

## 2025 AmeriHealth Caritas VIP Care DE DSNP

### 2025 Prior Authorization Criteria

CURRENT AS OF 01/01/2025

# ACITRETIN

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## Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Prophylaxis of skin cancer in patients with previously treated skin cancers who have undergone an organ transplantation: approve. Psoriasis - Initial: the patient has documented trial of, contraindication to, or medical reason for not using at least 2 of the following treatments: topical steroids, tazarotene, methotrexate, and cyclosporine. Continuation of therapy: patient has positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ACL INHIBITORS

## Products Affected

- NEXLETOL
- NEXLIZET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Primary Hyperlipidemia, Heterozygous Familial Hypercholesterolemia (HeFH) -Initial: [Note: documentation required] pt meets one of the following: (1) pt has untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL at baseline OR (2) patient has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low density lipoprotein receptor adaptor protein 1 gene OR (3) patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds: (i) the prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR (ii) the prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia AND (4) pt tried or has contraindication to high intensity statin (i.e. minimum of atorvastatin 40 mg daily or rosuvastatin 20 mg daily or higher) AND LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant (i.e. rhabdomyolysis or pt experienced skeletal related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin where symptoms resolved upon discontinuation of statin). Atherosclerotic Cardiovascular Disease (ASCVD) - Initial: (1) pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure AND (2) pt tried or has contraindication to high intensity statin (defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant (defined above).</p>
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ACTEMRA

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD. Exclude for indication of COVID-19 treatment in hospitalized patients.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Polyarticular juvenile idiopathic arthritis (pJIA) - Initial: trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, Humira, Hadlima, or Xeljanz [Note: Humira and Hadlima will count as 1 product]. Continuation of therapy: patient has been receiving Actemra for a minimum of 4 months and has positive response to treatment. Rheumatoid arthritis (RA): trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, Humira, Hadlima, Rinvoq, or Xeljanz [Note: Humira and Hadlima will count as 1 product]. Continuation of therapy: patient has been receiving Actemra for a minimum of 4 months and has positive response to treatment. Systemic juvenile idiopathic arthritis (sJIA), Giant Cell Arteritis and Systemic Sclerosis-Associated Interstitial Lung Disease: Approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ACTHAR

## Products Affected

- ACTHAR
- ACTHAR GEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	MS exacerbation, rheumatic disorders, collagen diseases, dermatologic diseases, serum sickness, edematous state (i.e. nephrotic syndrome without uremia), and respiratory diseases - Initial: trial of, contraindication to, or medical reason for not using (1) oral corticosteroids AND (2) Cortrophin. Ophthalmic disease - Initial: trial of, contraindication to, or medical reason for not using (1) oral or ophthalmic corticosteroids AND (2) Cortrophin. Continuation for MS exacerbation: documentation of symptom improvement and current use of a multiple sclerosis disease modifying agent for maintenance therapy. Continuation for all other conditions: documented evidence of clinical positive response to treatment (i.e. symptom improvement).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	MS exacerbation: 1 month. Other indications - Initial: 3 months, Continuation - end of contract year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ACTIMMUNE

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## Products Affected

- ACTIMMUNE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ADEMPAS

## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Phosphodiesterase Inhibitors used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group - Initial: [Note: documentation required] (1) PAH was confirmed by right heart catheterization AND (2) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg AND (3) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND (4) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. Continuation of therapy: patient has positive clinical response to treatment. Chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) - Initial: [Note: documentation required] (1) Patient has persistent or recurrent CTEPH after pulmonary endarterectomy (PEA) OR (2) patient has inoperable CTEPH with the diagnosis confirmed by right heart catheterization AND by computed tomography (CT), magnetic resonance imaging (MRI), or pulmonary angiography. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AIMOVIG

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## Products Affected

- AIMOVIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Prevention of migraine - Initial: (1) patient has greater than or equal to 4 migraine headache days per month at baseline prior to starting migraine preventative treatment OR patient has at least one severe migraine lasting 12 hours or longer despite use of abortive therapy AND (2) patient has tried and failed, intolerant or has medical reason for not using at least 2 preventative migraine therapy (i.e. antidepressants, antiepileptic drugs (AEDs), beta-adrenergic blocking agents) OR (3) patient has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine OR Botox (onabotulinumtoxinA injection) for the prevention of migraine. Continuation of therapy: must show a benefit of 1 headache day per month reduction since initiation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ALPHA-1 PROTEINASE INHIBITORS

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## Products Affected

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG, 500 MG
- GLASSIA
- PROLASTIN-C
- ZEMAIRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of hereditary alpha1-antitrypsin deficiency as evident by (1) pretreatment serum AAT levels below 11 micromol/L (50 mg/dL by nephelometry or 80 mg/dL by radial immunodiffusion) AND (2) clinically evident emphysema (or chronic obstructive pulmonary disease).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber by or in consultation with a pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Request for Glassia or Aralast NP: patient has a documented medical reason or contraindication for not using Prolastin-C or Zemaira.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AMBRISENTAN

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## Products Affected

- *ambrisentan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group - Initial: [Note: documentation required] (1) PAH was confirmed by right heart catheterization AND (2) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg AND (3) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND (4) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# APOKYN

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## Products Affected

- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with any 5-HT3 antagonist (e.g., ondansetron, alosetron, granisetron)
<b>Required Medical Information</b>	The member has a documented diagnosis of Parkinson's Disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Parkinson's disease - (1) member is currently receiving carbidopa/levodopa and (2) member is experiencing off episodes (i.e., difficulty starting movements, muscle stiffness, or slow movements), and (3) member has tried, failed, or has medical reason for not using at least one other treatment for off episodes.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# APOMORPHINE

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## Products Affected

- *apomorphine hcl subcutaneous*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# ARCALYST

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## Products Affected

- ARCALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	<p>Cryopyrin associated periodic syndrome (CAPs) - Initial: patient has diagnosis of CAPs. Continuation of therapy: patient has positive clinical response to treatment. Deficiency of interleukin-1 receptor antagonist (DIRA) - Initial: (1) patient weighs at least 10kg AND (2) genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. Continuation of therapy: patient has positive clinical response to treatment. Gout, flare prevention - Initial: (1) patient has had at least 2 gout flares within the past year AND (2) patient has tried, failed or has contraindication to maximum tolerated doses of non-steroidal inflammatory drug (NSAID) and colchicine AND (3) concurrently using urate-lowering therapy (i.e. allopurinol). Continuation of therapy: (1) patient has positive clinical response to treatment and (2) concurrently using urate-lowering therapy. Pericarditis - Initial: patient has recurrent pericarditis AND requires treatment for current episode. Continuation of therapy: patient has positive clinical response to treatment.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ARIKAYCE

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## Products Affected

- ARIKAYCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Mycobacterium avium complex (MAC): (1) Documented diagnosis of MAC lung disease as verified by failure to achieve at least 2 negative sputum cultures following 6 consecutive months of a combination antibacterial drug regimen AND (2) Provider attestation that medication is being used as part of a combination antibacterial drug regimen.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or an infectious disease specialist
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ARISTADA

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## Products Affected

- ARISTADA INITIO 441 MG/1.6ML, 662 MG/2.4ML, 882
- ARISTADA INTRAMUSCULAR MG/3.2ML  
PREFILLED SYRINGE 1064 MG/3.9ML,

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented history of receiving oral aripiprazole without any clinically significant side effects.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial and failure of, contraindication, or medical reason for not using at least two of the following: Abilify Maintena, Abilify Asimtufii, Risperidone Microsphere, Invega Sustenna, Invega Trinza, and Invega Hafyera.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AUVELITY

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## Products Affected

- AUVELITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Seizure disorder.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Initial: (1) trial of, contraindication to, or medical reason for not using to two generic antidepressants OR (2) patient has suicidal ideation and provider does not recommend use of other antidepressants.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AZACITIDINE INJECTION

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## Products Affected

- *azacitidine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Advanced malignant hepatic tumors.
<b>Required Medical Information</b>	Documented diagnosis of juvenile myelomonocytic leukemia (JMML) OR one of the following myelodysplastic syndrome (MDS) subtypes: 1) refractory anemia (RA) OR 2) refractory anemia with ringed sideroblasts (RARS) OR 3) refractory anemia with excess blasts (RAEB) OR 4) refractory anemia with excess blasts in transformation (RAEB-T) OR 5) chronic myelomonocytic leukemia (CMML).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS): Documentation of neutropenia or thrombocytopenia requiring transfusions.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AZTREONAM LYSINE

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## Products Affected

- CAYSTON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# BENDAMUSTINE

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## Products Affected

- *bendamustine hcl intravenous solution reconstituted*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic lymphocytic leukemia (CLL): 1) Documented diagnosis of CLL. Indolent B-cell non-Hodgkin's lymphoma (NHL): 1) Documented diagnosis of NHL AND 2) Documentation that NHL has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BENLYSTA

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## Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	New starts will be authorized for 6 months. Cont of therapy or reauth until end of contract year.
Other Criteria	<p>Lupus nephritis - Initial: (1) patient has a diagnosis of lupus nephritis confirmed on biopsy (i.e. World Health Organization class III, IV, or V lupus nephritis) AND (2) the medication is being used concurrently with an immunosuppressive regimen (i.e. azathioprine, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Continuation of therapy: (1) medication is being used concurrently with an immunosuppressive regimen (i.e. azathioprine, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND (2) patient has positive clinical response to treatment. Systemic lupus erythematosus (SLE) - Initial: (1) patient has autoantibody-positive SLE (defined as positive for antinuclear antibodies [ANA] and/or antidouble-stranded DNA antibody [anti-dsDNA]) AND (2) the medication is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by a healthcare provider. Continuation of therapy: (1) the medication is being used concurrently with at least one other standard therapy (defined above) unless the patient is determined to be intolerant due to a significant toxicity AND (2) patient has positive clinical response to treatment.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BERINERT

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## Products Affected

- BERINERT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented diagnosis of hereditary angioedema (HAE) as confirmed by C1 inhibitor deficiency or dysfunction. Documentation of one of the following: (1) C1 inhibitor antigenic level below the lower limit of normal OR (2) C1 inhibitor functional level below the lower limit of normal OR (3) member has HAE with normal C1 inhibitor confirmed by laboratory testing and of the following: (i) family history of angioedema that was refractory to a trial of high dose anti-histamines therapy for a duration of at least a month OR (ii) member test positive for an F12, angiotensin-1, heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), kininogen-1 (KNG1), plasminogen, or myoferlin (MYOF) gene mutation.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an immunologist, rheumatologist, or allergist
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BESREMI

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## Products Affected

- BESREMI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other interferon products.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescriber must be a hematologist, oncologist, or specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using Pegasys.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BOSENTAN

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## Products Affected

- *bosentan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group - Initial: [Note: documentation required] (1) PAH was confirmed by right heart catheterization AND (2) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg AND (3) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND (4) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CABLIVI

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## Products Affected

- CABLIVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# CAMZYOS

## Products Affected

- CAMZYOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: [Note: documentation required] (1) diagnosis of obstructive hypertrophic cardiomyopathy (HCM) AND (2) patient has New York Heart Association (NYHA) Class II or III symptoms AND (3) patient has a left ventricular ejection fraction of greater than or equal to 55% AND (4) patient has valsalva left ventricular outflow tract (LVOT) peak gradient which is greater than or equal to 50 mmHg at rest or with provocation AND (5) patient has tried and failed, or has contraindication or intolerance to both of the following at max tolerated dose: non-vasodilating beta blocker (i.e. bisoprolol, propranolol) AND calcium channel blocker (i.e. verapamil, diltiazem). Continuation of therapy: (1) patient must have a LVEF greater than or equal to 50% AND (2) patient has had clinically significant improvement of symptoms AND (3) prescriber attestation patient has not and will not receive septal reduction therapy (SRT) while on mavacamten therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	For all new starts, ALL of the following must be provided: 1) Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM) AND 2) Patient has a left ventricular ejection fraction (LVEF) greater than or equal to 55% AND 3) Assessment of Valsalva left ventricular outflow tract (LVOT) gradient AND 4) Trial of, medical reason for not using or contraindication to BOTH of the following: Beta blockers (i.e. metoprolol, propranolol, atenolol) AND Non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem) AND 5) Prescriber attests that patient is not using moderate to strong CYP2C19 or CYP3A4 inhibitors or inducers. For continuation of therapy or reauthorization, all of the following must be provided: 1)

<b>PA Criteria</b>	<b>Criteria Details</b>
	Documentation of clinical benefit as evidenced by an improvement from baseline in oHCM symptoms (i.e., improvement in fatigue, chest pain, shortness of breath, LVOT, peak oxygen consumption, etc.) OR improvement or no worsening of NYHA functional class AND 2) Member must also have a left ventricular ejection fraction (LVEF) greater than or equal to 50%.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CARGLUMIC ACID

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## Products Affected

- *carglumic acid oral tablet soluble*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N-Acetylglutamate synthase deficiency with hyperammonemia (NAGs): [Note: documentation required] (1) genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency OR (2) patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment: [Note: documentation required] (1) patient has plasma ammonia level is greater then or equal to 50 micromol/L AND (2) the requested medication will be used in conjunction with other ammonia-lowering therapies.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases.
<b>Coverage Duration</b>	NAGs genetic testing: end of the contract year, no genetic testing: 3 mos. Other indication: 7 days
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CASPOFUNGIN

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## Products Affected

- *casposfungin acetate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Documentation of a consultation with an infectious disease specialist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CEPROTIN

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## Products Affected

- CEPROTIN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of congenital protein C deficiency as confirmed by lab values indicating low protein C activity.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hemotologist or specialist in genetic disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CERDELGA

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## Products Affected

- CERDELGA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients with undetermined CYP2D6 metabolizer status.
<b>Required Medical Information</b>	Type 1 Gaucher Disease (GD1) - Initial: [Note: documentation required] (1) diagnosis confirmed by an enzyme assay demonstrating deficiency of beta-glucocerebrosidase enzyme activity OR genetic testing AND (2) patient's CYP2D6 metabolizer status has been confirmed by FDA cleared test AND (3) patient is CYP2D6 extensive metabolizer, intermediate metabolizer, or a poor metabolizer. Continuation of therapy: documentation has been provided that patient has obtained clinical benefit from medication (i.e. increased platelet count, improvement in anemia, PFTs, improvement in radiographic scans, improved quality of life).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist in treatment of Gaucher's disease.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CHENODAL

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## Products Affected

- CHENODAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented diagnosis of radiolucent gallstones.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial and failure of, contraindication, or medical reason for not using ursodiol.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CHOLBAM

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Chenodal.
<b>Required Medical Information</b>	Bile acid synthesis defect due to single enzyme defect - Initial: documented diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis. Continuation of therapy: (1) responded to initial Cholbam therapy with an improvement in LFTs AND (2) does not have complete biliary obstruction. Bile acid synthesis disorders due to peroxisomal disorders, including Zellweger spectrum disorders - Initial: (1) documented peroxisomal disorders with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND (2) has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (i.e. rickets). Continuation of therapy: (1) responded to initial Cholbam therapy as per the prescriber (i.e. improvements in liver enzymes, improvement in steatorrhea) AND (2) does not have complete biliary obstruction.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with hepatologist, gastroenterologist, metabolic specialist.
<b>Coverage Duration</b>	Initial: 3 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CIBINQO

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## Products Affected

- CIBINQO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# CIMZIA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For ankylosing spondylitis (AS): Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz [Note: Humira and Hadlima will count as 1 product]. For Crohns Disease (CD): Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Humira, Hadlima, Skyrizi or Stelara [Note: Humira and Hadlima will count as 1 product]. For non-radiographic axial spondylarthritis: approve. For psoriasis (PS): Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Skyrizi, Tremfya, Stelara, Enbrel, Hadlima, or Humira [Note: Humira and Hadlima will count as 1 product]. For Psoriatic arthritis (PsA): Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Stelara, Skyrizi, Tremfya, Xeljanz, Rinvoq, Enbrel, Hadlima, or Humira [Note: Humira and Hadlima will count as 1 product]. For Rheumatoid arthritis (RA): Trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz [Note: Humira and Hadlima will count as 1 product]. AS/CD/PS/PsA/RA Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CORLANOR

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## Products Affected

- CORLANOR ORAL SOLUTION
- *ivabradine hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# CORTROPHIN

