist-circumference of greater than or equal to 94 cm (37 inches) for women, (3) one of the following: (a) Waist-to-hip ratio of greater than or equal to 0.94 for men, OR (b) waist-to-hip ratio of greater than or equal to 0.88 for women, (4) body mass index (BMI) greater than 20 kg/m2, (5) fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L), (6) Member has been on a stable regimen of antiretrovirals (e.g. NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks.
Age Restrictions	
Prescriber Restrictions	(HIV-L): Prescribed by or in consultation with HIV-infection specialist OR endocrinologist.
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EMFLAZA 2025

Products Affected

- *deflazacort*
- EMFLAZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Duchenne Muscular Dystrophy (DMD): (1) Diagnosis of Duchenne Muscular Dystrophy (DMD) (2) Diagnosis confirmed by ONE of the following: (a) Mutation of the dystrophin gene (b) Absence of the dystrophin protein confirmed by muscle biopsy (3) 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 2025

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 or contraindication to 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 or contraindication to 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 (vi) candesartan. 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.

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

EMSAM 2025

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 2025

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, Leflunomide, 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	

PA Criteria	Criteria Details
Part B Prerequisite	No

ENDARI 2025

Products Affected

- ENDARI
- *l-glutamine oral packet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Sickle Cell Disease (SCD)(Initial): (1) One of the following: (A) Member is using Endari 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	(SCD)(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 2025

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

ENTADFI 2025

Products Affected

- ENTADFI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Benign Prostatic Hyperplasia (BPH): (1) Diagnosis of Benign Prostatic Hyperplasia (BPH) (2) inadequate response or inability to tolerate one of the following generics (alfuzosin, doxazosin, tamsulosin, terazosin, silodosin) (3) Inadequate response or inability to tolerate one of the following: (a) 5-alpha-reductase inhibitor (i.e., finasteride 5mg, dutasteride) (b) phosphodiesterase type 5 inhibitor (i.e., tadalafil 2.5mg or 5mg)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	26 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EPIDIOLEX 2025

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. (3) Concurrent use with additional anti-epileptic(s). 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. (3) Concurrent use with additional anti-epileptic(s). 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

EPSOLAY 2025

Products Affected

- EPSOLAY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Rosacea): (1) Diagnosis of rosacea (2) Member has inflammatory lesions (3) inadequate response or inability to tolerate one of the formulary topical products for rosacea (e.g. azelaic acid gel, metronidazole cream or gel) for sufficient duration (minimum 30-day supply)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ESBRIET 2025

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 2025 - Pending CMS Review

Products Affected

- EUCRISA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis (AD): (1) Diagnosis of mild to moderate atopic dermatitis (2) Inadequate response or inability to tolerate at least ONE of the following in patients 2 years of age or older: (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 2025

Products Affected

- *amphetamine sulfate*
- EVEKEO

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 2025

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 (2) 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). (3) 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 2025

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 2025 - Pending CMS Review

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 6.5%. All Indications: (1) Inadequate response or inability to tolerate a 12 week trial of 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 2025

Products Affected

- EYSUVIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Dry Eye Disease (DED)(Initial): (1) Diagnosis of DED (2) Trial and failure for a minimum 14 days duration of therapy, contraindication, or intolerance to 0.5% loteprednol suspension
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

FABHALTA 2025

Products Affected

- FABHALTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Paroxysmal Nocturnal Hemoglobinuria (PNH) (Initial): (1) Diagnosis of PNH, (2) Member's Hemoglobin (Hb) level is less than 10 g/dL despite prior eculizumab (Soliris) or ravulizumab-cwvz (Ultomiris) therapy
Age Restrictions	
Prescriber Restrictions	(PNH) (Initial, Continuation): Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	(Initial): 6 months, (Continuation): 12 months
Other Criteria	(PNH) (Continuation): (1) Positive clinical response to therapy (e.g. improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FASENRA 2025 - Pending CMS Review

Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent therapy with any other biologic agents for asthma/allergic conditions (e.g. dupilumab [Dupixent], mepolizumab [Nucala], omalizumab [Xolair], reslizumab [Cinqair])
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

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

FENTANYL CITRATE LOZENGE 2025

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of all of the following: (1) pain associated with cancer, (2) long-acting pain medication regimen AND (3) member is opioid tolerant (e.g. at least one week where total daily dose is at least one of the following: 25mcg of transdermal fentanyl hourly, 30mg of oxycodone daily, 60mg of oral morphine daily, 8mg of oral hydromorphone daily, 25mg of oral oxymorphone daily or an equianalgesic dose of another opioid)
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FERRIPROX 2025 - Pending CMS Review

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	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FILSPARI 2025

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	

PA Criteria	Criteria Details
Part B Prerequisite	No

FILSUVEZ 2025

Products Affected

- FILSUVEZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(EB)(Initial): (1) Diagnosis of one of the following: (a) Dystrophic epidermolysis bullosa (DEB) (b) Junctional epidermolysis bullosa (JEB) (2) Disease is confirmed by one of the following: (a) genetic testing confirms mutation in one of the following genes: (i) for DEB, collagen type VII (COL7A1) (ii) For JEB, one of the following mutations (ITGA6, ITGB4, collagen type XVII (COL17A1), LAMA3, LAMB3, LAMC2, ITGA3, LAMA3A) (b) skin biopsy (3) Medication is being used for the treatment of wounds (4) Wounds associated with DEB or JEB are present for at least 21 days and less than 9 months old (5) Member does not have signs of infection for wound being treated (6) Member has no evidence or history of basal or squamous cell carcinoma for wound being treated (7) Member does not have history of stem cell transplant or gene therapy (i.e. Vyjuvek) for the treatment of epidermolysis bullosa
Age Restrictions	
Prescriber Restrictions	(EB) (Initial, Reauth): Prescribed by or in consultation with a dermatologist with expertise in the treatment of epidermolysis bullosa.
Coverage Duration	(EB)(Initial): 3 months, (Reauth): 6 months
Other Criteria	(EB)(Reauth): (1) member demonstrates positive clinical response to therapy (2) Member does not have signs of infection for wound being treated (3) Member has no evidence or history of basal squamous cell carcinoma for would being treated
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FINTEPLA 2025

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 2025

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 2025 - Pending CMS Review

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Fabry Disease (FD)(Initial): (1) Member has amenable galactosidase alpha gene (GLA) variant based on in vitro assay data (2) Will not be used in combination with enzyme replacement therapy for FD (e.g. agalsidase beta or pegunigalsidase alfa)
Age Restrictions	(FD)(Initial, Reauth): Member is 18 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): (1) Positive clinical response to therapy (2) Will not be used in combination with enzyme replacement therapy for FD (e.g. agalsidase beta or pegunigalsidase alfa)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GATTEX 2025

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 2025

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

GRALISE 2025

Products Affected

- *gabapentin (once-daily)*
- GRALISE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Post Herpetic Neuralgia (PHN): (1) Diagnosis of post herpetic neuralgia, (2) Inadequate response to gabapentin immediate release or pregabalin.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GROWTH HORMONES 2025 - Pending CMS Review

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 (e.g., 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

PA Criteria	Criteria Details
Coverage Duration	(Initial, Continuation): 12 months
Other Criteria	(GHDA)(Continuation): Annual clinical re-evaluation by the treating endocrinologist. (GFC)(Continuation): (1) Annual clinical re-evaluation by the treating endocrinologist (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 2025

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 2025

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 2025

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 2025

Products Affected

- BELBUCA BUCCAL FILM 300 MCG, 450 MCG, 600 MCG, 750 MCG, 900 MCG
- DILAUDID ORAL TABLET 4 MG, 8 MG
- *fentanyl transdermal patch 72 hour 100 mcg/hr, 25 mcg/hr, 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr*
- *fentanyl transdermal patch 72 hour 50 mcg/hr, 75 mcg/hr*
- *hydrocodone bitartrate er oral tablet er 24 hour abuse-deterrent*
- *hydromorphone hcl er oral tablet extended release 24 hour*
- *hydromorphone hcl oral tablet 4 mg, 8 mg*
- HYSINGLA ER
- *levorphanol tartrate oral tablet 3 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*
- MS CONTIN ORAL TABLET EXTENDED RELEASE 100 MG, 200 MG, 60 MG
- NUCYNTA ER
- NUCYNTA ORAL TABLET 100 MG, 75 MG
- *oxycodone hcl oral tablet 30 mg*
- OXYCONTIN ORAL TABLET ER 12 HOUR ABUSE-DETERRENT
- *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*
- ROXICODONE ORAL TABLET 30 MG
- ROXYBOND
- 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	