## Products Affected

- CORTROPHIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	New starts for MS exacerbation, rheumatic disorders, collagen diseases, dermatologic diseases, serum sickness, edematous state (e.g. nephrotic syndrome without uremia), and respiratory diseases: trial of, contraindication to, or medical reason for not using oral corticosteroids. New starts for ophthalmic disease: trial of, contraindication to, or medical reason for not using oral or ophthalmic corticosteroids. Continuation of therapy or reauthorization for MS exacerbation: documentation of symptom improvement and current use of a multiple sclerosis disease modifying agent for maintenance therapy. Continuation of therapy or reauthorization for all other conditions: documented evidence of response to treatment and symptom improvement.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	MS exacerbation: 1 month. Other conditions: new start for 3 months and reauth end of contract year.
<b>Other Criteria</b>	MS exacerbation, rheumatic disorders, collagen diseases, dermatologic diseases, serum sickness, edematous state (i.e. nephrotic syndrome without uremia), and respiratory diseases - Initial: trial of, contraindication to, or medical reason for not using (1) oral corticosteroids AND (2) Cortrophin. Ophthalmic disease - Initial: trial of, contraindication to, or medical reason for not using (1) oral or ophthalmic corticosteroids AND (2) Cortrophin. Continuation for MS exacerbation: documentation of symptom improvement and current use of a multiple sclerosis disease modifying agent for maintenance therapy. Continuation for all other conditions: documented evidence of response to treatment and symptom improvement.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Formulary ID 25401

Last Updated: 10/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# COSENTYX

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# CRESEMBA

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## Products Affected

- CRESEMBA ORAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of medically accepted indication.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist or oncologist
<b>Coverage Duration</b>	Request will be authorized for 3 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CRYSVITA

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## Products Affected

- CRYSVITA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with oral phosphate or active vitamin D analogs. Use in patients with severe renal impairment or end stage renal disease (ESRD).
<b>Required Medical Information</b>	X-linked hypophosphatemia (XLH): Documented diagnosis of XLH as confirmed by one of the following: 1) elevated serum fibroblast growth factor-23 (FGF23) level OR 2) genetic testing. Tumor-induced osteomalacia (TIO): 1) Documented diagnosis of FGF23-related hypophosphatemia in TIO associated with phosphaturic mesenchymal tumors AND 2) provider attestation that disease cannot be curatively resected or localized.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, nephrologist or endocrinologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Documentation of low serum phosphate concentration.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CYSTAGON

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## Products Affected

- CYSTAGON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Procysbi.
<b>Required Medical Information</b>	For nephropathic cystinosis: documented diagnosis confirmed with at least one of the following: (1) the presence of increased cystine concentration in leukocytes, OR (2) genetic testing, OR (3) demonstration of corneal cystine crystals by slit lamp examination.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist or nephrologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CYSTARAN

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## Products Affected

- CYSTARAN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For cystinosis: (1) documented diagnosis confirmed with at least one of the following: (i) the presence of increased cystine concentration in leukocytes, OR (ii) genetic testing, OR (iii) demonstration of corneal cystine crystals by slit lamp examination. AND (2) the patient has corneal cystine crystal accumulation.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an ophthalmologist or metabolic disease specialist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DALFAMPRIDINE ER

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## Products Affected

- *dalfampridine er*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of seizure or moderate/severe renal impairment (CrCl less than or equal to 50 mL/min).
<b>Required Medical Information</b>	For multiple sclerosis - Initial: patient demonstrates sustained walking impairment. Continuation of therapy: (1) patient must have experienced an improvement in walking speed OR (2) other objective measure of walking ability (i.e. MS walking scale, timed 25-foot walk) since starting the requested drug.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DEFERASIROX

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## Products Affected

- *deferasirox*
- *deferasirox granules*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Creatinine clearance less than 40 mL/min or platelet counts less than 50,000/mm <sup>3</sup> .
<b>Required Medical Information</b>	Serum ferritin level.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Transfusion-related chronic iron overload - Initial: (1) patient is receiving blood transfusions at regular intervals for various conditions (i.e. chronic anemia, myelodysplastic syndrome, sickle cell disease, thalassemia syndromes) AND (2) prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload - Initial: approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DEFERIPRONE

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## Products Affected

- *deferiprone*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Serum ferritin level.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias - Initial: approve. Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# DIACOMIT

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## Products Affected

- DIACOMIT ORAL CAPSULE 250 MG, 500 MG
- DIACOMIT ORAL PACKET 250 MG, 500 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Initial therapy only: 6 months of age or older.
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Dravet Syndrome -Initial: patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DICHLORPHENAMIDE

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## Products Affected

- *dichlorphenamide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, neurologist, or endocrinologist.
<b>Coverage Duration</b>	New starts will be authorized for 2 months. Cont of therapy or reauth until end of contract year.
<b>Other Criteria</b>	Continuation of therapy or reauthorization: documentation of clinical improvement with therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DIFICID

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## Products Affected

- DIFICID ORAL SUSPENSION RECONSTITUTED
- DIFICID ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 10 days.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DIHYDROERGOTAMINE NASAL

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## Products Affected

- *dihydroergotamine mesylate nasal*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For new starts: Member has a diagnosis of migraine headaches with or without aura. Prescriber attestation that it will be used for the acute treatment of migraine. For continuation of therapy or reauthorization: Documentation or provider attestation of positive clinical response (e.g., improvement in pain, photophobia, phonophobia).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	New starts will be authorized for 6 months. Cont of therapy or reauth until end of contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason (e.g. intolerance, hypersensitivity or contraindication) for not using a triptan (e.g., rizatriptan, sumatriptan).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DOPTELET

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## Products Affected

- DOPTELET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# DOXEPIN CREAM

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## Products Affected

- *doxepin hcl external*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 14 days.
<b>Other Criteria</b>	(1) Trial of, contraindication to, or medical reason (i.e. treatment for axilla, face or groin) for not using a topical corticosteroid [potency of medium or higher] OR (2) topical calcineurin inhibitor.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DROXIDOPA

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## Products Affected

- *droxidopa oral capsule 100 mg, 200 mg, 300 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Neurogenic orthostatic hypotension (NOH): patient meets the following requirements (1) diagnosed with symptomatic NOH due to primary autonomic failure (Multiple system atrophy, Parkinson's disease, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND (2) patient has tried and failed midodrine.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a neurologist.
<b>Coverage Duration</b>	Request will be authorized for 3 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DUPIXENT

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## Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/0.67ML, 200 MG/1.14ML, 300 MG/2ML

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off-Label Uses	UNDER CMS REVIEW
Part B Prerequisite	No

# EGRIFTA

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## Products Affected

- EGRIFTA SV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of active antiretroviral therapy for at least 8 weeks.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ELAPRASE

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## Products Affected

- ELAPRASE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of mucopolysaccharidosis II as confirmed by one of the following: 1) enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity OR 2) generic testing
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist in genetic or metabolic disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EMGALITY

## Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prevention of migraine - Initial: (1) patient has greater than or equal to 4 migraine headache days per month at baseline prior to starting migraine preventative treatment OR patient has at least one severe migraine lasting 12 hours or longer despite use of abortive therapy AND (2) patient has tried and failed, intolerant or has medical reason for not using at least 2 preventative migraine therapy (i.e. antidepressants, antiepileptic drugs (AEDs), beta-adrenergic blocking agents) OR (3) patient has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine OR Botox (onabotulinumtoxinA injection) for the prevention of migraine. Prevention of migraine - Continuation of therapy: must show a benefit of 1 headache day per month reduction since initiation of therapy. Episodic cluster headache - Initial: must have trial of, contraindication to, or a medical reason for not using verapamil for at least 4 weeks at minimum effective doses. Episodic cluster headache - Continuation of therapy: must show documentation of reduction in frequency of headaches
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EMSAM

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## Products Affected

- EMSAM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with SSRIs, SNRIs, clomipramine and imipramine, meperidine, tramadol, methadone, pentazocine, and propoxyphene, and the antitussive agent dextromethorphan or carbamazepine
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Initial: (1) trial of, contraindication to, or medical reason for not using two generic antidepressants OR (2) patient is unable to swallow oral formulations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ENBREL

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Rheumatoid arthritis (RA) - Initial: Trial of, medical reason for not using, or contraindication at least one 1 disease modifying antirheumatic drug (DMARD) (i.e. methotrexate, leflunomide, or sulfasalazine). Polyarticular juvenile idiopathic arthritis (pJIA): Trial of, medical reason for not using, or contraindication to 1 of the following DMARDs: methotrexate or leflunomide. Psoriatic arthritis (PsA): approve. Plaque psoriasis (PsO) - Initial: patient meets the following requirements (1) psoriasis affects at least 3% body surface area (BSA) or involves sensitive areas (i.e. feet, hands, face, neck, groin, etc.) AND (2) patient has tried, failed or has contraindications to other conventional therapies (i.e. phototherapy, methotrexate, cyclosporine, acitretin, etc.) OR patient severity warrants biologic as first line therapy (i.e. at least 10% BSA affected). Ankylosing spondylitis (AS): Trial of, medical reason for not using, or contraindication to nonsteroidal anti-inflammatory drug (NSAIDs).RA/pJIA/PsA/PsO/AS Continuation of therapy: patient has been receiving Enbrel for a minimum of 4 months and has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

Formulary ID 25401

Last Updated: 10/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# ENDARI

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## Products Affected

- *l-glutamine oral packet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation that two or more painful sickle cell crises have occurred in the past 12 months.
<b>Age Restrictions</b>	5 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or provider specializing in sickle cell disease.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using hydroxyurea for at least three months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ENTYVIO

## Products Affected

- ENTYVIO SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Other Biologics or with Targeted Synthetic Disease Modifying Antirheumatic Drugs (DMARDs) used for an Inflammatory Condition.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	Initial: 14 weeks. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Crohn's Disease (CD) - Initial: (1) patient has tried, failed, has contraindication, or is currently taking corticosteroids OR (2) patient has tried, failed, or has contraindication to at least one conventional systemic therapy for Crohn's disease (i.e. azathioprine, 6-mercaptopurine, or methotrexate) OR (3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR (4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). Note: an exception to the requirement for (1) corticosteroid and (2) conventional systemic therapy can be made if the patient has already tried a biologic. Continuation of therapy: patient has positive clinical response to treatment. Ulcerative Colitis (UC) - Initial: (1) patient has tried, failure, or contraindication to at least one systemic agent (i.e. azathioprine, cyclosporine, methylprednisolone, prednisone, tacrolimus, 6-mercaptopurine) OR (2) patient has tried, failed, or has contraindication to biologic agent (i.e. Humira, Hadlima, Remicade, Simponi, etc.). Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# EPIDIOLEX

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## Products Affected

- EPIDIOLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	1 year of age or older.
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Dravet Syndrome -Initial: (1) patient has tried or is currently taking at least 2 other antiseizure medications OR (2) patient has tried or is currently taking clobazam, Diacomit, or Fintepla. Continuation of therapy: patient has positive clinical response to treatment. Lennox Gastaut Syndrome - Initial: patient has tried or is currently taking at least 2 other antiseizure medications. Continuation of therapy: patient has positive clinical response to treatment. Tuberous Sclerosis Complex - Initial: patient has tried or is currently taking at least 2 other antiseizure medications. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EPRONTIA

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## Products Affected

- EPRONTIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Epilepsy: 2 years of age or older. Migraine: 12 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	The request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Initial: documented trial of, contraindication to, or medical reason for not using topiramate. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ERYTHROPOIETIN STIMULATING AGENTS

## Products Affected

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION PREFILLED SYRINGE
- EPOGEN INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 4000 UNIT/ML
- PROCIT
- RETACRIT INJECTION SOLUTION 10000 UNIT/ML, 10000 UNIT/ML(1ML), 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For new starts for all indications: Hgb within compendia range for treatment of the requested medical condition. For continuation of therapy or re-authorization: Hgb must not exceed 10 g/dL (anemia related to cancer), 11 g/dL (anemia of CKD), 12 g/dL (zidovudine-related anemia in members with HIV and ribavirin-induced anemia), 13 g/dL (elective, noncardiac, nonvascular surgery needing red blood cell allogeneic transfusion reduction).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 6 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# EUCRISA

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## Products Affected

- EUCRISA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# EVRYSDI

## Products Affected

- EVRYSDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Prior treatment of gene replacement therapy for the treatment of SMA [i.e. Zolgensma (onasemnogene abeparvovec-xioi)]. Concomitant chronic survival motor neuron (SMN) modifying therapy [i.e. Spinraza (nusinersen)] not indicated for concurrent use. Patient is not dependent on invasive ventilation or tracheostomy OR not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep.
<b>Required Medical Information</b>	Initial - all of the following must be included: (1) documentation of genetic testing confirming diagnosis (i.e. homozygous gene deletion or mutation of SMN1 gene, compound heterozygous mutation of SMN1 gene). AND (2) documentation of baseline motor function or motor milestone achievement [i.e. CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type 1 or Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk]. Continuation of therapy: documentation of positive clinical response has been submitted (i.e. improvement in motor function/motor milestone achievement scores using CHOP-INTEND or HFMSE, 6 minute walk test or HINE improvement in more categories of motor milestones than worsening).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FABHALTA

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## Products Affected

- FABHALTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# FABRAZYME

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## Products Affected

- FABRAZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of Fabry disease as confirmed by one of the follow: 1) alpha galactosidase A (alpha-GAL-A) enzyme assay OR 2) molecular genetic testing for pathogenic mutations in the GLA gene
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FASENRA

## Products Affected

- FASENRA PEN
- FASENRA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 10 MG/0.5ML, 30 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For severe asthma - Initial: (1) patient has documented baseline blood eosinophil count of at least 150 cells per microliter OR (2) patient is dependent on systemic corticosteroids AND (3) patient has a history of severe asthma despite current treatment with both of the following medications: (i) medium-to-high-dose inhaled corticosteroid AND (ii) additional controller (i.e. long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. Continuation of therapy: asthma control has improved on treatment with the requested drug (i.e. reduction in the frequency and/or severity of symptoms and exacerbations or a decrease in the daily maintenance oral corticosteroid dose).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	New starts for severe asthma with an eosinophilic phenotype: 1) Baseline blood eosinophil count greater than or equal to 150 cells per microliter AND 2) symptoms persist with at least 1 exacerbation in the last 12 months requiring additional treatment (e.g. oral systemic steroids) while on a high dose inhaled corticosteroid with an additional controller medication (ie. long-acting B2 agonist). Continuation of therapy or re-authorization for severe asthma with an eosinophilic phenotype: clinical benefit from use of the drug.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FENTANYL CITRATE TRANSMUCOSAL PRODUCTS

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## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation must be provided for the all of the following: 1) fentanyl citrate oral transmucosal is being prescribed to treat cancer-related breakthrough pain AND 2) Patient has been taking opioids at a dose equal to 60 MME per day for at least one week.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Breakthrough pain in patients with cancer if: (1) patients in unable to swallow oral medication, has dysphagia, esophagitis, mucositis, or uncontrollable nausea and vomiting AND (2) patient is currently receiving around the clock opioid therapy for underlying cancer pain AND (3) patient is opioid tolerant (i.e. patient taking around the clock opioid equivalent to 60 MME daily for a minimum of one week or longer).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FILSPARI

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## Products Affected

- FILSPARI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (i.e. ambrisentan, bosentan, Opsumit), or aliskiren.
<b>Required Medical Information</b>	Initial: [Note: documentation is required] (1) diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy AND (2) patient is at risk of rapid progression (i.e. urine protein to creatinine ratio [UPCR] greater than or equal to 1.5 g/g or clinical risk score using the International IgAN Prediction Tool) AND (3) estimated glomerular filtration rate (eGFR) $\geq$ 30 mL/min/1.73 m <sup>2</sup> AND (4) used to reduce proteinuria AND (5) patient has been on minimum 90-day trial of a maximally tolerated dose of an angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) OR has history of failure, contraindication, or intolerance to ACE or ARB therapy. Continuation of therapy: documentation of positive clinical response (i.e. decrease in UPCR).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FINTEPLA

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## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	2 year of age or older.
Prescriber Restrictions	Initial therapy only: prescribed by or in consultation with a neurologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Dravet Syndrome - Initial: (1) patient has tried or is currently taking at least 2 other antiseizure medications OR (2) patient has tried or is currently taking clobazam, Diacomit, or Epidiolex. Continuation of therapy: patient has positive clinical response to treatment. Lennox Gastaut Syndrome - Initial: patient has tried or is currently taking at least 2 other antiseizure medications. Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# FIRDAPSE

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## Products Affected

- FIRDAPSE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Initial therapy only: history of seizures.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	6 years of age or older.
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a neurologist or neuromuscular specialist.
<b>Coverage Duration</b>	Initial: 3 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Initial: (1) diagnosis confirmed with anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing OR electrodiagnostic study (i.e. repetitive nerve stimulation). Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FLUCYTOSINE