PA Criteria	Criteria Details
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	
Part B Prerequisite	No

HORIZANT 2025

Products Affected

- HORIZANT ORAL TABLET EXTENDED RELEASE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Postherpetic neuralgia (PHN): (1) Diagnosis of PHN and (2) Inadequate response or inability to tolerate gabapentin or pregabalin. Restless legs syndrome (RLS): (1) Diagnosis of RLS and (2) Inadequate response or inability to tolerate pramipexole or ropinirole.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM 2025

Products Affected

- ALLZITAL
- ASCOMP-CODEINE
- *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-asa-caff-codeine*
- *butalbital-aspirin-caffeine oral capsule*
- *carbinoxamine maleate oral solution*
- *carbinoxamine maleate oral tablet*
- *chlorzoxazone oral*
- *clemastine fumarate oral syrup*
- *clemastine fumarate oral tablet 2.68 mg*
- DEMEROL INJECTION SOLUTION 25 MG/ML, 50 MG/ML
- *dipyridamole oral*
- ESGIC ORAL TABLET
- FIORICET ORAL CAPSULE
- FIORICET/CODEINE ORAL CAPSULE 50-300-40-30 MG
- INDOCIN ORAL
- INDOCIN RECTAL
- *indomethacin oral suspension*
- *indomethacin rectal suppository 50 mg*
- *meperidine hcl injection solution 100 mg/ml, 25 mg/ml, 50 mg/ml*
- *meperidine hcl oral solution*
- *meperidine hcl oral tablet 50 mg*
- *meprobamate*
- *metaxalone*
- *pentazocine-naloxone hcl*
- *promethazine hcl oral solution*
- RYVENT
- TENCON ORAL TABLET 50-325 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	

PA Criteria	Criteria Details
Part B Prerequisite	No

HRM CYCLOBENZAPRINE 2025 - Pending CMS Review

Products Affected

- AMRIX
- *cyclobenzaprine hcl er*
- *cyclobenzaprine hcl oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute Muscle Spasms (AMS): (1) Diagnosis of Acute Muscle Spasms (AMS):(2) Prescriber attestation that drug will be used only for short periods. 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. Other dx: 2 yearsPoly-ACH DUR: 1 year
Other Criteria	Subject to additional clinical review for Poly-ACH cDUR related use - if applicable. (1) The drug is being prescribed for a medically accepted indication (2) The prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) (3) The prescriber will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the member
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM ESTROGENS 2025

Products Affected

- ACTIVELLA ORAL TABLET 1-0.5 MG
- ANGELIQ
- BIJUVA
- CLIMARA
- CLIMARA PRO
- DIVIGEL
- DOTTI
- ELESTRIN
- ESTRACE ORAL
- *estradiol transdermal*
- *estradiol-norethindrone acet*
- EVAMIST
- FYAVOLV
- JINTELI
- LYLLANA
- MENOSTAR
- MIMVEY
- MINIVELLE
- *norethindrone-eth estradiol*
- PREMARIN ORAL
- VIVELLE-DOT

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 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 2025

Products Affected

- *ketorolac tromethamine oral*
- SPRIX

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 2025

Products Affected

- AMBIEN CR ORAL TABLET EXTENDED RELEASE 12.5 MG
- AMBIEN ORAL TABLET 10 MG
- EDLUAR SUBLINGUAL TABLET SUBLINGUAL 10 MG
- *eszopiclone oral tablet 3 mg*
- *zolpidem tartrate er oral tablet extended release 12.5 mg*
- *zolpidem tartrate oral capsule*
- *zolpidem tartrate oral tablet 10 mg*
- *zolpidem tartrate sublingual tablet sublingual 3.5 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 2025

Products Affected

- NORGESIC
- *norgesic forte*
- *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 Poly-ACH DUR- 1 year
Other Criteria	Subject to additional clinical review for Poly-ACH cDUR related use - if applicable. (1) The drug is being prescribed for a medically accepted indication (2) The prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) (3) The prescriber will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the member
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HRM SHORT TERM SKELETAL MUSCLE RELAXANTS 2025 - Pending CMS Review

Products Affected

- *carisoprodol oral*
- FEXMID
- SOMA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute Muscle Spasms (AMS): (1) Diagnosis of Acute Muscle Spasms (AMS):(2) Prescriber attestation that drug will be used only for short periods. 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

HYFTOR 2025

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 2025

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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Skyrizi, (d) Cosentyx, (e) Stelara, (f) Otezla 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 2025

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 2025

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 AND (2) height standard deviation score less than or equal to -3.0 AND (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 2025

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	(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 (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 2025

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 2025

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

INSULIN GLARGINE 2025

Products Affected

- *insulin glargine max solostar*
- *insulin glargine solostar subcutaneous solution pen-injector 300 unit/ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(DM): (1) Diagnosis of Diabetes Mellitus (2) inadequate response or inability to tolerate two of the following: (a) brand Lantus (b) Toujeo (c) Tresiba (3) Documentation provided stating that the Brand products has not been effective (4) Justification provided for why the target drug is expected to provide benefit when the Brand products have not been shown to be effective
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INTRAVENOUS IMMUNE GLOBULINS (IVIG) 2025

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.

PA Criteria	Criteria Details
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	
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

PA Criteria	Criteria Details
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. (19) Infections in Low-birthweight Neonates when severe hypogammaglobulinemia (IgG greater than or equal to 400 mg/dL) is present. (20) Graves' Ophthalmopathy (21) Immune mediated Necrotizing Myopathy when resistant to treatment with glucocorticoids and immunosuppressants (22) Graves 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

IQIRVO 2025

Products Affected

- IQIRVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary biliary cholangitis (PBC)(Initial): (1) Diagnosis of primary biliary cholangitis (PBC) (also known as primary biliary cirrhosis) (2) One of the following: (a) Both of the following: (i) Member has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) (ii) Used in combination with ursodeoxycholic acid (UDCA) (b) History of contraindication or intolerance to ursodeoxycholic acid (UDCA)
Age Restrictions	
Prescriber Restrictions	(PBC)(Initial, Reauth): Prescribed by or in consultation with hepatologist or gastroenterologist
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(PBC)(Reauth): (1) Member demonstrates positive clinical response to therapy (e.g., ALP level less than 1.67 times ULN, total bilirubin less than or equal to ULN, ALP decrease greater than equal to 15 percent from baseline).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ISTURISA 2025

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 2025

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 2025

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

PA Criteria	Criteria Details
Other Criteria	(HoFH)(REAUTH): (1) Documentation of reduction in LDL level since initiation of therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

JYNARQUE 2025

Products Affected

- JYNARQUE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Autosomal Dominant Polycystic Kidney Disease (ADPKD): (Initial): (1) Diagnosis of autosomal dominant polycystic kidney disease with risk of rapidly progressing kidney disease (2) 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 2025

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 2025

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

KEVZARA 2025

Products Affected

- KEVZARA

PA Criteria	Criteria Details
Exclusion Criteria	(RA, PMR): 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 (i.e. Humira, Adulimumab-ADBM), (b) etanercept (Enbrel), (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia 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)
Age Restrictions	(RA, PMR): Member is 18 years of age or older
Prescriber Restrictions	(RA, PMR): 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 2025

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 (i.e. Humira, Adulimumab-ADBM), (b) etanercept (Enbrel), (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia 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 2025

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 2025

Products Affected

- 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
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 2025 - Pending CMS Review

Products Affected

- *lidocaine external patch 5 %*
- LIDOCAN
- LIDODERM
- 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

LITFULO 2025

Products Affected

- LITFULO

PA Criteria	Criteria Details
Exclusion Criteria	(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	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	(Alopecia Areata): Member is 12 years of age or older
Prescriber Restrictions	(AA): Prescribed by or in consultation with a dermatologist
Coverage Duration	(AA): Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LIVMARLI 2025