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## Products Affected

- *flucytosine oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Complete dihydropyrimidine dehydrogenase (DPD) enzyme deficiency
<b>Required Medical Information</b>	Attestation member is taking in combination with amphotericin B.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 6 weeks.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FLUOROURACIL

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## Products Affected

- *fluorouracil external cream 0.5 %*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients who are pregnant or may become pregnant.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist or oncologist.
<b>Coverage Duration</b>	Request will be authorized for 3 months.
<b>Other Criteria</b>	Initial: if requested drug is used in a compound, all ingredients must be Food and Drug Administration (FDA) approved for topical use.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FULVESTRANT

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## Products Affected

- *fulvestrant intramuscular solution prefilled syringe*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of hormone receptor (HR)-positive advanced or metastatic breast cancer. Patient must have documentation of one of the following: 1) a negative human epidermal growth factor 2 (HER2) biopsy OR 2) disease progression following endocrine therapy (e.g., tamoxifen, toremifene).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GALAFOLD

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## Products Affected

- GALAFOLD

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Fabrazyme (agalsidase beta).
<b>Required Medical Information</b>	Initial: patient has all of the following confirmed by documentation: (1) diagnosis of Fabry disease AND (2) patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease.
<b>Coverage Duration</b>	Request will be authorized to the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GATTEX

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## Products Affected

- GATTEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For new starts: attestation of 1) Colonoscopy of full colon with removal of polyps within six months prior to starting treatment for adults or 2) Fecal occult blood testing within six months prior to starting treatment for pediatric patients. For continuation of therapy or reauthorization: Documentation is provided that the member has obtained a clinical benefit (e.g. reduction in parenteral fluid volume, reduction in number of days receiving parenteral nutrition).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, gastrointestinal surgeon, or nutritional support specialist.
<b>Coverage Duration</b>	Request will be authorized to the end of the contract year.
<b>Other Criteria</b>	Short Bowel Syndrome (SBS) - Adults: patient has been dependent on parental support for at least 12 months. Pediatric patients: patient is dependent on parental nutrition. Continuation of therapy: parental support requirement has decreased from baseline while on Gattex.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GLP-1 AGONISTS

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## Products Affected

- MOUNJARO
- 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
- TRULICITY
- VICTOZA SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis via chart notes and lab values (per other criteria).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized to the end of the contract year.
<b>Other Criteria</b>	Diabetes: (1) patient has diagnosis of type 2 diabetes mellitus AND (2) baseline A1C greater than or equal to 6.5%. All other indications: patient must have medically accepted indication.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GNRH AGONISTS

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## Products Affected

- CAMCEVI
- ELIGARD
- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG
- *leuprolide acetate (3 month)*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- TRELSTAR MIXJECT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Fibroids: 6 months. Endometriosis: 12 months. All other indications: end of contract year.
<b>Other Criteria</b>	If the medication request is for the treatment of prostate cancer and if the request is for any other GnRH agonist other than Eligard or leuprolide, the patient must have a documented trial of, contraindication to, or medical reason for not using Eligard or leuprolide to treat their prostate cancer. For uterine fibroids: (1) patient has anemia (i.e. hematocrit less than or equal to 30 percent and/or hemoglobin less than or equal to 10 g/dL) OR (2) the requested medication will be used prior to surgery for uterine fibroids.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GOCOVRI

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## Products Affected

- GOCOVRI ORAL CAPSULE  
EXTENDED RELEASE 24 HOUR 137  
MG, 68.5 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with neurologist.
<b>Coverage Duration</b>	Initial: 3 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Initial: (1) patient has been diagnosed with Parkinson's disease AND (2) patient is experiencing dyskinesia OR 'off' episodes AND (3) patient has trial of generic amantadine OR contraindication or medical reason for not using generic amantadine. Continuation of therapy: patient has positive clinical response to treatment (i.e. improvement in levodopa-induced dyskinesia).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GROWTH HORMONES

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## Products Affected

- GENOTROPIN MINIQUICK SUBCUTANEOUS PREFILLED SYRINGE
- GENOTROPIN SUBCUTANEOUS CARTRIDGE
- HUMATROPE INJECTION CARTRIDGE
- NGENLA
- 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
- SKYTROFA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# HADLIMA

## Products Affected

- HADLIMA PUSHTOUCH SUBCUTANEOUS SOLUTION AUTO-INJECTOR 40 MG/0.4ML, 40 MG/0.8ML
- HADLIMA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 40 MG/0.4ML, 40 MG/0.8ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Ankylosing spondylitis (AS) - Initial: Trial, failure, or contraindication to non-steroidal inflammatory drug (NSAIDs). Crohns Disease (CD) - Initial: Trial, failure, or contraindication to (1) methotrexate OR (2) disease modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Polyarticular juvenile idiopathic arthritis (pJIA) - Initial: Trial, failure or contraindication to one of the following DMARDs: methotrexate or leflunomide. Rheumatoid arthritis (RA): Trial, failure, or contraindication to at least one disease modifying antirheumatic drug (DMARD). Ulcerative colitis (UC): Trial, failure, or contraindication to at least one of the following conventional therapies: mercaptopurine, an aminosalicylate (i.e. mesalamine, sulfasalazine, azathioprine), or a corticosteroid (i.e. prednisone, methylprednisolone). Psoriatic arthritis (PsA), psoriasis (PsO), Hidradenitis Suppurativa (HS), or Uveitis (UV): approve. AS/CD/pJIA/RA/UC/PsA/PsO/HS/UV - Continuation of therapy: patient has been receiving Hadlima for a minimum of 4 months and has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# HEREDITARY ANGIOEDEMA AGENTS

## Products Affected

- CINRYZE
- HAEGARDA SUBCUTANEOUS SOLUTION RECONSTITUTED 2000 UNIT, 3000 UNIT
- ORLADEYO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, hematologist, immunologist, rheumatologist, or a provider that specializes in the treatment of HAE or related disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Prophylaxis of hereditary angioedema (HAE) - Initial: diagnosis of HAE confirmed by (1) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal OR (2) C1-INH functional level below the lower limit of normal OR (3) if patient has HAE with normal C1-INH levels they must have (i) recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema OR (ii) confirmed presence of a Factor XII (FXII), angiotensin-converting enzyme (ACE), or plasminogen gene mutation. Continuation of therapy: patient has positive clinical response to treatment. Treatment of acute HAE attacks - Initial: diagnosis of HAE confirmed by (1) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal OR (2) C1-INH functional level below the lower limit of normal OR (3) if patient has HAE with normal C1-INH levels they must have (i) recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema OR (ii) confirmed presence of a Factor XII (FXII), angiotensin-converting enzyme (ACE), or plasminogen gene mutation AND (4) patient has tried or has medical reason for not using icatibant. Continuation of therapy: patient has positive clinical response to treatment.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HETLIOZ LQ

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## Products Affected

- HETLIOZ LQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	3 to 15 years of age.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with sleep specialist or neurologist.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Nighttime sleep disturbances in Smith Magenis Syndrome (SMS) - Initial: confirmation of diagnosis. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HIGH DOSE OPIOID

## Products Affected

- *fentanyl transdermal patch 72 hour 100 mcg/hr*
- *methadone hcl oral tablet 10 mg*
- *morphine sulfate er oral tablet extended release 100 mg, 200 mg*
- *oxycodone hcl er oral tablet er 12 hour abuse-deterrent 80 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Members being treated for cancer related diagnoses (i.e. members being treated for cancer-related pain including those undergoing active cancer treatment and cancer survivors with chronic pain who have completed cancer treatment), sickle cell diagnoses, those in hospice care, or receiving palliative care will be approved. Initial: (1) taking opioids at a dose equal to 60 MME per day for at least one week AND (2) current regimen is the lowest possible effective dose of opioid therapy AND (3) if patient is on concurrent benzodiazepines and/or muscle relaxant therapy, the prescriber attests that concurrent therapy is medically necessary AND (4) patient is not being treated for substance abuse with buprenorphine-containing products. Continuation of therapy: (1) pain has been assessed within the last 6 months AND (2) patient has demonstrated clinical improvement in pain and function on current medication regimen AND (3) if patient is on concurrent benzodiazepines and/or muscle relaxant therapy, the prescriber attests that concurrent therapy is medically necessary AND (4) patient is not being treated for substance abuse with buprenorphine-containing products.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HIGH RISK MEDICATION

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## Products Affected

- *benztropine mesylate oral*
- *cyproheptadine hcl oral*
- *diphenoxylate-atropine oral liquid*
- *diphenoxylate-atropine oral tablet 2.5-0.025 mg*
- *dipyridamole oral*
- *hydroxyzine hcl oral syrup*
- *hydroxyzine hcl oral tablet 25 mg, 50 mg*
- *hydroxyzine pamoate oral*
- *megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml*
- *nifedipine oral*
- *promethazine vc*
- *promethazine-phenylephrine*
- *trihexyphenidyl hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For patients 65 years old and older the prescriber has documented: the benefits of treatment with the drug outweigh the potential risks identified for people 65 years old and older.
<b>Age Restrictions</b>	Prior authorization only applies to members 65 years old or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HIGH RISK MEDICATION - PROTECTED CLASS DRUGS

## Products Affected

- *estradiol oral*
- *estradiol transdermal patch twice weekly*
- *estradiol transdermal patch weekly*
- *megestrol acetate oral tablet*
- MENEST
- *phenobarbital oral elixir*
- *phenobarbital oral tablet*
- PREMARIN ORAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For patients 65 years old and older the prescriber has documented: the benefits of treatment with the drug outweigh the potential risks identified for people 65 years old and older.
<b>Age Restrictions</b>	Prior authorization only applies to members 65 years old or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HIGH RISK MEDICATION, BUTALBITAL

## Products Affected

- *butalbital-acetaminophen oral tablet 50-325 mg*
- *butalbital-apap-caff-cod oral capsule 50-325-40-30 mg*
- *butalbital-apap-caffeine oral capsule 50-325-40 mg*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *butalbital-asa-caff-codeine*
- *butalbital-aspirin-caffeine oral capsule*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For patients 65 years old and older the prescriber has documented: the benefits of treatment with the drug outweigh the potential risks identified for people 65 years old and older.
<b>Age Restrictions</b>	Prior authorization only applies to members 65 years old or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using an oral NSAID.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HIGH RISK MEDICATION, GENERAL

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## Products Affected

- *amitriptyline hcl oral tablet 10 mg, 100 mg, 150 mg, 25 mg, 50 mg, 75 mg*
- *amoxapine oral tablet 100 mg, 150 mg, 25 mg, 50 mg*
- *clomipramine hcl oral capsule 25 mg, 50 mg, 75 mg*
- *doxepin hcl oral capsule*
- *doxepin hcl oral concentrate*
- *ergotamine-caffeine*
- *imipramine hcl oral tablet 10 mg, 25 mg, 50 mg*
- *imipramine pamoate oral capsule 100 mg, 125 mg, 150 mg, 75 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# HIGH RISK MEDICATION, SHORT TERM MUSCLE RELAXANT

## Products Affected

- *carisoprodol oral*
- *chlorzoxazone oral tablet 500 mg*
- *cyclobenzaprine hcl oral tablet 10 mg, 5 mg*
- *metaxalone oral tablet 800 mg*
- *methocarbamol oral tablet 500 mg, 750 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For patients 65 years old and older the prescriber has documented: (1) the benefits of treatment with the drug outweigh the potential risks identified for people 65 years old and older AND (2) if the patient is taking one or more additional anticholinergic medication (i.e. amitriptyline, cyclobenzaprine, dicyclomine, meclizine, oxybutynin, paroxetine, etc.) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary.
<b>Age Restrictions</b>	Prior authorization only applies to members 65 years old or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	New starts will be authorized for 30 days. Continuation of therapy or reauth will be for 90 days.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HIGH RISK MEDICATION, SLEEP AGENTS

## Products Affected

- *eszopiclone*
- *temazepam*
- *zaleplon*
- *zolpidem tartrate er*
- *zolpidem tartrate oral tablet 10 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For patients 65 years old and older the prescriber has documented: the benefits of treatment with the drug outweigh the potential risks identified for people 65 years old and older. For zolpidem immediate release 10mg and zolpidem ER: trial of or medical reason for not using zolpidem immediate release 5mg.
<b>Age Restrictions</b>	Prior authorization only applies to members 65 years old or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HUMIRA

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off-Label Uses	UNDER CMS REVIEW
Part B Prerequisite	No

# HYFTOR

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## Products Affected

- HYFTOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrently receiving systemic mTOR inhibitor therapy such as everolimus.
<b>Required Medical Information</b>	Facial angiofibroma - Initial: patient must meet all of the following criteria: (1) documented diagnosis of tuberous sclerosis complex (TSC) AND (2) experiencing three or more facial angiofibromas. Continuation of therapy: patient has positive clinical response to treatment (i.e. improvement in size of redness of facial angiofibroma).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ICATIBANT

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## Products Affected

- *icatibant acetate subcutaneous solution prefilled syringe*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, immunologist, rheumatologist. Or provider that specializes in the treatment of HAE or related disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For acute angioedema attacks due to hereditary angioedema (HAE) patient meets either of the following - Initial: (1) patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR (2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and at least one of the following: i) the patient tested positive for an F12, angiotensin-1, heparan sulfate glucosaminase 3-O sulfotransferase 6 (HS3ST6), myoferlin (MYOF) gene mutation, or plasminogen, kininogen-1 (KNG1) OR ii) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ILARIS

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## Products Affected

- ILARIS SUBCUTANEOUS SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For sJIA: approve. For gout, both of the following are required: 1) Documented trial of, contraindication to, or medical reason for not using nonsteroidal anti-inflammatory drugs and colchicine AND 2) Documented medical reason that repeated corticosteroid use is not appropriate.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ILUMYA

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## Products Affected

- ILUMYA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# IMBRUVICA

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## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET 280 MG, 420 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an oncologist or specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Graft-versus-host disease (GVHD) - Initial: trial of, contraindication to, or medical reason for not using a systemic corticosteroid or other conventional systemic treatment for GVHD (i.e. corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, etc.). Continuation of therapy: documentation of clinical benefit from use of the drug (i.e. symptom improvement, reduction in corticosteroid dose). For all other indications, approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# IMPAVIDO

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## Products Affected

- IMPAVIDO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of diagnosis with one of the following: (a) Visceral leishmaniasis due to <i>Leishmania donovani</i> , (b) Cutaneous leishmaniasis due to <i>Leishmania braziliensis</i> , <i>Leishmania guyanensis</i> , or <i>Leishmania panamensis</i> , (c) Mucosal leishmaniasis due to <i>Leishmania braziliensis</i> .
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 28 days.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# INCRELEX

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## Products Affected

- INCRELEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug - Initial: (1) height 3 or more standard deviations (SDs) below the mean for children of the same age and gender AND (2) basal IGF-1 level 3 or more SDs below the mean for children of the same age and gender AND (3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH - Continuation of therapy: patient has positive clinical response.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# INTRON-A

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## Products Affected

- INTRON A INJECTION SOLUTION  
RECONSTITUTED 18000000 UNIT,  
50000000 UNIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# JAKAFI

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## Products Affected

- JAKAFI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an oncologist or specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For essential thrombocythemia - Initial: patient had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide. Continuation of therapy: patient has positive clinical response to treatment. For graft-versus-host disease (GVHD) - Initial: Trial of, contraindication to, or medical reason for not using a systemic corticosteroid. For continuation of therapy for treatment of GVHD: documentation of clinical benefit from use of the drug (i.e. symptom improvement, reduction in corticosteroid dose). For polycythemia vera - Initial: patient had an inadequate response or intolerance to interferon therapy or hydroxyurea. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# JUXTAPID

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: (1) generic confirmation of two mutant alleles at the LDLR, APOB, PCSK9 or LDLRAP1 gene locus OR (2) untreated LDL-C greater than 400 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: (a) xanthoma prior to ten years of age, (b) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Initial: Trial and failure of, contraindication, or medical reason for not using both of the following: (1) Lipid lowering therapy (i.e., statins, ezetimibe, bile acid sequestrants, etc.) AND (2) Praluent and/or Repatha. Reauthorization: Documentation of reduction in LDL level since initiation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# JYLAMVO

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## Products Affected

- JYLAMVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an oncologist, a rheumatologist, a dermatologist, or other appropriate specialist
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KALYDECO

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## Products Affected

- KALYDECO ORAL PACKET 13.4 MG, 25 MG, 5.8 MG, 50 MG, 75 MG
- KALYDECO ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Orkambi, Symdeko, or Trikafta.
<b>Required Medical Information</b>	Documentation of CFTR gene that is responsive to ivacaftor treatment.
<b>Age Restrictions</b>	1 month of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a provider specializing in treatment of CF.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KANUMA

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## Products Affected

- KANUMA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of lysosomal acid lipase (LAL) deficiency as confirmed by: 1) enzyme assay demonstrating a deficiency of LAL OR 2) genetic testing
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hepatologist, endocrinologist or specialist in genetic, metabolic or lipid disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KERENDIA

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## Products Affected

- KERENDIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 3 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Initial: (1) documentation of diagnosis of chronic kidney disease due to type 2 diabetes mellitus AND (2) documentation of serum potassium levels less than or equal to 5 mEq/L AND (3) eGFR greater than or equal to 25ml/min/1.73 m <sup>2</sup> AND documented urine albumin to creatinine ratio greater than or equal to 30mg/g AND (5) documentation that patient is taking Kerendia in combination with an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) at maximum tolerated doses or documentation has been provided that the patient is unable to tolerate ACEi or ARB AND (6) documented trial of, contraindication to, or medical reason for not using a sodium-glucose cotransporter-2 (SGLT2) inhibitor. Continuation of therapy: (1) documentation of serum potassium levels less than or equal to 5.5 mEq/L AND (2) documentation that patient is taking Kerendia in combination with an ACEi or ARB at maximum tolerated doses or documentation has been provided that the patient is unable to tolerate ACEi or ARB.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KEVZARA

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## Products Affected

- KEVZARA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	For RA: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz or 2) If utilized within the past 120 days, approve for continuation of therapy. For polymyalgia rheumatica (PMR): Trial of, medical reason for not using, or contraindication to corticosteroids. For pJIA: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, Humira, Hadlima, or Xeljanz or 2) If utilized within the past 120 days, approve for continuation of therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# KINERET

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## Products Affected

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Rheumatoid Arthritis (RA) - Initial: trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz [Note: Humira and Hadlima count as one drug]. Continuation of therapy: patient has positive clinical response to treatment. Neonatal-onset multisystem inflammatory disease (NOMID) or deficiency of interleukin-1 receptor antagonist (DIRA): approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LIBERVANT

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## Products Affected

- LIBERVANT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patient is between 2 to 5 years of age.
<b>Prescriber Restrictions</b>	Prescriber must be a neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LITFULO

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## Products Affected

- LITFULO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Absolute lymphocyte count less than 500 cells/mm <sup>3</sup> or platelet count less than 100,000 cells/mm <sup>3</sup> .
<b>Required Medical Information</b>	Initial: (1) documented diagnosis via chart notes of severe alopecia areata AND (2) patient is not receiving in combination with either of the following: (i) Targeted immunomodulator (i.e. Olumiant, Enbrel, Cimzia, Simponi, Orencia, adalimumab, Xeljanz, Rinvoq) OR (ii) potent immunosuppressant. Continuation of therapy: documentation of positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Documentation of confirmed diagnosis and other causes of hair loss have been ruled out.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LIVMARLI

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## Products Affected

- LIVMARLI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# LIVTENCITY

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## Products Affected

- LIVTENCITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# LODOCO

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## Products Affected

- LODOCO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) documentation patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease AND (2) documentation that patient does not have pre-existing blood dyscrasias (i.e. leukopenia, thrombocytopenia) AND (3) patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment AND (4) previous trial of or intolerance to colchicine.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Documentation that patient has established atherosclerotic disease or multiple risk factors for cardiovascular disease AND documentation that patient does not have pre-existing blood dyscrasias (ex. leukopenia, thrombocytopenia) and patient does not have renal failure (CrCl less than 15 ml/min) or severe hepatic impairment
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LUMIZYME

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## Products Affected

- LUMIZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of Pompe Disease as confirmed by one of the following: 1) enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin or muscle OR 2) genetic testing showing a mutation in the GAA gene
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a specialist in the treatment of Pompe disease, such as a genetic or metabolic specialist, neurologist or cardiologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LUPKYNIS

## Products Affected

- LUPKYNIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with cyclophosphamide.
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of Lupus Nephritis confirmed by (i) biopsy OR (ii) medical reason for why biopsy cannot be performed AND (2) documentation of urine protein/creatinine ratio (UPCR) AND (3) documentation that the patient has a baseline eGFR greater than 45 mL/min/1.73m <sup>2</sup> or that benefit outweighs risk of using this medication at current eGFR AND (4) concurrent use of or medical reason for not using background immunosuppressive therapy regimen (mycophenolate and corticosteroids) AND (5) provider attests to ONE of the following: (i) clinical progression or failure to respond after 3 months of induction therapy with immunosuppressive agents OR (ii) clinical failure to minimum of 6 months of induction therapy with immunosuppressive agents. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a rheumatologist, nephrologist, or other specialist in the treatment of autoimmune disorders.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	For new starts: 1) Documentation of urine protein/creatinine ratio (UPCR), 2) Documentation that the member has a baseline eGFR greater than 45 mL/min/1.73m <sup>2</sup> or that benefit outweighs risk of using this medication at current eGFR, and 3) Concurrent use of or medical reason for not using background immunosuppressive therapy regimen. For continuation of therapy or reauthorization: Documentation of improvement in renal function (i.e. reduction in UPCR or no confirmed decrease from baseline eGFR greater than or equal to 20%).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# LYBALVI

## Products Affected

- LYBALVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with opioids.
<b>Required Medical Information</b>	Schizophrenia - Initial: (1) diagnosis of schizophrenia AND (2) documented trial of or intolerance or contraindication to at least two generic antipsychotics, one of which must be generic olanzapine (at maximally tolerated dose) AND (3) attestation from the provider that the patient has had an opioid-free period of a minimum of 7 days after last use of shorting-acting opioids and 14 days from last use of long-acting opioids before initiating .Continuation of therapy: patient has positive clinical response to treatment. Bipolar I Disorder - Initial: (1) patient must have a diagnosis of bipolar I disorder AND (2) documented trial of or intolerance or contraindication to olanzapine and at least one other generic therapy (i.e. lamotrigine, lithium, valproate, quetiapine, etc.) AND (3) attestation from the provider that the patient has had an opioid-free period of a minimum of 7 days after last use of shorting-acting opioids and 14 days from last use of long-acting opioids before initiating. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Documented trial of, contraindication to, or medical reason for not using at least two generic antipsychotics, one of which must be generic olanzapine.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# MANNITOL INHALATION

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## Products Affected

- BRONCHITOL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of cystic fibrosis (CF) AND (2) attestation requested medication will be used in conjunction with standard CF therapies AND (3) patient has passed the Bronchitol Tolerance Test.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a pulmonologist or an expert in the treatment of cystic fibrosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# MAVYRET

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## Products Affected

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Detectable HCV RNA viral load prior to treatment within 6 months of request. In addition, documentation of treatment history, and if cirrhotic, documentation of compensated or decompensated cirrhosis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 8-16 weeks as per AASLD-IDSA guidance.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# METHYLTESTOSTERONE

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## Products Affected

- *methyltestosterone oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For primary hypogonadism or hypogonadotropic hypogonadism - Initial: (1) patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: documentation required] AND (2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one other testosterone product (i.e. injectable, topical, or transdermal testosterone). Continuation of therapy: patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# METYROSINE

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## Products Affected

- *metyrosine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of one of the following: 1) Concurrent use of alpha adrenergic blockers, 2) Medical reason for being unable to use an alpha adrenergic blocker, OR 3) Patient is not a candidate for surgical resection and requires long term treatment with metyrosine.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a provider who specializes in the management of pheochromocytoma.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Initial: patient has tried a selective alpha blocker (i.e. doxazosin, prazosin or terazosin). Continuation of therapy: approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# MIFEPRISTONE

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## Products Affected

- *mifepristone oral tablet 300 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with simvastatin, lovastatin, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a provider who specializes in the treatment of Cushing's syndrome.
<b>Coverage Duration</b>	Cushing's Syndrome: end of contract yr. Patients awaiting surgery/response after radiotherapy: 4 mos
<b>Other Criteria</b>	Endogenous Cushing's Syndrome - Initial: (1) patient is not a candidate for surgery or surgery has not been curative AND (2) requested drug is being used to control hyperglycemia secondary to hypercortisolism in patients who have Type 2 Diabetes Mellitus (T2DM) or glucose intolerance. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# MIGLUSTAT

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## Products Affected

- *miglustat*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) documentation of diagnosis for mild to moderate type 1 Gaucher disease. Continuation of therapy: documentation of positive clinical response (i.e. increased platelet count, improvement in anemia, PFT's).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist in treatment of Gaucher's disease.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# MULTIPLE SCLEROSIS AGENTS

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## Products Affected

- BAFIERTAM
- BETASERON SUBCUTANEOUS KIT
- *dimethyl fumarate oral capsule delayed release 120 mg, 240 mg*
- *dimethyl fumarate starter pack oral capsule delayed release therapy pack*
- *fingolimod hcl*
- *glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*
- KESIMPTA
- MAVENCLAD (10 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)
- MAVENCLAD (7 TABS)
- MAVENCLAD (8 TABS)
- MAVENCLAD (9 TABS)
- MAYZENT
- MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 12 X 0.25 MG, 7 X 0.25 MG
- PONVORY
- PONVORY STARTER PACK
- REBIF REBIDOSE SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF REBIDOSE TITRATION PACK SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- REBIF TITRATION PACK SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- TASCENSO ODT
- *teriflunomide*

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off-Label Uses	UNDER CMS REVIEW

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# MYFEMBREE

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## Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	24 months of total therapy between Myfembree or Oriahnn.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an OB, gynecologist or reproductive endocrinologist.
<b>Coverage Duration</b>	Requests will be authorized for 12 months.
<b>Other Criteria</b>	<p>Fibroids (Leiomyomas) - Initial: (1) patient is premenopausal AND (2) experiencing heavy menstrual bleeding associated with the uterine fibroids AND (3) uterine fibroids have been confirmed by appropriate test (i.e. pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging). Continuation of therapy: patient has positive clinical response to treatment.</p> <p>Endometriosis - Initial: (1) patient is premenopausal AND (2) patient has previously tried, failed or has contraindication to contraceptives (i.e. combination oral contraceptives, depo-medroxyprogesterone injection, or levonorgestrel-releasing intrauterine systems) or oral progesterone (i.e. norethindrone tablets) OR (3) patient has tried gonadotropin-releasing hormone agonist (i.e. leuprolide depot suspension) or Orilissa (elagolix tablets). Continuation of therapy: patient has positive clinical response to treatment.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NAGLAZYME

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## Products Affected

- NAGLAZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of mucopolysaccharidosis VI as confirmed by one of the following: 1) enzyme assay demonstrating a deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity OR 2) genetic testing
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist in genetic or metabolic disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NASAL ANTISEIZURE AGENTS

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Nayzilam: 12 years of age or older. ValtoCO: 6 years of age or older.
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NATPARA

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## Products Affected

- NATPARA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of serum calcium greater than 7.5 mg/dL and vitamin D level (within 30 days of request).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber is an endocrinologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NITISINONE

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## Products Affected

- *nitisinone*
- ORFADIN ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a geneticist, metabolic specialist, hepatologist, or liver transplant specialist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Hereditary Tyrosinemia Type 1 (HT-1): diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated levels of succinylacetone.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# NON-AMPHETAMINE CENTRAL NERVOUS SYSTEM AGENTS

## Products Affected

- *armodafinil*
- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For excessive sleepiness associated with narcolepsy - Initial: diagnosis has been confirmed by sleep lab evaluation. Continuation of therapy: patient has positive clinical response to treatment. For excessive sleepiness associated with obstructive sleep apnea (OSA) - Initial: diagnosis has been confirmed by polysomnography. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NUCALA

## Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 40 MG/0.4ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Asthma: 6 years of age or older. EGPA and CRSwNP: 18 years of age or older. HES: 12 years of age or older
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	<p>For severe asthma - Initial: (1) patient has documented baseline blood eosinophil count of at least 150 cells per microliter OR (2) patient is dependent on systemic corticosteroids AND (3) patient has a history of severe asthma despite current treatment with both of the following medications: (i) medium-to-high-dose inhaled corticosteroid AND (ii) additional controller (i.e. long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies.</p> <p>Continuation of therapy: asthma control has improved on treatment with the requested drug (i.e. reduction in the frequency and/or severity of symptoms and exacerbations or a decrease in the daily maintenance oral corticosteroid dose). For eosinophilic granulomatosis with polyangiitis (EGPA) - Initial: patient has a documented history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10 percent. Continuation of therapy: patient has a beneficial response to treatment with the requested drug (i.e. a reduction in the frequency of relapses, decrease in the daily oral corticosteroid dose, or no active vasculitis). For hypereosinophilic</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>syndrome (HES) - Initial: [note: documented diagnosis] (1) patient has had HES for minimum of 6 months AND (2) patient has HES without an identifiable non-hematologic secondary cause AND (3) patient does not have FIP1L1-PDGFR<math>\alpha</math> kinase-positive HES AND (4) patient has a history or presence of a blood eosinophil count of at least 1000 cells per microliter, AND (5) patient has been on a stable dose of at least one HES therapy (i.e. cytotoxic therapy, immunosuppressants, or oral corticosteroid).  Continuation of therapy: patient has a beneficial response to treatment as demonstrated by a reduction in HES flares. For chronic rhinosinusitis with nasal polyps (CRSwNP) - Initial: (1) Nucala is used as add-on maintenance treatment AND (2) the patient has experienced inadequate treatment response to Xhance. Continuation of therapy: patient has positive clinical response to treatment.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NUEDEXTA

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## Products Affected

- NUEDEXTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block. History of heart failure. Concomitant use with MAOIs or use of MAOIs within 14 days. Concomitant use with drugs containing quinidine, quinine, or mefloquine. History of quinine-, mefloquine-, dextromethorphan/quinidine-, or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome. Non-Part D indications.
<b>Required Medical Information</b>	Confirmation diagnosis is for Part D indication.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NUPLAZID

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For hallucinations and delusions associated with Parkinson's disease psychosis: documented diagnosis of Parkinson's disease must be made prior to the onset of psychotic symptoms.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NURTEC ODT

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## Products Affected

- NURTEC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prevention of migraine - Initial: (1) patient has greater than or equal to 4 migraine headache days per month at baseline prior to starting migraine preventative treatment OR patient has at least one severe migraine lasting 12 hours or longer despite use of abortive therapy AND (2) patient has tried and failed, intolerant or has medical reason for not using at least 2 preventative migraine therapy (i.e. antidepressants, antiepileptic drugs (AEDs), beta-adrenergic blocking agents) OR (3) patient has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine OR Botox (onabotulinumtoxinA injection) for the prevention of migraine. Continuation of therapy: must show a benefit of 1 headache day per month reduction since initiation of therapy. Acute treatment of migraine - Initial: patient has tried and failed, intolerant or has medical reason for not using at least one triptan 5-HT1 receptor agonist. Acute treatment of migraine - Continuation of therapy: must show documentation of improvement in migraine symptoms (pain, photophobia, phonophobia).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OCALIVA

## Products Affected

- OCALIVA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Members with decompensated cirrhosis, a prior decompensation event, compensated cirrhosis who have evidence of portal hypertension, or complete biliary obstruction.
<b>Required Medical Information</b>	For new starts: 1) Attestation that the member has failed at least a 12 month trial of ursodiol, or has a medical reason (e.g. intolerance, hypersensitivity) for being unable to tolerate ursodiol AND 2) lab results for baseline ALT/AST, alkaline phosphatase (ALP), and bilirubin within 90 days of request. For continuation of therapy or reauthorization: Documentation that that the member has responded to Ocaliva (e.g. improved biochemical markers (e.g., ALP, bilirubin, GGT, AST, ALT levels)).
<b>Age Restrictions</b>	Initial therapy only: 18 years of age or older.
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Primary biliary cholangitis (PBC) - Initial: (1) patient has a diagnosis of PBC as defined by two of the following tests: (i) alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values OR (ii) positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies (including sp100 or gp210) OR if AMA is negative (iii) histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy AND (2) patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response OR patient is unable to tolerate ursodiol therapy. Continuation of therapy: patient has positive clinical response to Ocaliva therapy (i.e. improved biochemical markers of PBC).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# OCREVUS

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## Products Affected

- OCREVUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age and older.
<b>Prescriber Restrictions</b>	Specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For new starts for Clinically Isolated Syndrome (CIS), Relapsing Remitting Multiple Sclerosis (RRMS), or Secondary Progressive Multiple Sclerosis (SPMS): 1) Documentation of CIS, RRMS, or SPMS AND 2) The member must have a documented trial of, contraindication to, or medical reason for not using both dimethyl fumarate AND glatiramer or Glatopa. For new starts for Primary Progressive Multiple Sclerosis (PPMS): Documentation of PPMS. For all continuation of therapy or reauthorization: Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OCTREOTIDE