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 BOTH of the following: (A) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene AND (B) ONE of the following (i) total serum bile acid greater than 2 times upper limit of normal (ii) conjugated bilirubin greater than 1 mg/dl (iii) fat soluble vitamin deficiency otherwise unexplainable, or (iv) gamma-glutamyl transpeptidase (GGT) greater than 3 times upper limit of normal (3) Member is experiencing moderate to severe cholestatic pruritis (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	(CPALGS): Member is 3 months of age or older
Prescriber Restrictions	(CPALGS) (Initial, Reauth): Prescribed by or in consultation with a gastroenterologist or hepatologist.
Coverage Duration	(CPALGS)(Initial): 6 months (CPALGS)(Reauth): End of contract year
Other Criteria	(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	
Part B Prerequisite	No

LIVTENCITY 2025 - Pending CMS Review

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 (3) Oncology
Coverage Duration	8 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LODOCO 2025

Products Affected

- LODOCO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(CV)(Initial): (1) Diagnosis of cardiovascular disease (CV) (2) Used for the secondary prevention of CV disease (e.g. very high risk patients) (3) Member is on guideline therapy management for multiple risk factors (e.g. dyslipidemia, hypertension, hyperglycemia) associated with CV disease
Age Restrictions	(CV)(Initial, Reauth): Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	(Initial, Reauth): 6 months
Other Criteria	(CV)(Reauth): (1) Documentation of positive clinical response is provided
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LUMRYZ 2025

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 tolerate BOTH of the following: (a) modafinil or armodafinil and (b) one stimulant based product
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

LYRICA CR 2025

Products Affected

- LYRICA CR
- *pregabalin er*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neuropathic Pain Associated with Diabetic Peripheral Neuropathy (DPN): (1) Diagnosis of neuropathic pain associated with diabetic peripheral neuropathy, (2) inadequate response or inability to tolerate gabapentin or pregabalin. Post-Herpetic Neuralgia (PHN): (1) Diagnosis of post-herpetic neuralgia (2) inadequate response or inability to tolerate gabapentin or pregabalin.
Age Restrictions	(DPN, PHN): 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

METFORMIN IR 2025

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

MODAFINIL 2025 - Pending CMS Review

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). (2) Both of the following (a): 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study is not feasible) AND (b) One of the following symptoms: Unintentional sleep episodes during wakefulness, or daytime sleepiness, or unrefreshing sleep, or fatigue, or insomnia, or waking up breath holding, gasping, or choking, or loud snoring, or breathing interruptions during sleep. 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 (All Indications): Inadequate response or inability to tolerate generic modafinil
Age Restrictions	
Prescriber Restrictions	(Narcolepsy, SWSD, OSAHS): Prescribed by or in consultation with a neurologist or sleep specialist.
Coverage Duration	Indefinite
Other Criteria	

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

MULPLETA 2025

Products Affected

- MULPLETA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Liver Disease (CLD): (1) Diagnosis of Chronic Liver Disease (CLD) (2) Member is scheduled to undergo a procedure (3) 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 2025

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 2025

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 2025

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 Non menstrual pelvic pain) (2) Treatment duration of therapy has not exceeded a total of 24 months

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

MYTESI 2025

Products Affected

- MYTESI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Noninfectious Diarrhea associated with HIV/AIDS (NID): (1) Diagnosis of HIV/AIDS and member is on antiretroviral therapy. (2) Member requires symptomatic relief of non-infectious diarrhea. (3) Inadequate response or inability to tolerate at least one anti-diarrheal medication (e.g. loperamide, atropine/diphenoxylate, etc.). (4) Infectious diarrhea (e.g. cryptosporidiosis, C. Difficile, etc.) has been ruled out.
Age Restrictions	(NID): 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

NEXLETOL/NEXLIZET 2025

Products Affected

- NEXLETOL
- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Heterozygous Familial Hypercholesterolemia (HeFH) OR Atherosclerotic Cardiovascular Disease (ASCVD) (Initial): (1) One of the following: (A) Diagnosis of HeFH, OR (B) Diagnosis of 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 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	(HeFH, ASCVD) (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)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NGENLA 2025

Products Affected

- NGENLA

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) (b) Growth velocity is greater than 2 SD below mean for age and gender (c) 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) (2) documentation of bone age, (3) abnormal response from provocative testing, such as insulin-induced hypoglycemia test, levodopa, or clonidine.
Age Restrictions	(GFC) (Initial, Continuation): Member is 3 years of age or greater.
Prescriber Restrictions	(GFC) (Initial, Continuation): 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 (2) Growth velocity greater than or equal to 2.5 cm/year.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NON-ORAL ANTIBIOTICS 2025

Products Affected

- DALVANCE
- NUZYRA
- SIVEXTRO
- VABOMERE
- ZEMDRI
- ZERBAXA

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 2025

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 GLP-1 AGONISTS 2025

Products Affected

- BYDUREON BCISE
- BYETTA 10 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR
- BYETTA 5 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SOLIQUA
- XULTOPHY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(DM2): (1) One of the following: (a) For members requiring ongoing treatment for type 2 diabetes mellitus, submission of medical records (e.g. chart notes) confirming diagnosis of type 2 diabetes mellitus (b) Submission of medical records (e.g. chart notes) confirming diagnosis of type 2 diabetes mellites as evidenced by one of the following laboratory values (i) A1C greater than or equal to 6.5 percent (ii) Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL (iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test) (2) Inadequate response or inability to tolerate a minimum 90 day-supply of two of the following preferred brands: Ozempic, Trulicity, Rybelsus, Mounjaro, Victoza
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NON-PREFERRED HEPATITIS C AGENTS 2025

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 2025

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 2025 - Pending CMS Review

Products Affected

- NOXAFIL ORAL
- *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).
Age Restrictions	(TAI): 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 2025

Products Affected

- NOXAFIL ORAL

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 2025

Products Affected

- NUCALA

PA Criteria	Criteria Details
Exclusion Criteria	(SA, EGPA, CRSwNP) Concurrent therapy with any 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 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 intranasal corticosteroid for CRSwNP.

PA Criteria	Criteria Details
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.
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. Hyper eosinophilic 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 intranasal corticosteroid for CRSwNP.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

NUEDEXTA 2025 - Pending CMS Review

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	(PBA): Presence of Prolonged QT interval, Congential long QT Syndrome, or Torsades de pointes 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 2025

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 2025

Products Affected

- NURTEC

PA Criteria	Criteria Details
Exclusion Criteria	(AM)(Initial, Reauth): Medication will be used in combination with another oral CGRP inhibitor. (MP) (Initial, Reauth): 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, (f) (candesartan).
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 2025

Products Affected

- OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary biliary cholangitis (PBC): (1) Diagnosis of Primary biliary cholangitis (PBC) (2) Used in combination with ursodeoxycholic acid (e.g. Urso, Urso Forte, ursodiol), OR (2) inability to tolerate ursodeoxycholic acid. (3) 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 2025

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 2025 - Pending CMS Review

Products Affected

- OLUMIANT

PA Criteria	Criteria Details
Exclusion Criteria	(RA, 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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia OR documentation demonstrating that a trial may be inappropriate. 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, 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
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OMVOH SQ 2025

Products Affected

- OMVOH SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	(UC): Concurrent therapy with biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Ulcerative Colitis (UC): (1) Diagnosis of moderately to severely active Ulcerative Colitis (2) Inadequate response or inability to tolerate two of the following: (a) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) ustekinumab (Stelara), (c) upadacitinib (Rinvoq), (d) tofacitinib (Xeljanz/Xeljanz XR) OR documentation demonstrating that a trial may be inappropriate
Age Restrictions	(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

ONGENTYS 2025

Products Affected

- ONGENTYS

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

ONYCHOMYCOSIS AGENTS 2025

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

OPSYNVI 2025

Products Affected

- OPSYNVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(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 is confirmed by catheterization (right-heart or Swan-Ganz) or echocardiography (3) Member is currently on both of the following for the treatment of pulmonary arterial hypertension (a) macitentan (Opsumit) (b) Tadalafil
Age Restrictions	
Prescriber Restrictions	(PAH) (Initial, Continuation): Prescribed by or in consultation with pulmonologist or cardiologist
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