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## Products Affected

- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acromegaly - Initial: (1) documented diagnosis of acromegaly AND (2) patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range AND (3) patient had an inadequate or partial response to surgery or radiotherapy OR there is a medical reason for why the patient has not had surgery or radiotherapy. Continuation of therapy: patient's IGF-1 level has decreased or normalized since Initial of therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Continuation of therapy or reauthorization: documentation of clinical improvement with therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OFEV

## Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Chronic fibrosing interstitial lung disease - Initial: [Note: documentation required] (1) documented diagnosis AND (2) forced vital capacity is greater than or equal to 45 percent of the predicted value AND (3) patient has fibrosing lung disease impacting more than 10 percent of lung volume on high-resolution computed tomography AND (3) patient has clinical signs of progression. Continuation of therapy: patient has positive clinical response to treatment. Interstitial lung disease associated with systemic sclerosis - Initial: [Note: documentation required] (1) documented diagnosis AND (2) FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Continuation of therapy: patient has positive clinical response to treatment. Idiopathic pulmonary fibrosis (IPF) - Initial: [Note: documentation required] (1) documented diagnosis AND (2) FVC greater than or equal to 40 percent of the predicted value AND (3) IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. Continuation of therapy: patient has positive clinical response to treatment.</p>
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	IPF: prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis: prescribed by or in consultation with a pulmonologist or rheumatologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For a diagnosis of idiopathic pulmonary fibrosis: 1) Documentation of disease as demonstrated on a high resolution CT scan or through lung biopsy and 2) Documented trial of, contraindication to, or medical reason for not using pirfenidone. For a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD): documented trial of, contraindication to, or medical reason for not using mycophenolate mofetil or

<b>PA Criteria</b>	<b>Criteria Details</b>
	cyclophosphamide. For a diagnosis of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype: documentation is provided confirming diagnosis.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OPSUMIT

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## Products Affected

- OPSUMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of pulmonary arterial hypertension (PAH) WHO Group I and PAH Functional Class
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a pulmonologist or cardiologist
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using sildenafil.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORAL ANTINEOPLASTIC AGENTS

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## Products Affected

- *abiraterone acetate oral tablet 250 mg, 500 mg*
- AKEEGA
- ALECENSA
- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK
- AUGTYRO
- AYVAKIT
- BALVERSA
- *bexarotene*
- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG
- BRAFTOVI ORAL CAPSULE 75 MG
- BRUKINSA
- CABOMETYX
- CALQUENCE
- CAPRELSA ORAL TABLET 100 MG, 300 MG
- 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 ORAL TABLET 100 MG, 25 MG
- ERIVEDGE
- ERLEADA ORAL TABLET 240 MG, 60 MG
- *erlotinib hcl oral tablet 100 mg, 150 mg, 25 mg*
- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet soluble*
- FOTIVDA
- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG
- GAVRETO
- *gefitinib*
- GILOTRIF
- IBRANCE
- ICLUSIG
- IDHIFA
- *imatinib mesylate oral tablet 100 mg, 400 mg*
- IMBRUVICA ORAL SUSPENSION
- INLYTA ORAL TABLET 1 MG, 5 MG
- INQOVI
- INREBIC
- IWILFIN
- JAYPIRCA ORAL TABLET 100 MG, 50 MG
- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KISQALI FEMARA (200 MG DOSE)
- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (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 ORAL TABLET 100 MG, 25 MG
- LUMAKRAS
- LYNPARZA ORAL TABLET
- LYTGobi (12 MG DAILY DOSE)
- LYTGobi (16 MG DAILY DOSE)
- LYTGobi (20 MG DAILY DOSE)

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- MEKINIST ORAL SOLUTION RECONSTITUTED
- MEKINIST ORAL TABLET 0.5 MG, 2 MG
- MEKTOVI
- NERLYNX
- *nilutamide*
- NINLARO
- NUBEQA
- ODOMZO
- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG
- OJEMDA
- OJJAARA
- ONUREG
- ORGOVYX
- ORSERDU ORAL TABLET 345 MG, 86 MG
- *pazopanib hcl*
- PEMAZYRE
- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)
- POMALYST
- PURIXAN
- QINLOCK
- RETEVMO ORAL CAPSULE 40 MG, 80 MG
- RETEVMO ORAL TABLET
- REZLIDHIA
- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PACKET
- RUBRACA
- RYDAPT
- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG
- SOLTAMOX
- *sorafenib tosylate*
- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG
- STIVARGA
- *sunitinib malate*
- TABRECTA
- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET SOLUBLE
- TAGRISSO
- TALZENNA
- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG
- TAZVERIK
- TEPMETKO
- THALOMID ORAL CAPSULE 100 MG, 150 MG, 200 MG, 50 MG
- TIBSOVO
- *toremifene citrate*
- *tretinoin oral*
- TRUQAP ORAL TABLET
- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)
- TUKYSA ORAL TABLET 150 MG, 50 MG
- TURALIO ORAL CAPSULE 125 MG
- VANFLYTA
- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK
- VERZENIO
- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION
- VIZIMPRO
- VONJO
- WELIREG
- XALKORI ORAL CAPSULE
- XALKORI ORAL CAPSULE SPRINKLE 150 MG, 20 MG, 50 MG
- 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 ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG
- YONSA
- ZEJULA ORAL TABLET
- ZELBORAF
- ZOLINZA
- ZYDELIG
- ZYKADIA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an oncologist or specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORAL ANTIPSYCHOTICS

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## Products Affected

- CAPLYTA
- FANAPT
- FANAPT TITRATION PACK
- VRAYLAR ORAL CAPSULE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For schizophrenia and manic or mixed episodes associated with bipolar I disorder and major depressive disorder associated with bipolar I or II disorder: trial of, contraindication to, or medical reason for not using two generic antipsychotics. If the request is for Vraylar for major depressive disorder: provider attestation that the member is concurrently using an antidepressant.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORENCIA

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## Products Affected

- ORENCIA CLICKJECT
- ORENCIA INTRAVENOUS
- ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 125 MG/ML, 50 MG/0.4ML, 87.5 MG/0.7ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# ORIAHNN

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## Products Affected

- ORIAHNN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patient has history of osteoporosis or hepatic impairment.
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) AND (2) patient is premenopausal AND (3) trial of, contraindication to, or medical reason for not using an estrogen-progestin contraceptive therapy. For new starts if one of the following has been tried previously, a trial of estrogen-progestin contraceptive therapy is not required: gonadotropin-releasing hormone (GnRH) agonists or tranexamic acid, OR patient has had a previous interventional therapy to reduce bleeding. Continuation of therapy: (1) treatment does not exceed the eligible maximum lifetime treatment duration of 2 years AND (2) documentation of positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an OB, gynecologist or reproductive endocrinologist.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	For new starts: Trial of, contraindication to, or medical reason for not using an estrogen-progestin contraceptive therapy. For new starts if one of the following drugs has been tried previously, a trial of estrogen-progestin contraceptive therapy is not required: gonadotropin-releasing hormone (GnRH) agonists or tranexamic acid. For continuation of therapy or reauthorization both of the following are required: 1) Treatment does not exceed the eligible maximum lifetime treatment duration of 2 years, and 2) Documentation has been provided that the member has obtained clinical benefit from medication (e.g. reduced menstrual bleeding from baseline).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# ORILISSA

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## Products Affected

- ORILISSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# ORKAMBI

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## Products Affected

- ORKAMBI ORAL PACKET
- ORKAMBI ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Kalydeco, Symdeko, or Trikafta.
<b>Required Medical Information</b>	Cystic Fibrosis (CF) - Initial: documented diagnosis confirmed by homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation). Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	1 year of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a provider who specializes in treatment of CF.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OTEZLA

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## Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent Use with a Biologic or with a Targeted Synthetic Disease Modifying Antirheumatic Drugs (DMARD).
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Psoriasis, moderate to severe - Initial: trial of, medical reason for not using, or contraindication to 2 of the following therapies: Stelara, Skyrizi, Tremfya, Enbrel, Hadlima, or Humira [Note: Humira and Hadlima count as 1 drug]. Continuation of therapy: patient has positive clinical response to treatment. Psoriatic arthritis (PsA) - Initial: trial of, medical reason for not using, or contraindication to 2 of the following therapies: Stelara, Skyrizi Tremfya, Xeljanz, Rinvoq, Enbrel, Hadlima, or Humira [Note: Humira and Hadlima count as 1 drug]. Continuation of therapy: patient has positive clinical response to treatment. Bechet's Syndrome or mild psoriasis: Approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OXBRYTA

## Products Affected

- OXBRYTA ORAL TABLET 300 MG, 500 MG
- OXBRYTA ORAL TABLET SOLUBLE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Adakveo (crizanlizumab-tmca).
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of sickle cell disease AND (2) patient is currently receiving hydroxyurea therapy OR patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy AND (3) patient has previously experienced 1 or more sickle cell-related vaso-occlusive crises within the previous 12 months AND (4) baseline hemoglobin (Hb) less than or equal to 10.5 grams per deciliter AND (5) patient is not receiving concomitant chronic, prophylactic blood transfusion therapy Continuation of therapy:(1) Hb increase from baseline OR (2) reduced number of vaso-occlusive/pain crises OR (3) decrease in indirect bilirubin from baseline OR (4) decrease in percentage of reticulocytes from baseline.
<b>Age Restrictions</b>	4 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OXERVATE

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## Products Affected

- OXERVATE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Treatment duration greater than 16 weeks per affected eye(s).
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by an ophthalmologist or an optometrist.
<b>Coverage Duration</b>	Initial: 8 weeks. Continuation of therapy: additional 8 weeks.
<b>Other Criteria</b>	Initial: confirmed diagnosis. Continuation of therapy: patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OXYCODONE ER

## Products Affected

- *oxycodone hcl er oral tablet er 12 hour abuse-deterrent 10 mg, 20 mg, 40 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Patient is being treated for cancer related diagnoses (i.e. members being treated for cancer-related pain including those undergoing active cancer treatment and cancer survivors with chronic pain who have completed cancer treatment), sickle cell diagnoses, those in hospice care, or receiving palliative care will be excluded from the concurrent benzodiazepine and muscle relaxant therapy requirement. Initial: (1) documented history of receiving an immediate-release opioid, (2) documented trial of, contraindication to, or medical reason for not using long-acting morphine sulfate, (3) if patient is on concurrent benzodiazepines and/or muscle relaxant therapy, the prescriber attests that concurrent therapy is medically necessary AND (4) patient is not being treated for substance abuse with buprenorphine-containing products. Continuation of therapy: (1) pain has been assessed within the last 6 months AND (2) patient has demonstrated clinical improvement in pain and function on current medication regimen AND (3) if patient is on concurrent benzodiazepines and/or muscle relaxant therapy, the prescriber attests that concurrent therapy is medically necessary AND (4) patient is not being treated for substance abuse with buprenorphine-containing products.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PCSK9 INHIBITORS

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## Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off-Label Uses	UNDER CMS REVIEW
Part B Prerequisite	No

# PEGINTERFERON

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## Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For Hepatitis C: 1) Labs within 3 months of request: liver function tests and detectable HCV RNA viral load. 2) Documentation of genotype, treatment history, and if cirrhotic, documentation of compensated or decompensated cirrhosis. For Hepatitis B: 1) Labs within 3 months of request: ALT/AST, and 2) HBeAg status. For polycythemia vera, approve.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a gastroenterologist, hepatologist, infectious disease doctor or transplant specialist.
<b>Coverage Duration</b>	Request will be authorized for 24 to 48 weeks as defined by compendia.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PENICILLAMINE

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## Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Rheumatoid arthritis (RA) - Initial: patient has trial, intolerance or medical reason for not using at least 2 of the following: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz [note: Humira and Hadlima count as one drug]. Wilson's disease - Initial: documented diagnosis confirmed by one of the following methods (1 or 2) (1) genetic testing showing biallelic pathogenic ATP7B mutations (pt can be asymptomatic or symptomatic) OR (2) at least two of the following (i) serum ceruloplasmin level less than 20 mg/dL, (ii) presence of Kayser-Fleischer rings, (iii) 24-hour urinary copper greater than 40 mcg/24 hours, or (iv) liver biopsy findings consistent with Wilson's disease. For other indications, approve. Continuation of therapy for all indications: patient has a positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PENTAMIDINE SOLUTION FOR INJECTION

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## Products Affected

- *pentamidine isethionate injection*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PERSERIS

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## Products Affected

- PERSERIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented history of receiving oral risperidone without any clinically significant side effects.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial and failure of, contraindication, or medical reason for not using at least two of the following: Abilify Maintena, Abilify Asimtufii, Risperidone Microsphere, Invega Sustenna, Invega Trinza, and Invega Hafyera.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PHENOXYBENZAMINE

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## Products Affected

- *phenoxybenzamine hcl oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# PIRFENIDONE

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## Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 267 mg, 534 mg, 801 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Idiopathic pulmonary fibrosis - Initial: [Note: documentation required] (1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern OR (2) HRCT study of the chest reveals a result other than the UIP pattern (i.e. probable UIP, indeterminate for UIP) AND (3) the diagnosis is supported either by a lung biopsy OR by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted. Continuation of therapy: patient has positive clinical response to therapy.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# POSACONAZOLE

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## Products Affected

- *posaconazole oral suspension*
- *posaconazole oral tablet delayed release*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of medically accepted indication. The requested drug will be used orally. For prophylaxis of invasive Aspergillus and Candida infections: patient weighs greater than 40 kilograms.
<b>Age Restrictions</b>	Prophylaxis of Invasive Aspergillus and Candida Infections: 2 years of age or older. Treatment of Invasive Aspergillosis: 13 years of age or older.
<b>Prescriber Restrictions</b>	Documentation of a consultation with an infectious disease specialist, a transplant specialist, or an oncologist.
<b>Coverage Duration</b>	Request will be authorized for 6 months.
<b>Other Criteria</b>	For treatment of oropharyngeal candidiasis: trial of, contraindication to, or medical reason for not using fluconazole or itraconazole. For prophylaxis of invasive aspergillus infections due to being severely immunocompromised: trial of, contraindication to, or medical reason for not using voriconazole.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PRETOMANID

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## Products Affected

- PRETOMANID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of pulmonary extensively drug resistant (XDR) tuberculosis (TB) OR (2) treatment-intolerant or nonresponsive multidrug-resistant TB AND (3) will be used in combination with bedaquiline and linezolid AND (4) documentation of prior trial of or medical reason for not using first-line TB regimen containing isoniazid and rifampin.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with infectious disease specialist, pulmonologist, or provider specializing in treatment of tuberculosis.
<b>Coverage Duration</b>	Request will be authorized for 26 weeks.
<b>Other Criteria</b>	Documentation of prior trial of or medical reason for not using first-line TB regimen containing isoniazid and rifampin.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PREVYMIS

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## Products Affected

- PREVYMIS ORAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prophylaxis of CMV disease in kidney transplant: (1) patient is CMV seronegative AND (2) the patient is a high risk recipient of kidney transplant. For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): (1) patient is CMV seropositive AND (2) patient is a recipient of an allogeneic HSCT.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a hematologist, oncologist, infectious disease, or transplant specialist.
<b>Coverage Duration</b>	Request will be authorized for 7 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PROMACTA

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## Products Affected

- PROMACTA ORAL PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# PYRIMETHAMINE

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## Products Affected

- *pyrimethamine oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Toxoplasma gondii Encephalitis (Chronic Maintenance): patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary): patient is immunosuppressed.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PYRUKYND

## Products Affected

- PYRUKYND
- PYRUKYND TAPER PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (i.e. decreased haptoglobin, increased indirect bilirubin, elevated lactated dehydrogenase [LDH], increased reticulocyte count) AND (2) documented diagnosis of pyruvate kinase deficiency confirmed by molecular testing requiring all of the following: (i) patient is not homozygous for the c.1436G A (p.R479H) variant AND (ii) patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene AND (iii) 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 AND (3) hemoglobin is less than or equal to 10g/dL AND (4) exclusion of other causes of hemolytic anemias (i.e. drugs, infections, toxins). Continuation of therapy: (1) documentation of clinical improvement (i.e. reduction in number of blood transfusions, increase or stabilization in hemoglobin level). If the criteria are not met, may authorize up to 14 days of a Pyrukynd Taper Pack to allow for tapering.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year. Denial: 14 days for dose tapering.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# QULIPTA

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## Products Affected

- QULIPTA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	Prevention of migraine - Initial: (1) patient has greater than or equal to 4 migraine headache days per month at baseline prior to starting migraine preventative treatment OR patient has at least one severe migraine lasting 12 hours or longer despite use of abortive therapy AND (2) patient has tried and failed, intolerant or has medical reason for not using at least 2 preventative migraine therapy (i.e. antidepressants, antiepileptic drugs (AEDs), beta-adrenergic blocking agents) OR (3) patient has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine OR Botox (onabotulinumtoxinA injection) for the prevention of migraine. Continuation of therapy: patient has a reduction in migraine days per month from baseline.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# RADICAVA

## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a provider who specializes in the treatment of ALS.
<b>Coverage Duration</b>	Request will be authorized for 6 months.
<b>Other Criteria</b>	Amyotrophic lateral sclerosis (ALS) - Initial: (1) patient has definitive or probable ALS diagnosis (based on the application of the El Escorial or the revised Airlie House diagnostic criteria AND (2) patient has a minimum score of two points on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [i.e. has retained most or all activities of daily living] AND (3) patient has a percent predicted FVC greater than or equal to 80% (i.e. has normal respiratory function) AND (4) patient has been diagnosed with ALS for less than or equal to 2 years. Continuation of therapy: patient has positive clinical response to treatment OR patient has tried Tiglutik or Exservan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RAVICTI

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## Products Affected

- RAVICTI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of urea cycle disorder (UCD) AND (2) inadequate response to ONE of the following: (i) amino acid supplementation OR (ii) dietary protein restriction AND (3) trial and failure, contraindication, or intolerance to generic sodium phenylbutyrate. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Provider is a geneticist, metabolic specialist, gastroenterologist, hepatologist, or liver transplant specialist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using sodium phenylbutyrate.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RECORLEV

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## Products Affected

- RECORLEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of Cushing's disease AND (2) patient is not a candidate for pituitary surgery or surgery has not been curative AND (3) trial of, contraindication to, or medical reason for not using ketoconazole tablets.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using ketoconazole tablets.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# REGRANEX

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## Products Affected

- REGRANEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 20 weeks.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RELISTOR

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## Products Affected

- RELISTOR ORAL MG/0.6ML (0.6ML SYRINGE), 8
- RELISTOR SUBCUTANEOUS SOLUTION 12 MG/0.6ML, 12 MG/0.4ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Patient must have documented trial of or medical reason for not using the following: 1) lubiprostone, AND 2) lactulose AND 3) Movantik. Additionally, patient must have a medical reason for not being able to use oral Relistor in order to receive Relistor injection.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RELYVRIO

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## Products Affected

- RELYVRIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For new starts: Documentation of diagnosis of ALS. For continuation of therapy or reauthorization: Documentation or provider attestation of positive clinical response (such as improvement, stabilization, or reduced rate of reduction in the Revised ALS Functional Rating Scale (ALSFRS-R) total score)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis.
<b>Coverage Duration</b>	New starts: 6 months. Cont. of therapy or reauthorization: until end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# REXULTI

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## Products Affected

- REXULTI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For schizophrenia: trial of, contraindication to, or medical reason for not using two generic antipsychotics. For major depressive disorder: trial of, contraindication to, or medical reason for not using to two generic antidepressants. For agitation associated with dementia: approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# REZUROCK

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## Products Affected

- REZUROCK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	12 years of age or older.
<b>Prescriber Restrictions</b>	Prescriber must be a hematologist, oncologist, or transplant specialist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Graft-versus-host disease - Initial: (1) patient has chronic graft-versus host disease AND (2) patient has tried at least two conventional systemic treatments (i.e. cyclosporine, ibrutinib). Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RINVOQ

## Products Affected

- RINVOQ
- RINVOQ LQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For RA: Trial of, medical reason for not using, or contraindication to 1 disease modifying antirheumatic drug (DMARD) (methotrexate, leflunomide, or sulfasalazine) and 1 tumor necrosis factor (TNF) blocker (Enbrel, Hadlima, or Humira). For PsA: Trial of, medical reason for not using, or contraindication to 1 TNF blocker (Enbrel, Hadlima, or Humira). For atopic dermatitis: trial of, contraindication to, or medical reason for not using: 1) topical tacrolimus or pimecrolimus and 2) Eucrisa. For ankylosing spondylitis: Trial of, medical reason for not using, or contraindication to naproxen and 1 TNF blocker (Enbrel, Hadlima, or Humira). For UC: Trial of, medical reason for not using, or contraindication to 1 of the following conventional therapies: mercaptopurine, an aminosalicylate (i.e. mesalamine, sulfasalazine, azathioprine), or a corticosteroid (i.e. prednisone, methylprednisolone) and Humira, or Hadlima. For non radiographic axial spondyloarthritis: Trial of, medical reason for not using, or contraindication to naproxen. For Crohns Disease: trial of, medical reason for not using, or contraindication to 1 TNF blocker. For pJIA: Trial of, medical reason for not using, or contraindication to 1 TNF blocker (Enbrel, Hadlima, or Humira).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No

# RUFINAMIDE

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## Products Affected

- *rufinamide oral suspension*
- *rufinamide oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of familial Short QT syndrome
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	1 year of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Initial: rufinamide is being used for adjunctive treatment. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RYKINDO

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## Products Affected

- RYKINDO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented history of receiving oral risperidone without any clinically significant side effects.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason (e.g. intolerance, hypersensitivity or contraindication) for not using Abilify Maintena.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RYLAZE

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## Products Affected

- RYLAZE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an oncologist, hematologist, or specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SAPROPTERIN

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## Products Affected

- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Phenylketonuria (PKU) - Initial: (1) patient has documented diagnosis of PKU and (2) patient has pretreatment phenylalanine level greater than 6 mg/dL or 360 micromol/L (note: pretreatment includes prior to dietary management). Continuation of therapy: patient has documented positive clinical response to treatment (i.e. improvement in neuropsychiatric symptoms or reduction in blood phenylalanine levels).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases.
<b>Coverage Duration</b>	Initial: 12 weeks. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SECUADO

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## Products Affected

- SECUADO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	(1) patient has been diagnosed with schizophrenia AND (2) patient has tried, intolerant or has medical reason for not using at least two generic antipsychotics (i.e. aripiprazole, olanzapine, risperidone, etc.).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SEROSTIM

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a HIV specialist, gastroenterologist, nutritional support specialist or ID specialist.
Coverage Duration	Request will be authorized for 12 weeks.
Other Criteria	HIV wasting/cachexia - Initial: (1) patient is currently on anti-retroviral therapy AND(2) trial of, contraindication to or medical reason for not using megestrol OR dronabinol AND (3) patient has experienced weight loss defined by one of the following: (i) 5% body cell mass (BCM) OR (ii) 7.5% unintentional weight loss in past 6 months OR (iii) 10% unintentional weight loss in past 12 months OR (iv) for men, BCM less than 35% of total body weight or BMI less than 27 OR (v) for women, BCM less than 23% of total body weight and BMI less than 27 OR (vi) BMI less than 18.5 AND (4) alternative causes of wasting have been ruled out (i.e. altered metabolism, diarrhea, inadequate caloric intake, malignancies, etc.). Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# SIGNIFOR

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## Products Affected

- SIGNIFOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Member is not a candidate for surgery or surgery was not curative.
<b>Age Restrictions</b>	Initial therapy only: 18 years of age or older.
<b>Prescriber Restrictions</b>	Initial therapy only: prescribed by or in consultation with an endocrinologist or a provider specializing in the treatment of Cushing's syndrome.
<b>Coverage Duration</b>	Initial: 4 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Cushing's disease - Initial: patient is not a candidate for surgery or surgery has not been curative. Continuation of therapy: patient has positive clinical response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SILDENAFIL ORAL

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Documentation of concurrent nitrate or Adempas use.
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) - Initial: [Note: documentation required] (1) diagnosis confirmed by right heart catheterization AND (2) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg AND (3) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg AND (4) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units AND (5) documentation of diagnosis via chart notes. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For sildenafil suspension: Documentation of trial of, contraindication to, or medical reason for not using sildenafil tablet.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SILIQ

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## Products Affected

- SILIQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Psoriasis - Initial: trial of, medical reason for not using, or contraindication to 2 of the following therapies: Stelara, Skyrizi, Tremfya, Enbrel, Hadlima, or Humira [Note: Humira and Hadlima will count as 1 product]. Continuation of therapy: patient has been receiving Siliq for a minimum of 4 months and has positive response to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SIMPONI

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For ankylosing spondylitis: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz, or 2) If utilized within the past 120 days, approve for continuation of therapy. For PsA: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Stelara, Skyrizi, Tremfya, Xeljanz, Rinvoq, Enbrel, Hadlima, or Humira, or 2) If utilized within the past 120 days, approve for continuation of therapy. For RA: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz or 2) If utilized within the past 120 days, approve for continuation of therapy. For UC: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following: Skyrizi, Humira, Hadlima, Rinvoq, Stelara or Xeljanz or 2) If utilized within the past 120 days, approve for continuation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SIRTURO

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## Products Affected

- SIRTURO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patient weighs less than 15 kilograms.
<b>Required Medical Information</b>	Documentation (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) that the member is currently taking 3 additional antimycobacterial drugs in combination to treat MDR-TB.
<b>Age Restrictions</b>	5 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious diseases specialist.
<b>Coverage Duration</b>	Request will be authorized for 9 months.
<b>Other Criteria</b>	Tuberculosis (Pulmonary): (1) patient has multidrug-resistant tuberculosis AND (2) Sirturo is prescribed as part of a combination regimen with other anti-tuberculosis agents.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SKYRIZI

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## Products Affected

- SKYRIZI INTRAVENOUS
- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE 180 MG/1.2ML, 360 MG/2.4ML
- SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	For PsA or psoriasis: approve. For Crohns Disease: Either 1) Trial of, medical reason for not using (i.e. severe Crohns disease), or contraindication to 1 of the following: mercaptopurine, azathioprine, sulfasalazine, methotrexate or corticosteroid (e.g., prednisone, methylprednisolone) or 2) If utilized within the past 120 days, approve for continuation of therapy. For UC: Trial of, medical reason for not using, or contraindication to 1 of the following conventional therapies: mercaptopurine, an aminosalicylate (i.e. mesalamine, sulfasalazine, azathioprine), or a corticosteroid (i.e. prednisone, methylprednisolone).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# SODIUM OXYBATE

## Products Affected

- *sodium oxybate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Xywav, Wakix or Sunosi.
<b>Required Medical Information</b>	For the treatment of excessive daytime sleepiness in a patient with narcolepsy - Initial: [Note: documented diagnosis] (1) diagnosis has been confirmed by sleep lab evaluation AND (2) patient meets one of the following criteria: (i) if the patient is 17 years of age or younger, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (i.e. amphetamine, dextroamphetamine, methylphenidate) or has medical reason for inability to use CNS stimulant OR (ii) If the patient is 18 years of age or older, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (i.e. armodafinil or modafinil) or has medical reason for inability to use CNS wakefulness promoting drugs. For the treatment of cataplexy in a patient with narcolepsy - Initial: documented diagnosis has been confirmed by sleep lab evaluation. Continuation of therapy: patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy.
<b>Age Restrictions</b>	7 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a sleep disorder specialist or neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SODIUM PHENYL BUTYRATE

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## Products Affected

- *sodium phenylbutyrate oral powder 3 gm/tsp*
- *sodium phenylbutyrate oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with phenylbutyrate product.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist or provider specializing in treatment of metabolic diseases.
<b>Coverage Duration</b>	Patient has genetic test: end of contract year. Patient meets criteria w/o genetic test: 3 months.
<b>Other Criteria</b>	Urea cycle disorders: (1) patient has documented genetic testing confirming mutation resulting in a urea cycle disorder OR (2) patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SOFOSBUVIR/VELPATASVIR

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## Products Affected

- SOFOSBUVIR-VELPATASVIR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Detectable HCV RNA viral load prior to treatment within 6 months of request. In addition, documentation of treatment history, and if cirrhotic, documentation of compensated or decompensated cirrhosis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 12-24 weeks based on AASLD-IDSA guidelines
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SOMAVERT

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## Products Affected

- SOMAVERT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For new starts for acromegaly: pt meets one of the following (1) inadequate response to surgery and/or radiotherapy OR (2) pt is not an appropriate candidate for surgery and/or radiotherapy OR (3) pt is experiencing negative effects due to tumor size (ex: optic nerve compression). Continuation of therapy or reauthorization: documentation of clinical improvement with therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Acromegaly: (1) patient has had an inadequate response to radiotherapy and/or surgery OR (2) patient is not a candidate for radiotherapy and/or surgery OR (3) patient is experiencing negative effects from tumor (i.e. optic nerve compression) AND (4) patient documented baseline (prior to treatment) insulin-like growth factor-1 (IGF-1) level is above the upper limit of normal (ULN) based on the age and gender for the reporting laboratory.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SOTYKTU

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## Products Affected

- SOTYKTU

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# STELARA

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## Products Affected

- STELARA INTRAVENOUS
- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Crohns Disease (CD) - Initial: Trial of, medical reason for not using (i.e. severe Crohns disease), or contraindication to 1 of the following: mercaptopurine, azathioprine, methotrexate, sulfasalazine, or corticosteroid (e.g., prednisone, methylprednisolone). Continuation of therapy: patient has been receiving Stelara for a minimum of 4 months and has a positive clinical response. Psoriasis (PsO) or Psoriatic arthritis (PsA) : Approve. Ulcerative Colitis (UC): Trial of, medical reason for not using, or contraindication to 1 of the following conventional therapies: mercaptopurine, an aminosalicylate (i.e. mesalamine, sulfasalazine, azathioprine), or a corticosteroid (i.e. prednisone, methylprednisolone). Continuation of therapy: patient has been receiving Stelara for a minimum of 4 months and has a positive clinical response.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# STRENSIQ

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## Products Affected

- STRENSIQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documented diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia (HPP). Patient needs one of the following: 1) documentation of clinical signs and symptoms of hypophosphatasia prior to 18 years of age (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, delayed walking) OR 2) radiographic evidence supporting the diagnosis of hypophosphatasia prior to 18 years of age (e.g., craniosynostosis, infantile rickets, non-traumatic fractures). Documentation of low serum alkaline phosphatase (ALP) levels.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist or specialist in metabolic disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SUCRAID

## Products Affected

- SUCRAID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	(1) Patient has symptomatic congenital sucrose-isomaltase deficiency (i.e. abdominal cramping, bloating, diarrhea) AND (2) documented diagnosis is established by one of the following: (i) molecular genetic testing demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrose isomaltase gene variant OR (ii) patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by all of the following: (a) decreased normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein] AND (b) decreased normal lactase (normal reference: greater than 15 U/g protein) AND (c) decreased maltase (normal reference: greater than 100 U/g protein) AND (d) decreased (typically absent) sucrose (normal reference: greater than 25 U/g protein).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, geneticist, metabolic disorder specialist, or a provider who specializes in the treatment of congenital diarrheal disorders.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SYMDEKO

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## Products Affected

- SYMDEKO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Kalydeco, Orkambi or Trikafta. Patients with unknown CFTR gene mutations.
<b>Required Medical Information</b>	Documentation of CFTR gene that is responsive to tezacaftor-ivacaftor treatment.
<b>Age Restrictions</b>	6 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a provider who specializes in CF.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Cystic Fibrosis (CF): patient must be homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to the requested medication.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SYMLIN

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patient has confirmed gastroparesis.
<b>Required Medical Information</b>	For new starts: HbA1C values within 90 days of request is greater than or equal to 7% despite receiving insulin therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using two alternative anti-diabetic agents.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SYNAREL

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## Products Affected

- SYNAREL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# TADALAFIL

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## Products Affected

- *tadalafil (pah)*
- TADLIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Documentation of concurrent nitrate or Adempas use.
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) - Initial: [Note: documentation required] (1) diagnosis confirmed by right heart catheterization AND (2) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg AND (3) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg AND (4) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units AND (5) documentation of diagnosis via chart notes. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For Tadliq: Documentation of trial of, contraindication to, or medical reason for not using tadalafil tablets.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TADALAFIL, BPH

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## Products Affected

- *tadalafil oral tablet 5 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Diagnosis of erectile dysfunction
<b>Required Medical Information</b>	Diagnosis of Benign prostatic hyperplasia (BPH) required AND trial of, contraindication to, or medical reason for not using an alpha blocker (e.g. tamsulosin, terazosin).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TALTZ