OPZELURA 2025

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	

PA Criteria	Criteria Details
Part B Prerequisite	No

ORAL ANTIBIOTICS 2025

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 2025

Products Affected

- *abiraterone acetate*
- AFINITOR
- AFINITOR DISPERZ
- AKEEGA
- ALECENSA
- ALUNBRIG
- AUGTYRO
- 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
- 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
- IRESSA
- IWILFIN
- JAKAFI
- JAYPIRCA
- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KOSELUGO
- KRAZATI
- *lapatinib ditosylate*
- *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
- 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
- REVLIMID
- REZLIDHIA
- ROZLYTREK
- RUBRACA
- RYDAPT
- SCEMBLIX
- *sorafenib tosylate*
- SPRYCEL
- STIVARGA
- *sunitinib malate*
- SUTENT
- TABRECTA
- TAFINLAR
- TAGRISSO
- TALZENNA
- TARGRETIN
- TASIGNA
- TAZVERIK
- TEPMETKO
- THALOMID ORAL CAPSULE 100 MG, 50 MG
- TIBSOVO
- TORPENZ
- TRUQAP
- TUKYSA
- TURALIO ORAL CAPSULE 125 MG
- TYKERB
- VANFLYTA
- VENCLEXTA
- VENCLEXTA STARTING PACK
- VERZENIO
- VITRAKVI
- VIZIMPRO
- VONJO
- 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 2025

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 2025 - Pending CMS Review

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. Polyarticular Juvenile idiopathic arthritis (pJIA): (1) Diagnosis of JIA. (2) Inadequate response or inability to tolerate one of the following: methotrexate, leflunomide, 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 in consultation 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 2025

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 2025

Products Affected

- ORILISSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pain Associated with Endometriosis (PAE): (1) Diagnosis of Pain Associated with Endometriosis (PAE) (2) 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. (3) 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 2025

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 2025

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

OSMOLEX 2025

Products Affected

- OSMOLEX ER ORAL TABLET EXTENDED RELEASE 24 HOUR 129 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Parkinson's Disease (PD): (1) Diagnosis of PD, (2) inadequate response or inability to tolerate amantadine immediate release, (3) Inadequate response or inability to tolerate one of the following: (a) Carbidopa-levodopa (b) MAO-B Inhibitor (e.g. rasagiline, selegiline) (c) Dopamine Agonist (e.g. pramipexole, ropinirole) . Drug-induced extrapyramidal symptoms (DIEPS): (1) BOTH of the following: (A) ONE of the following: (i) Member has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication or (ii) Member is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. (B) Inadequate response or inability to tolerate amantadine immediate release
Age Restrictions	
Prescriber Restrictions	(DIEPS): Prescribed by or in consultation with a neurologist or psychiatrist (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

OTEZLA 2025 - Pending CMS Review

Products Affected

- OTEZLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Oral Ulcers Associated with Bechet's Disease (OU-BD): (1) Diagnosis of OU-BD. 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 PsO.
Age Restrictions	(OU-BD): Member is 18 years of age or older. (PsA, PsO) Member is 6 years of age and 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

OVERACTIVE BLADDER AGENTS (OAB) ACH 2025

Products Affected

- DETROL
- DETROL LA
- OXYTROL
- VESICARE
- VESICARE LS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Trial of three of the following: oxybutynin, darifenacin, Myrbetriq, tolterodine, trospium, solifenacin. Always applies.
Age Restrictions	POLY-ACH DUR: Apply if member is greater than or equal to 65 years
Prescriber Restrictions	
Coverage Duration	PA: Indefinite Poly-ACH DUR: 1 year
Other Criteria	Subject to additional clinical review for Poly-ACH cDUR related use - if applicable. (1) The drug is being prescribed for a medically accepted indication (2) The prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) (3) The prescriber will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the member
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OXBRYTA 2025

Products Affected

- OXBRYTA

PA Criteria	Criteria Details
Exclusion Criteria	(SCD)(Initial, Continuation): Concurrent therapy with Adakveo (crizanlizumab-tmca)
Required Medical Information	Sickle Cell Disease (SCD) (Initial): (1) Diagnosis of sickle cell disease, (2) Member had at least 1 vaso-occlusive crisis (VOC) event within the past 12 months (e.g. acute painful crisis, acute chest syndrome,) (3) Hemoglobin level that is between 5.5 g/dL and 10.5 g/dL prior to therapy initiation (4) Inadequate response or inability to tolerate hydroxyurea (i.e., Siklos, Droxia) or L-glutamine (i.e., Endari)
Age Restrictions	(SCD)(Initial, Continuation): Member is 4 years of age or greater
Prescriber Restrictions	(SCD)(Initial, Continuation): Prescribed by or in consultation with a hematologist, oncologist, or specialist with expertise in the diagnosis and management of sickle cell disease
Coverage Duration	(Initial, Continuation): 12 months
Other Criteria	(SCD)(Continuation): Member has had a positive clinical response to Oxbryta therapy (e.g. an increase in hemoglobin level of greater than or equal to 1 g/dL from baseline, decreased annualized incidence rate of VOCs)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OXERVATE 2025

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 rationale 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 2025

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 2025

Products Affected

- CRINONE
- IMVEXXY MAINTENANCE PACK
- IMVEXXY STARTER PACK
- INTRAROSA
- OSPHENA
- VFEND IV
- *voriconazole intravenous*
- ZTLIDO

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 2025

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 2025

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 GLP-1 AGONISTS 2025

Products Affected

- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)
- RYBELSUS
- VICTOZA SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(DM2): (1) One of the following: (a) For members requiring ongoing treatment for type 2 diabetes mellitus, submission of medical records (e.g. chart notes) confirming diagnosis of type 2 diabetes mellitus (b) Submission of medical records (e.g. chart notes) confirming diagnosis of type 2 diabetes mellites as evidenced by one of the following laboratory values (i) A1C greater than or equal to 6.5 percent (ii) Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL (iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PREFERRED HEPATITIS C AGENTS 2025

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 2025

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 2025

Products Affected

- PROCYSBI ORAL PACKET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Nephrotic Cystinosis (NC) (Initial): (1) Diagnosis of nephrotic cystinosis, (2) inadequate response or titration from cysteamine bitartrate immediate-release capsules (Cystagon).
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): Positive Clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PROLIA 2025

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 2025

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 2025

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, (e.g. reduction in transfusions compared to the member's historical transfusion burden, improvement in markers of hemolysis from baseline (e.g. bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)).
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

QUALAQUIN 2025

Products Affected

- QUALAQUIN
- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Use for treatment or prevention of nocturnal leg cramps
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

QULIPTA 2025

Products Affected

- QULIPTA

PA Criteria	Criteria Details
Exclusion Criteria	(MP) (Initial, Reauth): Medication will be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Required Medical Information	Migraine Prevention (MP)(Initial): (1) Diagnosis of episodic migraines defined as 4 to 14 headache days per month AND (2) Inadequate response or inability to tolerate BOTH of the following: (a) Emgality AND (b) Aimovig.
Age Restrictions	(Migraine Prevention) (Initial, Reauth): Member 18 years of age
Prescriber Restrictions	(Migraine Prevention) (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	(Migraine Prevention) (Initial): 6 months (Migraine Prevention) (Reauth): 12 months
Other Criteria	(Migraine Prevention) (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

QUVIVIQ 2025

Products Affected

- QUVIVIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(Insomnia): (1) Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance (2) inadequate response or inability to tolerate ramelteon and Belsomra
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of contract year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RADICAVA 2025

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) Normal respiratory function defined as forced vital capacity (FVC) of greater than or equal to 80% at the start of treatment. (3) 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 2025

Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	(UCD): Acute hyperammonemia. N-acetyl glutamate synthase (NAGS) deficiency
Required Medical Information	Urea Cycle Disorder (UCD): (1) Diagnosis of urea cycle disorder involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AAS) confirmed via enzymatic, biochemical, or genetic testing. (2) Inadequate response or inability to tolerate sodium phenylbutyrate (3) Inadequate response to one of the following: Dietary protein restriction or Amino acid supplementation
Age Restrictions	(UCD): Member is 2 months of age or older
Prescriber Restrictions	(UCD) (Initial) (Reauth): Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders
Coverage Duration	Initial: 6 months Reauth: 12 months
Other Criteria	(Reauth) (1) Documentation of positive clinical response to therapy (e.g. plasma ammonia or amino acid levels within normal limits) (2) Will be used concomitantly with dietary protein restriction and, in some cases, dietary supplements.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RECORLEV 2025

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 2025

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.