## Products Affected

- TALTZ SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- TALTZ SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 20 MG/0.25ML, 40 MG/0.5ML, 80 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For ankylosing spondylitis: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Enbrel, Humira, Hadlima, Rinvoq or Xeljanz, or 2) If utilized within the past 120 days, approve for continuation of therapy. For non-radiographic axial spondyloarthritis: approve. For psoriasis: Either 1) Trial of, medical reason for not using, or contraindication (e.g., safety concerns, not indicated for patient's age) to 2 of the following therapies: Stelara, Skyrizi, Tremfya, Enbrel, Hadlima, or Humira, or 2) If utilized within the past 120 days, approve for continuation of therapy. For PsA: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Stelara, Skyrizi, Tremfya, Xeljanz, Rinvoq, Enbrel, Hadlima, or Humira, or 2) If utilized within the past 120 days, approve for continuation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TARPEYO

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## Products Affected

- TARPEYO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# TASIMELTEON

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## Products Affected

- *tasimelteon*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Non 24: 18 years of age or older. SMS: 16 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with sleep specialist or neurologist.
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	Nighttime sleep disturbances in Smith Magenis Syndrome (SMS) - Initial: confirmation of diagnosis. Continuation of therapy: patient has positive clinical response to treatment. Non-24-Hour Sleep Wake Disorder - Initial: patient has diagnosis of total blindness in both eyes AND inability to perceive light in either eye. Continuation of therapy: patient experiences increase in total nighttime sleep OR decreased daytime nap duration.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TAVNEOS

## Products Affected

- TAVNEOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: [Note: documentation required] (1) diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis AND (2) documentation of diagnosis with one of the following types: (i) granulomatosis with polyangiitis (GPA) or (ii) microscopic polyangiitis (MPA) AND (3) Tavneos is being prescribed as part of adjunctive treatment used concurrently with standard therapy (i.e. azathioprine, cyclophosphamide, methotrexate, etc.) AND (4) patient is being treated with an initial immunosuppressive regimen to induce remission (i.e. cyclophosphamide, rituximab). Continuation of therapy: (1) patient does not show evidence of disease progression AND (2) Tavneos is being prescribed as part of adjunctive treatment used concurrently with standard therapy (defined above).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist, nephrologist, pulmonologist, rheumatologist or vascular medicine specialist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For new starts: 1) Prescriber attests that Tavneos will be prescribed in combination with corticosteroids AND cyclophosphamide unless there is documented trial of, contraindication to, or medical reason for not using these therapies. 2) Documentation of baseline Birmingham Vasculitis Activity Score (BVAS) score 3) Prescriber attestation that the patient will have liver function tests before treatment (ALT, AST, alkaline phosphate, and total bilirubin) and every 4 weeks after start of therapy for the first 6 months of treatment 4) Prescriber attestation that the patient has been screened for and does not have active hepatitis B virus (HBV) infection at baseline. For continuation of therapy or reauthorization: 1) Documentation of remission (BVAS score of 0) OR improvement in BVAS score 2) Prescriber attestation that patient has no abnormality in liver function tests (abnormality: ALT or AST greater than 3 times the upper limit of normal

<b>PA Criteria</b>	<b>Criteria Details</b>
	and bilirubin greater than 2 times the upper limit of normal) 3) Prescriber attestation that patient has no active HBV infection.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TEFLARO

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## Products Affected

- TEFLARO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Documentation of a consultation with an infectious disease specialist.
<b>Coverage Duration</b>	Request will be authorized for 14 days.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TERIPARATIDE

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## Products Affected

- TERIPARATIDE SUBCUTANEOUS  
SOLUTION PEN-INJECTOR 600  
MCG/2.4ML, 620 MCG/2.48ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# TESTOSTERONE CYPIONATE

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## Products Affected

- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml, 200 mg/ml (1 ml)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Primary hypogonadism or hypogonadotropic hypogonadism - Initial: (1) patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines AND (2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one other testosterone product (i.e. injectable, topical, or transdermal testosterone). Continuation of therapy: patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy. Gender dysphoria - Initial: the patient is able to make an informed decision to engage in hormone therapy. Continuation of therapy: approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TESTOSTERONE ENANTHATE

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## Products Affected

- *testosterone enanthate intramuscular solution*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Primary hypogonadism or hypogonadotropic hypogonadism - Initial: (1) patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines AND (2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one other testosterone product (i.e. injectable, topical, or transdermal testosterone). Continuation of therapy: patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy. Gender dysphoria - Initial: the patient is able to make an informed decision to engage in hormone therapy. Continuation of therapy: approve.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# THIOLA

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## Products Affected

- *tiopronin oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	(1) Patient has diagnosis of cystinuria AND (2) diagnosis confirmed by laboratory testing (i.e. quantitative urine cystine assay, urinary cystine crystals present on microscopy) AND (3) patient weight at least 20 kilograms AND (4) prescriber attestation that patient has had inadequate response to dietary modifications, high fluid intake, and urinary alkalization. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with nephrologist, urologist or provider specializing in treatment of cystinuria.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TIGECYCLINE

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## Products Affected

- *tigecycline*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	(1) Patient must have documented diagnosis of one of the following infections: (a) complicated skin and skin structure infection, (b) complicated intraabdominal infection, (c) community-acquired pneumonia AND (2) Trial of, contraindication to, or medical reason (e.g. intolerance, hypersensitivity or contraindication) for not using preferred first-line antibiotics.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist.
<b>Coverage Duration</b>	Request will be authorized for 14 days.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TOLVAPTAN

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## Products Affected

- *tolvaptan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Jynarque.
<b>Required Medical Information</b>	Hyponatremia - Initial: (1) patient has documented serum sodium less than 125 mEq/L at baseline OR (2) marked hyponatremia (defined as less than 135 mEq/L at baseline) and is symptomatic which can include confusion, headache, nausea and vomiting). Continuation of therapy: patient has received less than 30-days of therapy.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist, endocrinologist, hepatologist, or nephrologist.
<b>Coverage Duration</b>	Request will be authorized for 30 days.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TOPICAL ANTINEOPLASTIC RETINOIDS

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## Products Affected

- *bexarotene*
- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# TOPICAL TESTOSTERONE

## Products Affected

- *testosterone transdermal gel 1.62 %, 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*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient has history of prostate cancer or breast cancer.
<b>Required Medical Information</b>	New starts of topical testosterone therapy for hypogonadism must have both of the following characteristics of hypogonadism: 1) symptoms associated with hypogonadism (e.g. unexplained mild anemia, low libido, decreased energy, etc.) 2) Two separate instances of low serum total or free testosterone taken in the morning, as defined by the lab reference range.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Primary hypogonadism or hypogonadotropic hypogonadism - Initial: (1) patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines AND (2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one other testosterone product (i.e. injectable, topical, or transdermal testosterone). Continuation of therapy: patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy. Gender dysphoria - Initial: the patient is able to make an informed decision to engage in hormone therapy. Continuation of therapy: approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TRANSDERMAL LIDOCAINE

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## Products Affected

- *lidocaine external patch 5 %*
- ZTLIDO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# TREMFYA

## Products Affected

- TREMFYA SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML
- TREMFYA SUBCUTANEOUS SOLUTION PEN-INJECTOR
- TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Moderate to severe Psoriasis - Initial: (1) patient has psoriasis affecting 3% or greater surface area involvement OR (2) psoriasis in sensitive areas such as face, groin, palms, soles of feet or scalp AND (2) patient has history of failure or medical reason for not using at least one conventional topical therapy (i.e. calcineurin inhibitors, corticosteroids, tazarotene or vitamin D analogs). Continuation of therapy: patient has been receiving Tremfya for a minimum of 4 months and has positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TRIENTINE

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## Products Affected

- CUVRIOR
- *trientine hcl oral capsule 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant specialist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Wilson's Disease - Initial: (1) diagnosis of Wilson's disease is confirmed by genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals) OR confirmation of at least two of the following (i, ii, iii, and/or iv): (i) 24-hour urinary copper greater than 40 micrograms/24 hours OR (ii) liver biopsy findings consistent with Wilson's disease OR (iii) presence of Kayser Fleischer rings OR iv) serum ceruloplasmin levels less than 20mg/dL AND (2) patient has tried, intolerance to (i.e. autoimmune tendency, congestive splenomegaly causing severe thrombocytopenia, history of any renal disease) or has medical reason for not using penicillamine therapy OR (3) patient has neurologic manifestations of Wilson's disease OR (4) patient is pregnant. Continuation of therapy: approve.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# TRIKAFTA

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## Products Affected

- TRIKAFTA ORAL TABLET THERAPY • TRIKAFTA ORAL THERAPY PACK PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Kalydeco, Orkambi, or Symdeko. Patients with unknown CFTR gene mutations.
<b>Required Medical Information</b>	Documentation of CFTR gene that is responsive to elexacaftor-tezacaftor-ivacaftor treatment.
<b>Age Restrictions</b>	2 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a provider who specializes in treatment of CF.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Cystic Fibrosis (CF) - Initial: patient must have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication. Continuation of therapy: approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TYMLOS

## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation showing patient falls into one of the following categories: a bone mineral density (BMD) value consistent with osteoporosis (i.e., T-scores equal to or less than -2.5) or patient has had an osteoporotic fracture or patient has T-scores from -1.5 to -2.5 at the femoral neck or spine, and a 10-year probability of hip fracture greater than or equal to 3% or a 10-year probability of any major osteoporosis-related fracture greater than or equal to 20% based on the United States-adapted FRAX model.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	New Therapy: 24 months. Continuation of therapy: up to a total of 24 months
<b>Other Criteria</b>	<p>Postmenopausal osteoporosis - Initial: [Note: documentation required] (1) patient has history of fragility fracture OR (2) pretreatment T-score equal to less than -2.5 OR (3) pretreatment T-score less than -1 or greater than -2.5 with a high pretreatment Fracture Risk Assessment Tool (FRAX) fracture probability AND (4) patient has at least one of the following: (i) indicators for higher fracture risk (i.e. advanced age, frailty, glucocorticoid therapy, increased fall risk, or very low T-scores) OR (5) patient has tried and failed or is intolerant or has medical reason for not using oral or injectable bisphosphonate therapy (trial duration minimum of 12 months). Continuation of therapy: patient has positive clinical response to treatment.</p> <p>Primary or hypogonadal osteoporosis in men - Initial: [Note: documentation required] (1) patient has history of osteoporotic vertebral or hip fracture OR (2) pretreatment T-score equal to less than -2.5 OR (3) pretreatment T-score less than -1 or greater than -2.5 with a high pretreatment FRAX fracture probability AND (3) patient has tried and failed or is intolerant or has medical reason for not using oral or injectable bisphosphonate therapy (trial duration minimum of 12 months). Continuation of therapy: patient has positive clinical response to treatment.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>Glucocorticoid-induced osteoporosis - Initial: [Note: documentation required] (1) patient has tried, intolerant or has medical reason for not using oral bisphosphonate for minimum of at least 1 year AND (2) patient has history of fragility fracture OR (3) patient has pretreatment T-score of less than or equal to -2.5 OR (4) pretreatment T-score of greater than -2.5 and less than -1 with a high pretreatment FRAX fracture probability. Continuation (patient has been treated with teriparatide for at least 24 months of therapy): (1) Patient has remained or reverted back to high risk for fracture AND (2) provider has determined benefit of prolonged therapy exceeding 24 months outweighs the potential risks.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TYVASO

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# UBRELVY

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## Products Affected

- UBRELVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute treatment of migraine - Initial: patient has tried and failed, intolerant or has medical reason for not using at least one triptan 5-HT1 receptor agonist. Continuation of therapy: must show documentation of improvement in migraine symptoms (pain, photophobia, phonophobia).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# UPTRAVI

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## Products Affected

- UPTRAVI ORAL
- UPTRAVI TITRATION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) - Initial: [Note: documentation required] (1) diagnosis confirmed by right heart catheterization AND (2) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg AND (3) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg AND (4) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. Continuation of therapy: patient has positive clinical response to treatment.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not using a generic phosphodiesterase inhibitor and a generic endothelin receptor antagonist.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# UZEDY

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## Products Affected

- UZEDY SUBCUTANEOUS SUSPENSION PREFILLED SYRINGE 100 MG/0.28ML, 125 MG/0.35ML, 150 MG/0.42ML, 200 MG/0.56ML, 250 MG/0.7ML, 50 MG/0.14ML, 75 MG/0.21ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented history of receiving oral risperidone without any clinically significant side effects.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial and failure of, contraindication, or medical reason for not using at least two of the following: Abilify Maintena, Abilify Asimtufii, Risperidone Microsphere, Invega Sustenna, Invega Trinza, and Invega Hafyera.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VALCHLOR

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## Products Affected

- VALCHLOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial of, contraindication to, or medical reason for not being able to use one of the following: a topical corticosteroids or a topical retinoids.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VEMLIDY

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## Products Affected

- VEMLIDY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For new starts: attestation that member has been tested for HIV infection. If member is HIV-positive, Vemlidy is not used alone.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VENTAVIS

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## Products Affected

- VENTAVIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of pulmonary arterial hypertension (PAH) WHO Group I classification and PAH Functional Class.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a pulmonologist or cardiologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VEOZAH

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## Products Affected

- VEOZAH

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) Documented diagnosis of moderate to severe vasomotor symptoms due to menopause AND (2) Trial of, contraindication to, or medical reason (e.g. intolerance, hypersensitivity or contraindication) for not using a hormonal therapy (e.g., estradiol, oral Premarin, Prempro). Reauthorization: (1) Documentation of positive clinical response to therapy (e.g., decrease in frequency or severity of vasomotor symptoms from baseline)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VIGABATRIN

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## Products Affected

- *vigabatrin*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For infantile spasms or West syndrome, the request will be approved. For diagnosis of refractory complex partial seizures: 1) documentation of diagnosis, and 2) attestation the member is currently receiving another antiepileptic drug, and 3) attestation the member has experienced treatment failure from two generic alternative formulary antiepileptic agents.
<b>Age Restrictions</b>	Refractory complex partial seizures: 2 years of age or older. Infantile spasms: less than or equal to 2 years of age.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Infantile spasms: 6 mos. Refractory Partial Seizures: Initial: 3 months, Cont.: end of contract yr
<b>Other Criteria</b>	Infantile spasm - Initial: requested medication is being used as monotherapy. Continuation of therapy: patient has positive clinical response to treatment. Treatment refractory complex partial seizures - Initial: patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Continuation of therapy: patient has positive clinical response to treatment (i.e. reduced seizure severity, frequency, or duration).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VIJOICE

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## Products Affected

- VIJOICE ORAL PACKET
- VIJOICE ORAL TABLET THERAPY PACK 125 MG, 200 & 50 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) AND documentation of mutation in the PIK3CA gene AND (2) documentation of severe clinical manifestations AND (3) at least one target lesion identified on imaging. Continuation of therapy: documentation of positive clinical response to treatment.
<b>Age Restrictions</b>	2 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, dermatologist, vascular surgeon, hematologist/oncologist, or other specialist in the treatment of PIK3CA-Related Overgrowth Spectrum(PROS).
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VMAT-2 INHIBITORS

## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO PATIENT TITRATION KIT
- AUSTEDO XR
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 & 30 MG
- INGREZZA ORAL CAPSULE
- INGREZZA ORAL CAPSULE SPRINKLE
- INGREZZA ORAL CAPSULE THERAPY PACK
- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	If the request is for tetrabenazine, Ingrezza or Ingrezza Sprinkle, request will be approved. If the request is for Austedo or Austedo XR, the member must have trial of or medical reason for not using tetrabenazine. Reauthorization: Confirmation of improvement in tardive dyskinesia symptoms or chorea associated with Huntington disease symptoms.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# VORICONAZOLE

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## Products Affected

- *voriconazole intravenous*
- *voriconazole oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 6 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VOSEVI

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## Products Affected

- VOSEVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Detectable HCV RNA viral load prior to treatment within 6 months of request. In addition, documentation of treatment history, and if cirrhotic, documentation of compensated or decompensated cirrhosis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized for 12 weeks as per AASLD-IDSA guidance.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VOWST

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## Products Affected

- VOWST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Treatment of Clostridioides difficile infection (CDI)
<b>Required Medical Information</b>	Initial: (1) documented diagnosis of recurrent clostridioides difficile infection (CDI) AND (2) patient has a history of two or more recurrent episodes of CDI within 12 months AND (3) documentation patient has completed at least 10 consecutive days of CDI treatment antibiotic therapies 2-4 days prior to initiating therapy.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with gastroenterologist or infections disease specialist.
<b>Coverage Duration</b>	Request will be authorized for 14 days
<b>Other Criteria</b>	Diagnosis of at least 1 recurrent episode of CDI
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VYNDAMAX