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, 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.
Off Label Uses	
Part B Prerequisite	No

RESPIRATORY ENZYMES 2025

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	
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

REZDIFFRA 2025

Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(MASH) (Initial): (1) Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH) (2) Documentation of ONE of the following: (a) FibroScan-aspartate aminotransferase (FAST) (b) MRI-aspartate aminotransferase (MAST) (c) Liver biopsy (3) Documentation that disease is fibrosis stage F2 or F3 as confirmed by ONE of the following: (a) FibroScan (b) Fibrosis-4 index (FIB-4) (c) Magnetic Resonance Elastography (MRE). (4) Presence of greater than or equal to 3 metabolic risk factors (e.g. Type 2 diabetes, hypertension, obesity) (5) Drug is used as adjunct to lifestyle modification (e.g. dietary or caloric restriction, exercise, behavioral support, community-based program)
Age Restrictions	
Prescriber Restrictions	(Initial, Reauth) Prescribed by or in consultation with a gastroenterologist or hepatologist
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(MASH) (Reauth): (1) Member demonstrates positive response to therapy (e.g. MASH resolution, fibrosis stage improvement, etc.) (2) Member has not progressed to cirrhosis
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

REZUROCK 2025 - Pending CMS Review

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 2025 - Pending CMS Review

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, Adulimumab-ADBM) 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, Adulimumab-ADBM) or documentation demonstrating that a trial may be inappropriate. Atopic Dermatitis (AD): (1) Diagnosis of moderate to severe atopic dermatitis, (2) Inadequate response of or inability to tolerate at least TWO of the following: (a) medium or higher potency topical corticosteroid, (b) pimecrolimus cream, (c) Topical 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, Adulimumab-ADBM) 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

PA Criteria	Criteria Details
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.
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, Adalimumab-ADBM) OR documentation demonstrating that a trial may be inappropriate. Non-radiographic axial spondylarthritis (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, Adalimumab-ADBM, Cimzia) 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, Adalimumab-ADBM) 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, adalimumab-ADBM), or documentation demonstrating that a trial may be inappropriate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RIVFLOZA 2025

Products Affected

- RIVFLOZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(PH1)(Initial): (1) Diagnosis of primary hyperoxaluria type 1 (PH1) (2) Disease has been confirmed by both of the following: (a) One of the following: (i) elevated urinary oxalate excretion (ii) elevated plasma oxalate concentration (iii) spot urinary oxalate to creatinine molar ratio greater than normal for age (b) One of the following: (i) genetic testing demonstrating a mutation in the alanine: glyoxylate aminotransferase (AGXT) gene (ii) Liver biopsy demonstrating absence or reduced alanine: glyoxylate aminotransferase (AGT) activity (3) Member has preserved kidney function (e.g., eGFR greater than or equal to 30 mL/min/1.73 m2)
Age Restrictions	
Prescriber Restrictions	(PH1) (Initial, Reauth): Prescribed by or in consultation with one of the following: hepatologist, nephrologist, urologist, geneticist, specialist with expertise in the treatment of PH1
Coverage Duration	(PH1) (Initial, Reauth): 12 months
Other Criteria	(PH1) (Reauth): Member demonstrates positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SAMSCA 2025

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 (2) Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days
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 2025

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. AND (2) One of the following: (a) Unintentional weight loss of greater than 10% over the last 12 months OR unintentional weight loss of greater than 7.5% over the last 6 months OR loss of 5% body cell mass within 6 months OR body mass index less than 20kg/m2 OR (b) One of the following: (i) Patient is male, BCM less than 35% of total body weight, BMI less than 27kg/m2 OR (ii) Patient is female, BCM less than 23% of total body weight, BMI less than 27kg/m2 AND (3) Member is receiving concomitant antiretroviral therapy AND (4) Nutritional evaluation since onset of wasting first occurred AND (5) Patient has tried and failed or unable to tolerate either dronabinol or megestrol acetate.
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 2025

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 2025

Products Affected

- REVATIO ORAL TABLET
- *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 2025

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 (i.e. Humira, Adulimumab-ADBM), (b) etanercept (Enbrel), (c) Skyrizi, (d) Cosentyx, (e) Stelara, (f) Otezla OR documentation demonstrating that a trial may be inappropriate.
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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SIMPONI 2025 - Pending CMS Review

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 (i.e. Humira, Adulimumab-ADBM), (b) etanercept (Enbrel), (c) secukinumab (Cosentyx), (d) tofacitinib (Xeljanz/Xeljanz XR), (e) upadacitinib (Rinvoq) 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) Adalimumab (i.e., Humira, Adulimumab-ADBM), (b) Enbrel, (c) Xeljanz/Xeljanz XR, (d) Rinvoq, (e) Skyrizi, (f) Cosentyx, (g) Stelara, (h) Orencia, (i) Otezla 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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia 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) Adalimumab (i.e. Humira, Adulimumab-ADBM), and (b) Xeljanz/Xeljanz XR, (c) Stelara, (d) Rinvoq 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	

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

SIRTURO 2025

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 2025

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 2025

Products Affected

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	(PsO, PsA, CD): 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: (e.g. methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine). 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) Used only for maintenance therapy following induction therapy with the IV formulation.
Age Restrictions	(PsO, PsA, CD): Member is 18 years of age or older
Prescriber Restrictions	(PsO): Prescribed by or in consultation a dermatologist (PsA): Prescribed by or consultation with a rheumatologist or dermatologist (CD): 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 2025

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 mid parental 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 (5) Inadequate response or inability to tolerate both of the following: Genotropin and Nutropin AQ or Nutropin AQ NuSpin
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 (2) Growth velocity greater than or equal to 2.5 cm/year. (GHDA)(Continuation): Annual clinical re-evaluation by the treating endocrinologist.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SOGROYA 2025

Products Affected

- SOGROYA

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 mid parental height (ii) Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender). (b) Growth velocity is greater than 2 SD below mean for age and gender.(c) 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) (2) documentation of bone age, (3) abnormal response from provocative testing, such as insulin-induced hypoglycemia test, levodopa, or clonidine (4) Inadequate response or inability to tolerate both of the following: Genotropin and Nutropin AQ, or Nutropin AQ NuSpin. Diagnostically confirmed Growth Hormone Deficiency in adults (GHDA)(Initial)
Age Restrictions	(GFC) (Initial, Continuation): Member is 2.5 years of age or greater. (GHDA)(Initial, Continuation): Member is 18 years of age or older.
Prescriber Restrictions	(GFC, GHDA)(Initial, Continuation): 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 (2) Growth velocity greater than or equal to 2.5 cm/year. (GHDA)(Continuation): Annual clinical re-evaluation by the treating endocrinologist.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No

SOHONOS 2025

Products Affected

- SOHONOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(FOP)(Initial): (1) Diagnosis of Fibrodysplasia Ossificans Progressiva (FOP) (2) Molecular genetic testing confirms mutations in the ACVR1 gene
Age Restrictions	(FOP) (Initial, Reauth): For female members: 8 years of age or older. For male members: 10 years of age or older
Prescriber Restrictions	(FOP) (Initial, Reauth): Prescribed by or in consultation with geneticist or orthopedic physician
Coverage Duration	(Initial, Reauth): 12 months
Other Criteria	(FOP)(Reauth): (1) Documentation is provided that member demonstrates positive clinical response to therapy (e.g. reduction in volume in new abnormal bone growth)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SOTATERCEPT 2025

Products Affected

- WINREVAIR

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 III (2) inadequate response or inability to tolerate TWO of the following: (a) Endothelin Receptor Antagonist (bosentan, ambrisentan, macitentan) (b) Phosphodiesterase 5 inhibitor (tadalafil, sildenafil) (c) IV prostacyclin therapy (treprostinil, epoprostenol) (3) Member continues to receive other PAH therapies (e.g. ambrisentan, tadalafil)
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with 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

SOTYKTU 2025

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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (b) Enbrel, (c) Skyrizi (d) Cosentyx, (e) Stelara, (f) Otezla 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

SPEVIGO 2025

Products Affected

- SPEVIGO SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	(GPP): (1) Member has received two infusions of Spevigo for a single flare
Required Medical Information	Generalized Pustular Psoriasis (GPP): (1) Diagnosis of generalized pustular psoriasis (GPP) flares (2) Member has a moderate to severe GPP flare based on one of the following: (a) a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate), (b) Presence of fresh pustules (new appearance or worsening of pustules), (c) GPPPGA pustulation sub score of at least 2 (mild), (d) at least 5% of body surface area (BSA) covered with erythema and the presence of pustules
Age Restrictions	
Prescriber Restrictions	(GPP): Prescribed by or in consultation with a dermatologist
Coverage Duration	14 days
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

STELARA SQ 2025 - Pending CMS Review

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. 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, methotrexate, 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

SUNOSI 2025

Products Affected

- SUNOSI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	NARCOLEPSY: (1) One of the following: (2) Diagnosis Confirmed by Polysomnography (PSG) or Multiple sleep latency test (MSLT) (b) prescriber provides justification that a sleep study is not feasible, (2) Inadequate response or inability to tolerate modafinil or armodafinil. 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), (2) documentation that the medication is being used as an adjunct treatment for the underlying obstruction, (3) inadequate response or inability to tolerate modafinil or armodafinil.
Age Restrictions	
Prescriber Restrictions	(Narcolepsy, 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

SYMDEKO 2025

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 2025

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 2025

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 III, (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 2025

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 2025

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 2025

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) Adalimumab (i.e. Humira, Adulimumab-ADBM) (d) Skyrizi, (e) Stelara, (f) Otezla 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) Adalimumab(i.e. Humira, Adulimumab-ADBM) (c) Cosentyx (d) Rinvoq (e) Skyrizi (f) Stelara (g) Xeljanz/Xeljanz XR, (h) Orencia, (i) Otezla 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 (i.e. Humira, Adulimumab-ADBM), (b) etanercept (Enbrel), (c) secukinumab (Cosentyx), (d) upadacitinib (Rinvoq), (e) tofacitinib (Xeljanz/Xeljanz XR) 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, nr-axSpA): 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.

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

TARPEYO 2025

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 2025

Products Affected

- TAVALISSE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Immune Thrombocytopenia (ITP)(Initial): (1) Diagnosis of Chronic Immune Thrombocytopenia (ITP) (2) Documentation of baseline platelet count less than 30,000/mcL, (3) 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 2025

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

TEGSEDI 2025

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	(Initial, Continuation): 1) A history of liver transplant or is likely to be a candidate and 2) used in combination with any other RNA interference agents (e.g. transthyretin stabilizers)
Required Medical Information	Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)(Initial): (1) Diagnosis of hATTR amyloidosis with polyneuropathy confirmed by molecular genetic testing that reveals pathogenic variation(s) in the TTR gene (e.g. variation of V30M). (2) ONE of the following baseline ambulation parameters in either the Familial Amyloid Polyneuropathy (FAP) Stage or Polyneuropathy Disability (PND) Score (a) Stage 1 (unimpaired ambulation) or 2 (assisted ambulation) on the Familial Amyloid Polyneuropathy (FAP) staging tool, or (b) Score I, II, IIIa, or IIIb on the Polyneuropathy Disability (PND) scoring tool. (3) Documented presence of cardiac or renal manifestations, or motor, sensory, or autonomic neuropathy related to the hATTR amyloidosis with polyneuropathy (e.g. neuropathic pain, muscle weakness that affects daily living, orthostatic hypotension, diarrhea, nausea, vomiting, heart failure, arrhythmias, proteinuria, renal failure, vision disorders, such as vitreous opacity, dry eyes, glaucoma, or pupils with an irregular or scalloped appearance)
Age Restrictions	
Prescriber Restrictions	(hATTR Amyloidosis)(Initial, Continuation): Prescribed by or in consultation with a neurologist, geneticist, or professional provider specializing in the treatment of amyloidosis
Coverage Duration	(Initial): 16 months. (Continuation): Indefinite

PA Criteria	Criteria Details
Other Criteria	(hATTR Amyloidosis)(Continuation): (1) Documented improvement or stability in the signs and symptoms hATTR amyloidosis with polyneuropathy (e.g. neuropathic pain, muscle weakness that affects daily living, orthostatic hypotension, diarrhea, nausea, vomiting, heart failure, arrhythmias, proteinuria, renal failure, vision disorders, such as vitreous opacity, dry eyes, glaucoma, or pupils with an irregular or scalloped appearance), based on objective or standard evaluation scales, and (2) ONE of the following: (a) Stage 1 (unimpaired ambulation) or 2 (assisted ambulation) on the Familial Amyloid Polyneuropathy (FAP) staging tool, or (b) Score I, II, IIIa, or IIIb on the Polyneuropathy Disability (PND) scoring tool
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TERIPARATIDE 2025

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. low-trauma fracture of the hip, spine, pelvis, or distal forearm, 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. low-trauma fracture of the hip, spine, pelvis, or distal forearm, 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).
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

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

TESTOSTERONE PRODUCTS 2025

Products Affected

- AVEED
- DEPO-TESTOSTERONE INTRAMUSCULAR SOLUTION
- 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) (2) Used for palliative treatment 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	(HG) Member is 12 years of age or older (applies to generic testosterone cypionate only) and member is 18 years of age or older for all other products
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

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

TOCILIZUMAB SQ 2025

Products Affected

- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	(PJIA, SJIA, RA, GCA, SSc- ILD): Concurrent therapy with 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 (i.e. Humira, adalimumab-adbm), (b) etanercept (Enbrel), (c) Xeljanz, (d) Orencia, (e) 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 antiinflammatory 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) Adalimumab (i.e. Humira, adalimumab-adbm), (b) Enbrel, (c) Rinvoq, (d) Xeljanz/Xeljanz XR, (e) Orencia, 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

PA Criteria	Criteria Details
Other Criteria	Subject to Part B vs Part D review.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TOPICAL CHEMO AGENTS 2025

Products Affected

- *bexarotene*
- TARGRETIN
- 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 2025

Products Affected

- *adapalene external cream*
- *adapalene external gel 0.3 %*
- *adapalene external pad*
- *adapalene-benzoyl peroxide external gel*
- AKLIEF
- ALTRENO
- ATRALIN
- CABTREO
- *clindamycin-tretinoin*
- DIFFERIN EXTERNAL CREAM
- DIFFERIN EXTERNAL GEL 0.3 %
- DIFFERIN EXTERNAL LOTION
- EPIDUO
- EPIDUO FORTE
- RETIN-A
- RETIN-A MICRO
- RETIN-A MICRO PUMP EXTERNAL GEL 0.06 %, 0.08 %
- *tretinoin external*
- *tretinoin microsphere external gel 0.04 %, 0.1 %*
- *tretinoin microsphere pump external gel 0.08 %*
- TWYNEO
- ZIANA

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 2025

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

TRAMADOL SOLUTION 2025

Products Affected

- QDOLO
- *tramadol hcl oral solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pain: (1) Diagnosis of pain, severe enough to require an opioid analgesic (2) One of the following: (A) inadequate response or inability to tolerate both of the following: (i) generic formulary tramadol tablets (ii) generic formulary tramadol ER tablets OR (B) Patient is unable to swallow tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TREMFYA 2025

Products Affected

- TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML

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) Adalimumab (i.e. Humira, Adulimumab-ADBM), (d) Skyrizi, (e) Stelara, (f) Otezla 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) Adalimumab (i.e. Humira, Adulimumab-ADBM) (b) Enbrel (c) Cosentyx (d) Rinvoq (e) Skyrizi (f) Stelara (g) Xeljanz/Xeljanz XR, (h) Orencia, (i) Otezla 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 2025

Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF): (1) Diagnosis of Cystic Fibrosis. (2) 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 2025

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. Low-trauma fracture of the hip, spine, pelvis, or distal forearm, 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, 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	

PA Criteria	Criteria Details
Part B Prerequisite	No

TYVASO DPI 2025

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 2025

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 2025

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 2025

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

VELSIPITY 2025

Products Affected

- VELSIPITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Ulcerative Colitis (UC): (1) Diagnosis of moderately to severely active Ulcerative Colitis (2) Inadequate response or inability to tolerate TWO of the following (a) Adalimumab (i.e. Humira, Adulimumab-ADBM) (b) Xeljanz/Xeljanz XR (c) Stelara (d) Rinvoq OR documentation demonstrating that a trial may be inappropriate.
Age Restrictions	(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