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## Products Affected

- VYNDAMAX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Member has documented diagnosis with transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) with documentation of one of the following: (1) Member has a transthyretin (TTR) mutation (e.g., V122I) OR (2) Cardiac or non-cardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits OR (3) all of the following: (a) echocardiogram or cardiac magnetic resonance image suggestive of amyloidosis, (b) scintigraphy scan suggestive of cardiac TTR amyloidosis, (c) absence of light-chain amyloidosis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or prescriber specializing in treatment of amyloidosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# WEGOVY

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## Products Affected

- WEGOVY SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.25 MG/0.5ML, 1.7 MG/0.75ML, 2.4 MG/0.75ML, 0.5 MG/0.5ML, 1

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off-Label Uses	UNDER CMS REVIEW
Part B Prerequisite	No

# WHITE BLOOD CELL STIMULATORS

## Products Affected

- FULPHILA
- FYLNETRA
- LEUKINE INJECTION SOLUTION RECONSTITUTED
- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- NIVESTYM
- NYVEPRIA
- RELEUKO
- STIMUFEND
- UDENYCA
- UDENYCA ONBODY
- ZARXIO
- ZIEXTENZO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of medically accepted indication.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Specialist for submitted diagnosis.
<b>Coverage Duration</b>	New starts will be authorized for 4 months. Cont of therapy or reauth until end of contract year.
<b>Other Criteria</b>	Cancer patient undergoing chemotherapy: (1) patient is receiving myelosuppressive chemotherapy associated with high risk of febrile neutropenia OR (2) patient has one or more risk factors for febrile neutropenia as documented by the prescriber (i.e. 65 years of age or older, prior chemotherapy or radiation therapy, persistent neutropenia, recent surgery, liver and/or renal impairment, bone marrow involvement by tumor, poor performance status or HIV infection) OR (3) patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a dose reduction or change in frequency of chemotherapy may compromise treatment. For new starts for Neulasta, Udenyca, Ziextenzo, Stimufend and Nyvepria: documentation of trial of, contraindication to, or medical reason for not using Fylnetra and Fulphila. Continuation of therapy or re-authorization criteria: diagnosis of chronic neutropenia or a medical reason for continued need for GCSF.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XATMEP

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## Products Affected

- XATMEP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an oncologist or rheumatologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Polyarticular Juvenile Idiopathic Arthritis (pJIA) - Initial: (1) patient had been diagnosed with pJIA AND (2) patient had tried, intolerant or has medical reason for not using at least one non-steroidal anti-inflammatory agents (NSAIDs) AND methotrexate.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XDEMVY

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## Products Affected

- XDEMVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XELJANZ

## Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Ankylosing spondylitis (AS) - Initial: Trial of, medical reason for not using, or contraindication to naproxen and 1 TNF blocker (Enbrel, Hadlima, or Humira) [Note: Humira and Hadlima will count as 1 product]. Polyarticular juvenile idiopathic arthritis (pJIA) - Initial: Trial of, medical reason for not using, or contraindication to 1 of the following DMARDs: methotrexate or leflunomide and 1 TNF blocker (Enbrel, Hadlima, or Humira). [Note: Humira and Hadlima will count as 1 product]. Psoriatic arthritis (PsA) - Initial: Trial of, medical reason for not using, or contraindication to 1 TNF blocker (Enbrel, Hadlima, or Humira). [Note: Humira and Hadlima will count as 1 product]. Rheumatoid Arthritis (RA) - Initial: Trial of, medical reason for not using, or contraindication to 1 disease modifying antirheumatic drug (DMARD) (methotrexate, leflunomide, or sulfasalazine) and 1 tumor necrosis factor (TNF) blocker (Enbrel, Hadlima, or Humira). [Note: Humira and Hadlima will count as 1 product]. Ulcerative Colitis (UC) - Initial: Trial of, medical reason for not using, or contraindication to 1 of the following conventional therapies: mercaptopurine, an aminosalicylate (i.e. mesalamine, sulfasalazine, azathioprine), or a corticosteroid (i.e. prednisone, methylprednisolone) and Humira OR Hadlima. Continuation of therapy: patient has been receiving Xeljanz for a minimum of 4 months and has a positive clinical response.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XERMELO

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## Products Affected

- XERMELO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist or an oncologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Initial: patient meets all of the following criteria: (1) patient has been on long-acting somatostatin analog (SSA) therapy (i.e. Somatuline Depot) AND (2) while on long-acting SSA therapy (prior to Xermelo start), the patient continues to have at least four bowel movements daily AND (3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation of therapy: patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XGEVA

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## Products Affected

- XGEVA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients with baseline hypocalcemia
<b>Required Medical Information</b>	New starts: Serum calcium levels. Reauthorization criteria for malignant hypercalcemia: albumin-adjusted serum calcium level below 12.5mg/dl within 30 days of request.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XIAFLEX

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## Products Affected

- XIAFLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Peyronie's plaques that involve the penile urethra.
<b>Required Medical Information</b>	Dupuytren's Contracture: 1) Documented diagnosis of Dupuytren's Contracture with a palpable cord AND 2) Documentation that flexion deformity results in functional limitations AND 3) Documentation of which cords are being treated and dates of treatment. Peyronie's Disease: 1) Documented diagnosis of Peyronie's Disease with a palpable plaque AND 2) Documentation that prior to start of therapy curvature deformity is at least 30 degrees.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Dupuytren's Contracture: Prescribed by or in consultation with an orthopedic surgeon or other orthopedic specialist. Peyronie's Disease: Prescribed by or in consultation with a urologist.
<b>Coverage Duration</b>	Dupuytren's Contracture: 3 months. Peyronie's Disease: 6 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XIFAXAN

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## Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	UNDER CMS REVIEW
<b>Required Medical Information</b>	UNDER CMS REVIEW
<b>Age Restrictions</b>	UNDER CMS REVIEW
<b>Prescriber Restrictions</b>	UNDER CMS REVIEW
<b>Coverage Duration</b>	UNDER CMS REVIEW
<b>Other Criteria</b>	UNDER CMS REVIEW
<b>Indications</b>	UNDER CMS REVIEW
<b>Off-Label Uses</b>	UNDER CMS REVIEW
<b>Part B Prerequisite</b>	No

# XOLAIR

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	<p>Asthma, moderate to severe persistent - Initial: [Note: documentation required] (1) patient has a positive skin test or blood test to at least one perennial aeroallergen AND (2) patient has baseline IgE level greater than or equal to 30 IU/mL AND (3) Patient has inadequate asthma control despite current treatment with both of the following medications: (i) medium-to-high-dose inhaled corticosteroid AND (ii) additional controller (i.e. long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to controller. Continuation of therapy: asthma control has improved on treatment with the requested drug (reduction in the frequency and/or severity of symptoms and exacerbations or a decrease in the daily maintenance oral corticosteroid dose). Chronic spontaneous urticaria (CSU) - Initial: [Note: documentation required] (1) patient has been evaluated for other causes of urticaria including bradykinin-related angioedema and IL-1-associated urticarial syndromes (i.e. auto-inflammatory disorders, urticarial vasculitis) AND (2) patient has experienced a spontaneous onset of wheals and/or angioedema for at least 6 weeks AND (3) patient remains symptomatic despite H1 antihistamine treatment. Continuation of therapy: patient has positive clinical response to treatment. Chronic rhinosinusitis with nasal polyps (CRSwNP) - Initial: [Note: documentation required] (1) Xolair used as add-on maintenance treatment AND (2) patient has experienced inadequate treatment response to Xhance. Continuation of therapy: patient has positive clinical response to treatment. Food allergy - Initial: (1) documented diagnosis of IgE-mediated food allergy AND (2) Xolair will be used in conjunction with food allergen avoidance.</p>
<b>Age Restrictions</b>	CSU: 12 years of age or older. Asthma: 6 years of age or older. CRSwNP: 18 years of age or older
<b>Prescriber Restrictions</b>	Prescriber must be a pulmonologist, allergist, immunologist, dermatologist, or otolaryngologist.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	CSU Initial: 6 months. All others: end of the contract year.
<b>Other Criteria</b>	<p>New starts for moderate to severe persistent allergic asthma: 1) Evidence of specific allergic sensitivity confirmed by positive skin test (i.e. prick/puncture test) or blood test (i.e. radioallergosorbent test) for a specific IgE or in vitro reactivity to a perennial aeroallergen, AND 2) Pretreatment serum IgE levels greater than 30 IU/mL, AND 3) Symptoms are not adequately controlled with high-dose inhaled corticosteroid (ICS) plus additional controller medication (ie. long-acting B2 agonist) for at least 3 months, or there is a medical reason for not using these drugs. Continuation of therapy or reauthorization criteria for moderate to severe persistent allergic asthma: 1) Reduction in asthma exacerbation resulting in systemic steroid use and/or hospitalization, OR 2) Reduction of rescue inhaler use, OR 3) Documentation of improvement in pulmonary function tests since baseline (prior to initiation of Xolair). New starts for chronic idiopathic urticaria: 1) inadequate symptomatic relief despite trial of two weeks of two different oral antihistamine therapies (unless contraindicated), AND 2) disease must be severe enough to warrant short term systemic corticosteroid therapy for management of urticaria. Continuation of therapy or reauthorization criteria for chronic idiopathic urticaria: 1) improvement from baseline of symptoms associated with urticaria within 6 months of Xolair use. New starts for nasal polyps: 1) currently using an intranasal corticosteroid, will be prescribed an intranasal corticosteroid with request, or has a medical reason for not using an intranasal corticosteroid. Continuation of therapy or reauthorization criteria for nasal polyps: 1) Documentation has been provided that demonstrates a clinical benefit (e.g. improvements in symptom severity, nasal polyp score [NPS], sino-nasal outcome test-22 [SNOT-22], nasal congestion score [NCS]) AND 2) continued use of intranasal corticosteroid, or has a medical reason for not using one.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XOLREMDI

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## Products Affected

- XOLREMDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be an immunologist, dermatologist, or a hematologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For new starts: 1) A diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome confirmed by genotype variant of chemokine receptor 4 (CXCR4) and absolute neutrophil count (ANC) of less than or equal to 400 cells/microliter or white blood cells (WBC) less than or equal to 400 cells/microliter and 2) Documentation of baseline ANC and absolute lymphocyte count (ALC). For renewal 1) Documentation or provider attestation of positive clinical response (i.e. improvement from baseline in ANC, WBC and/or ALC or reduced frequency, duration, or severity of infections, fewer warts, or improved or stabilized clinical signs and/or symptoms of WHIM).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XYWAV

## Products Affected

- XYWAV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For use for narcolepsy with cataplexy - Initial: documented diagnosis of narcolepsy with cataplexy. Continuation of therapy: documentation of clinical response, reduction in frequency of cataplexy attacks associated. For use for narcolepsy with excessive daytime sleepiness: (1) patient has a documented diagnosis of narcolepsy according to ICSD-3 or DSM-5 criteria AND (2) patient has condition of excessive daytime sleepiness (EDS) associated with narcolepsy as confirmed AND (3) previous treatment, intolerance, or contraindication to at least one CNS stimulant or modafinil or armodafinil. Continuation of therapy: documentation demonstrating a reduction in symptoms of EDS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a sleep specialist, pulmonologist or a neurologist.
<b>Coverage Duration</b>	Initial authorization: 3 months. Reauthorization: 6 months.
<b>Other Criteria</b>	For treatment of somnolence associated with narcolepsy, patient must have documentation of either trial of or a medical reason for being unable to use a CNS stimulant (e.g. methylphenidate, modafinil, armodafinil, etc.). For the treatment of cataplexy associated with narcolepsy or idiopathic hypersomnia, approve.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZAVZPRET

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## Products Affected

- ZAVZPRET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Acute treatment of migraine - Initial: (1) patient has tried and failed, intolerant or has medical reason for not using at least one triptan 5-HT1 receptor agonist AND Ubrelvy AND Nurtec . Continuation of therapy: must show documentation of improvement in migraine symptoms (pain, photophobia, phonophobia).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Initial: 6 months. Continuation of therapy: end of contract year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZEPOSIA

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## 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
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of liver function tests (for new starts and for continuation of therapy or reauthorization)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Specialist for submitted diagnosis.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	For multiple sclerosis: Trial of, contraindication to, or medical reason for not using two of the following: dalfampridine ER, dimethyl fumarate, fingolimod, glatiramer, glatopa, or teriflunomide. For ulcerative colitis: Either 1) Trial of, medical reason for not using, or contraindication Humira or 2) If utilized within the past 120 days, approve for continuation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZILBRYSQ

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## Products Affected

- ZILBRYSQ SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 16.6 MG/0.416ML, 23 MG/0.574ML, 32.4 MG/0.81ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescriber must be a neurologist, rheumatologist, or other appropriate specialist
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Patient has tried and failed, a medical reason for not using, or has a contraindication to two (2) or more conventional therapies (i.e. pyridostigmine, corticosteroids, or non-steroidal immunosuppressive therapies)
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZTALMY

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## Products Affected

- ZTALMY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	2 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder - Initial: (1) patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene AND (2) patient has tried or is concomitantly receiving two other antiepileptic drugs. Continuation of therapy: patient has positive clinical response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZURZUVAE

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## Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Previous treatment with Zurzuvae during the current episode of postpartum depression.
<b>Required Medical Information</b>	The member has a documented diagnosis of postpartum depression
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist or an obstetrician gynecologist.
<b>Coverage Duration</b>	Request will be authorized for 14 days.
<b>Other Criteria</b>	Postpartum depression: (1) patient is not currently pregnant AND (2) patient has been diagnosed with severe depression AND (3) onset of symptoms occurred during the third trimester of pregnancy or up to 4 weeks post-delivery.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZYPREXA RELPREVV

## Products Affected

- ZYPREXA RELPREVV INTRAMUSCULAR SUSPENSION RECONSTITUTED 210 MG, 300 MG, 405 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The member has a documented history of receiving oral olanzapine without any clinically significant side effects.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Request will be authorized until the end of the contract year.
<b>Other Criteria</b>	Trial and failure of, contraindication, or medical reason for not using at least two of the following: Abilify Maintena, Abilify Asimtufii, Risperidone Microsphere, Invega Sustenna, Invega Trinza, and Invega Hafyera.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## PART B VERSUS PART D

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### Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- *acetylcysteine inhalation solution 10 %, 20 %*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, (5 mg/ml) 0.5%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- *amphotericin b intravenous solution reconstituted 50 mg*
- *amphotericin b liposome intravenous suspension reconstituted 50 mg*
- *aprepitant oral 80 & 125 mg*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- ASTAGRAF XL ORAL CAPSULE EXTENDED RELEASE 24 HOUR 0.5 MG, 1 MG, 5 MG
- *azathioprine oral tablet 50 mg*
- *budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml*
- *clinisol sf intravenous solution 15 %*
- *cromolyn sodium inhalation nebulization solution 20 mg/2ml*
- *cyclophosphamide oral capsule 25 mg, 50 mg*
- *cyclophosphamide oral tablet 25 mg, 50 mg*
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- DIPHTHERIA-TETANUS TOXOIDS DT INTRAMUSCULAR SUSPENSION 25-5 LFU/0.5ML
- *dronabinol oral capsule 10 mg, 2.5 mg, 5 mg*
- EMEND ORAL SUSPENSION RECONSTITUTED 125 MG/5ML
- ENGERIX-B INJECTION SUSPENSION 20 MCG/ML
- ENGERIX-B INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/0.5ML, 20 MCG/ML
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- *everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- *formoterol fumarate inhalation nebulization solution 20 mcg/2ml*
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- *gengraf oral capsule 100 mg, 25 mg*
- *gengraf oral solution 100 mg/ml*
- *granisetron hcl oral tablet 1 mg*
- HEPLISAV-B INTRAMUSCULAR SOLUTION PREFILLED SYRINGE 20 MCG/0.5ML
- IMOVAX RABIES INTRAMUSCULAR SUSPENSION RECONSTITUTED 2.5 UNIT/ML
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml*

- *levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/3ml*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension reconstituted 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet delayed release 180 mg, 360 mg*
- *mycophenolic acid oral tablet delayed release 180 mg, 360 mg*
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- NUTRILIPID INTRAVENOUS EMULSION 20 %
- *ondansetron hcl oral solution 4 mg/5ml*
- *ondansetron hcl oral tablet 24 mg, 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
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- *plenamine intravenous solution 15 %*
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- PROGRAF ORAL PACKET 0.2 MG, 1 MG
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- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
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- TETANUS-DIPHThERIA TOXOIDS TD INTRAMUSCULAR SUSPENSION 2-2 LF/0.5ML
- *tobramycin inhalation nebulization solution 300 mg/4ml, 300 mg/5ml*

## Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

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