VEOZAH 2025

Products Affected

- VEOZAH

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(VMS)(Initial): (1) Diagnosis of moderate to severe vasomotor symptoms due to menopause (2) Inadequate response or inability to tolerate one of the following (a) menopausal hormone therapy (e.g. estradiol tablets) (b) non-hormonal therapy (e.g. paroxetine, venlafaxine, clonidine, etc.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(VMS)(Initial): 6 months, (Reauth): 12 months
Other Criteria	(VMS)(Reauth): (1) Documentation of positive clinical response to therapy (e.g. decrease in frequency and severity of vasomotor symptoms from baseline, etc.)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VIJOICE 2025

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

VIVJOA 2025

Products Affected

- VIVJOA

PA Criteria	Criteria Details
Exclusion Criteria	Recurrent vulvovaginal candidiasis (RVVC): Member is of reproductive potential
Required Medical Information	(RVVC): (1) Diagnosis of recurrent vulvovaginal candidiasis (RVVC) (2) Diagnosis of RVVC confirmed by one of the following: (a) positive potassium hydroxide (KOH) preparation (b) vaginal fungal culture (3) Member has experienced 3 or more symptomatic episodes of vulvovaginal candidiasis (VVC) within the past 12 months (4) Inadequate response or inability to tolerate BOTH of the following: (a) one intravaginal product (e.g. clotrimazole, miconazole, terconazole) (b) oral fluconazole
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	4 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOQUEZNA PAK 2025

Products Affected

- VOQUEZNA DUAL PAK
- VOQUEZNA TRIPLE PAK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(H. pylori): (1) Diagnosis of Helicobacter pylori infection (2) Inadequate response or inability to tolerate ONE of the following first line treatment regimens: (a) Clarithromycin based therapy (e.g. clarithromycin based triple therapy, clarithromycin based concomitant therapy), (b) Bismuth quadruple therapy (e.g. bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(H. pylori): 1 month
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOQUEZNA TABLETS 2025

Products Affected

- VOQUEZNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(H. pylori): (1) Diagnosis of Helicobacter pylori infection (2) One of the following: (a) Used in combination with amoxicillin and clarithromycin for the treatment of H. pylori infection OR (b) Used in combination with amoxicillin for the treatment of H. pylori infection (3) An inadequate response or inability to tolerate ONE of the following: (a) Clarithromycin based therapy (e.g. clarithromycin based triple therapy, clarithromycin based concomitant therapy) OR (b) Bismuth quadruple therapy (e.g. bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI]). Erosive Esophagitis: (1) ONE of the following: (a) Used for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis OR (b) Used to maintain healing and relief of heartburn associated with erosive esophagitis (2) An inadequate response or inability to tolerate TWO of the following generic proton pump inhibitors (PPI's): omeprazole, esomeprazole, pantoprazole, lansoprazole, rabeprazole, and dexlansoprazole.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	(H. pylori): 1 month. Healing erosive esophagitis (EE): 8 weeks. Maintenance of EE: 6 months.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOWST 2025

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prevention of the recurrence of Clostridioides difficile infection (PCDI): (1) Diagnosis of recurrent Clostridioides difficile infection as defined by both of the following: (a) Presence of diarrhea defined as passage of 3 or more loose bowel movements within a 24-hour period for at least 2 consecutive days (b) a positive stool test for C. difficile toxin or toxigenic C. difficile (2) Member has a history of two or more recurrent episodes of CDI within 12 months (3) Member has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst: (a) oral vancomycin (b) Dificid (fidaxomicin) (4) Member has completed the recommended bowel prep (e.g. 296mL of magnesium citrate) the day before and at least 8 hours prior to initiating Vowst (5) Previous episode of CDI is under control (e.g. less than 3 unformed or loose [i.e., Bristol Stool Scale type 6-7] stools per day for at least 2 consecutive days)
Age Restrictions	(PCDI): Member is 18 years of age or older
Prescriber Restrictions	(PCDI): Prescribed by or in consultation with gastroenterologist or infectious disease specialist
Coverage Duration	(PCDI): 14 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOXZOGO 2025

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

VTAMA 2025

Products Affected

- VTAMA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(PsO) (Initial): (1) Diagnosis of plaque psoriasis (2) Inadequate response or inability to tolerate TWO of the following topical therapies for sufficient duration (e.g. minimum of 4 weeks): (a) corticosteroids (e.g. betamethasone, clobetasol) (b) Vitamin D analogs (e.g. calcitriol, calcipotriene) (c) Concurrent combination of Vitamin D analog and corticosteroid (e.g. Enstilar, Taclonex) (d) tazarotene (e) Calcineurin inhibitors (e.g. tacrolimus, pimecrolimus)
Age Restrictions	
Prescriber Restrictions	(PsO) (Initial, Reauth): Prescribed by or in consultation with a dermatologist
Coverage Duration	(Initial): 6 months. (Reauthorization): 12 months
Other Criteria	(PsO) (Reauthorization): (1) Documentation of positive clinical response to therapy (e.g. reduction in the body surface area (BSA) involvement from baseline, improvement in symptoms such as pruritus or inflammation from baseline)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VUITY 2025

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

VYVANSE 2025

Products Affected

- *lisdexamfetamine dimesylate*
- VYVANSE

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 one of the following: immediate release formulations of amphetamine, dextroamphetamine, or methylphenidate Binge Eating Disorder (BED): (1)Diagnosis of BED. (2) Member has BED for 3 months or longer.
Age Restrictions	(ADHD): Member is 6 years of age or older (BED): 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

WAINUA 2025

Products Affected

- WAINUA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(hATTR amyloidosis)(Initial): (1) Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy (2) Member has a transthyretin (TTR) mutation (e.g., V30M) (3) One of the following: (a) Member has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2 (b) member has a baseline neuropathy impairment score (NIS) greater than or equal to 10 and less than or equal to 130 (c) Member has a baseline Karnofsky Performance Status score greater than 50 percent (4) Presence of clinical signs and symptoms of the disease (e.g., neuropathy)
Age Restrictions	
Prescriber Restrictions	(hATTR amyloidosis)(Initial, Cont): Prescribed by or in consultation with a neurologist
Coverage Duration	(hATTR amyloidosis)(Initial, Cont): 12 months
Other Criteria	(hATTR amyloidosis)(Cont): (1) Member demonstrates positive clinical response to therapy (2) One of the following: (a) Member continues to have a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2 (b) member continues to have a baseline neuropathy impairment score (NIS) greater than or equal to 10 and less than or equal to 130 (c) Member continues to have a baseline Karnofsky Performance Status score greater than 50 percent
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

WAKIX 2025

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

WEGOVY 2025

Products Affected

- WEGOVY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use of other GLP-1 receptor agonist (e.g. Adlyxin, Byetta, Bydureon, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza)
Required Medical Information	(Initial): (1) Documentation of both of the following: (a) BMI greater than or equal to 27 kg/m2 (b) member has a history of cardiovascular disease, as evidenced by at least one of the following: (i) prior myocardial infarction (ii) prior stroke (ischemic and hemorrhagic stroke) (iii) symptomatic peripheral arterial disease, as evidenced by intermittent claudication with ankle-brachial index less than 0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease and (2) Documentation showing member is on guideline therapy management for multiple risk factors (e.g. dyslipidemia, hypertension) associated with cardiovascular disease as evidenced by presence of all of the following: (a) one of the following: (i) platelet aggregation inhibitor (e.g. acetylsalicylic acid, P2Y12 receptor inhibitors) or anti-thrombotic medication (e.g. vitamin K antagonists, direct oral anticoagulants) (ii) member has inability to tolerate platelet aggregation inhibitor or anti-thrombotic medication (b) one of the following: (i) lipid-lowering medications (e.g. statins, ezetimibe, fibrate, PCSK-9 inhibitors) or (ii) member has inability to tolerate lipid-lowering medications (c) one of the following: (i) other cardiac medications including beta blocker, angiotensin-converting-enzyme inhibitor, angiotensin-receptor blocker, calcium channel blocker (ii) member has inability to tolerate other cardiac medications including beta blocker, angiotensin converting-enzyme inhibitor, angiotensin-receptor blocker, calcium channel blocker (3) Member does not have a history of Type 1 or Type 2 Diabetes Mellitus
Age Restrictions	Member is 45 years of age or older
Prescriber Restrictions	
Coverage Duration	(Initial, Reauth): End of contract year

PA Criteria	Criteria Details
Other Criteria	(Reauth): (1) Documentation showing member is on guideline therapy management for multiple risk factors (e.g. dyslipidemia, hypertension) associated with cardiovascular disease as evidenced by presence of all of the following: (a) one of the following: (i) platelet aggregation inhibitor (e.g. acetylsalicylic acid, P2Y12 receptor inhibitors) or anti-thrombotic medication (e.g. vitamin K antagonists, direct oral anticoagulants) (ii) member has inability to tolerate platelet aggregation inhibitor or anti-thrombotic medication (b) one of the following: (i) lipid-lowering medications (e.g. statins, ezetimibe, fibrate, PCSK-9 inhibitors) or (ii) member has inability to tolerate lipid-lowering medications (c) one of the following: (i) other cardiac medications including beta blocker, angiotensin-converting-enzyme inhibitor, angiotensin-receptor blocker, calcium channel blocker (ii) member has inability to tolerate other cardiac medications including beta blocker, angiotensin converting-enzyme inhibitor, angiotensin-receptor blocker, calcium channel blocker (2) Documentation is provided confirming one of the following: (a) Member has not experienced a cardiovascular event since starting treatment (i.e., nonfatal myocardial infarction, nonfatal stroke) (b) Member has experienced a non-fatal myocardial infarction or nonfatal stroke since starting treatment, but the prescriber attests the benefit outweighs risk for member to continue treatment with semaglutide (Wegovy)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

WILSONS DISEASE 2025

Products Affected

- CUVRIOR
- *trientine hcl oral capsule 500 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Wilson's disease (WD): (1) Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration) (2) Inadequate response or inability to tolerate a penicillamine product (e.g. Depen, Cuprimine)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XDEMVY 2025

Products Affected

- XDEMVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of treatment of demodex blepharitis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or optometrist
Coverage Duration	6 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XELJANZ 2025

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, Adulimumab-ADBM) 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, Adulimumab-ADBM) 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) 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) 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.

PA Criteria	Criteria Details
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.
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, etanercept (Enbrel)) OR documentation that a trial may be inappropriate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XENAZINE 2025

Products Affected

- *tetrabenazine*
- XENAZINE

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 2025

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 2025

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 2025

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 2025

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent therapy with any other biologic agents for asthma/allergic conditions (e.g. benralizumab [Fasenra], dupilumab [Dupixent], mepolizumab [Nucala], omalizumab [Xolair])
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
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.

PA Criteria	Criteria Details
Coverage Duration	(Initial): 12 months. (Reauth): 12 months.
Other Criteria	Subject to Part B vs Part D review. (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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XOLREMDI 2025

Products Affected

- XOLREMDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(WHIM)(Initial): (1) Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome (2) Member has genotype confirmed variant of CXCR4 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) (3) Member has an absolute neutrophil count (ANC) less than or equal to 500 cells /?L
Age Restrictions	
Prescriber Restrictions	(WHIM) (Initial) (Reauth): Prescribed by or in consultation with immunologist, hematologist, geneticist or allergist
Coverage Duration	(Initial) 6 months (Reauth) 12 months
Other Criteria	(WHIM)(Reauth): Documentation of positive clinical response to therapy (e.g., improvement in ANC, reduction in infections)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XYREM 2025

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 2025

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 2025

Products Affected

- *miglustat*
- YARGESA
- ZAVESCA

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

ZAVZPRET 2025

Products Affected

- ZAVZPRET

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 (4) Inadequate response or inability to tolerate ONE of the following: (a) Nurtec ODT (b) Ubrelvy
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

ZEPOSIA 2025

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, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) (2) Inadequate response or inability to tolerate at least 4 weeks trial of the following medications: (a) Avonex (interferon beta-1a), (b) Betaseron (interferon beta-1b), (c) Glatopa (glatiramer acetate), (d) Tecfidera (Dimethyl Fumarate), (e) Gilenya (fingolimod), or (f) teriflunomide 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) Adalimumab (i.e. Humira, Adulimumab-ADBM) (b) Xeljanz/Xeljanz XR (c) Stelara (d) Rinvoq OR documentation demonstrating that a trial may be inappropriate. (3) Inadequate response or inability to tolerate at least ONE conventional treatment: (e.g. corticosteroid, Aminosalicylate, azathioprine or 6-mercaptopurine)
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	(MS, UC): Indefinite
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZILBRYSQ 2025

Products Affected

- ZILBRYSQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(gMG)(Initial): (1) Diagnosis of generalized myasthenia gravis (gMG) (2) Member is anti-acetylcholine receptor (AChR) antibody positive (3) One of the following: (a) Inadequate response or inability to tolerate two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) (b) Both of the following: (i) Inadequate response or inability to tolerate one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) (ii) Inadequate response or inability to tolerate one of the following: (1) Chronic plasmapheresis or plasma exchange (PE) (2) Intravenous immunoglobulin (IVIG)
Age Restrictions	
Prescriber Restrictions	(gMG) (Initial, Reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	(gMG) (Initial, Reauth): 12 months
Other Criteria	(gMG) (Reauth): Member demonstrates positive clinical response to therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZORYVE 2025

Products Affected

- ZORYVE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(PsO) (Initial): (1) Diagnosis of plaque psoriasis (2) Inadequate response or inability to tolerate TWO of the following topical therapies for sufficient duration (e.g. minimum of 4 weeks): (a) corticosteroids (e.g. betamethasone, clobetasol) (b) Vitamin D analogs (e.g. calcitriol, calcipotriene) (c) Concurrent combination of Vitamin D analog and corticosteroid (e.g. Enstilar, Taclonex) (d) Tazarotene (e) Calcineurin inhibitors (e.g. tacrolimus, pimecrolimus)
Age Restrictions	
Prescriber Restrictions	(PsO) (Initial, Reauth): Prescribed by or in consultation with a dermatologist
Coverage Duration	(Initial): 6 months. (Reauthorization): 12 months
Other Criteria	(PsO) (Reauthorization): (1) Documentation of positive clinical response to therapy (e.g. reduction in the body surface area (BSA) involvement from baseline, improvement in symptoms such as pruritus or inflammation from baseline)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZORYVE FOAM 2025

Products Affected

- ZORYVE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	(SD)(Initial): (1) Diagnosis of seborrheic dermatitis (2) Inadequate response or inability to tolerate a minimum of a 4-week trial of TWO of the following generic topical therapies: (a) corticosteroids (e.g. betamethasone, clobetasol) (b) Antifungals (e.g. ciclopirox, ketoconazole) (c) calcineurin inhibitors (e.g. tacrolimus)
Age Restrictions	
Prescriber Restrictions	(SD) (Initial, Reauth): Prescribed by or in consultation with a dermatologist
Coverage Duration	(Initial): 6 months (Reauth): 12 months
Other Criteria	(SD) (Reauth): Documentation of positive clinical response to therapy (e.g. reduction in the body surface area (BSA) involvement from baseline, improvement in symptoms such as pruritus or inflammation from baseline)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZTALMY 2025

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 2025

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	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

ZYMFENTRA SQ 2025

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	(UC, CD): Concurrent therapy with any other biologic disease modifying anti-rheumatic drug (DMARD), e.g. tumor necrosis factor antagonists
Required Medical Information	Ulcerative Colitis (UC): (1) Diagnosis of moderately to severely active Ulcerative Colitis (2) Member has achieved a clinical response following a minimum of 10 weeks of one of the following: (a) Remicade (b) Infliximab. Crohn's Disease (CD): (1) Diagnosis of moderately to severely active CD (2) Member has achieved a clinical response following a minimum of 10 weeks of one of the following: (a) Remicade (b) Infliximab.
Age Restrictions	
Prescriber Restrictions	(UC, CD): Prescribed by or in consultation with a gastroenterologist
Coverage Duration	(UC, CD)(initial): 6 months, (Reauth): 12 months
Other Criteria	(UC, CD)(Reauth): (1) Positive clinical response to therapy as evidenced by ONE of the following: (A) Improvement in intestinal inflammation (e.g. mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline (B) Reversal of high fecal output state
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes

Index