## **2026** AmeriHealth Caritas VIP Care PA (HMO-DSNP)

#### **2026 Prior Authorization Criteria**

CURRENT AS OF 01/01/2026

## **ACITRETIN**

#### **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
Prerequisite Therapy Required	Yes

# **ACL INHIBITORS**

### **Products Affected**

NEXLETOL

### NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.

PA Criteria	Criteria Details
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **ACTEMRA**

### **Products Affected**

• ACTEMRA ACTPEN

### • ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Polyarticular juvenile idiopathic arthritis (pJIA) - Initial: trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, an adalimumab product, or Xeljanz. 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, an adalimumab product, or Xeljanz. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **ACTIMMUNE**

### **Products Affected**

• ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Chronic granulomatous disease: prescribed by or in consultation with an hematologist, immunologist, or infectious disease specialist. Malignant osteopetrosis: prescribed by or in consultation with an endocrinologist or hematologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Chronic granulomatous disease - Initial: documented diagnosis confirming granulomatous disease. Cotinuation of therapy: patient does not show evidence of disease progression. Malignant osteopetrosis, severe infantile - Initial: documented diagnosis confirming severe, maligant osteopetrosis. Continuation of therapy: patient does not show evidence of disease progression.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **ADALIMUMAB**

#### **Products Affected**

- adalimumab-fkjp (2 pen)
- adalimumab-fkjp (2 syringe) subcutaneous
   prefilled syringe kit 20 mg/0.4ml, 40
   mg/0.8ml
- SIMLANDI (1 PEN) SUBCUTANEOUS AUTO-INJECTOR KIT 40 MG/0.4ML, 80 MG/0.8ML
- SIMLANDI (1 SYRINGE)
- SIMLANDI (2 PEN)
- SIMLANDI (2 SYRINGE)
   SUBCUTANEOUS PREFILLED
   SYRINGE KIT 20 MG/0.2ML, 40
   MG/0.4ML

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
Prerequisite Therapy Required	Yes

## **ADEMPAS**

### **Products Affected**

ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Phosphodiesterase Inhibitors used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.
Required Medical Information	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1)- 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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
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
Prerequisite Therapy Required	No

## **AIMOVIG**

### **Products Affected**

• AIMOVIG

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
Prerequisite Therapy Required	Yes

## **ALPHA-1 PROTEINASE INHIBITORS**

#### **Products Affected**

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG, 500 MG
- GLASSIA

- PROLASTIN-C INTRAVENOUS SOLUTION
- ZEMAIRA

· OLI IDDII I	
PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescriber by or in consultation with a pulmonologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Request for Glassia or Aralast NP: patient has a documented medical reason or contraindication for not using Prolastin-C or Zemaira.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **ALYFTREK**

### **Products Affected**

• ALYFTREK ORAL TABLET 10-50-125 MG, 4-20-50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Trikafta, Kalydeco, Orkambi, or Symdeko. Patients with unknown CFTR gene mutations.
Required Medical Information	Documentation of CFTR gene that is responsive to vanzacaftor-tezacaftor-deutivacaftor treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a provider who specializes in treatment of CF.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **AMBRISENTAN**

### **Products Affected**

• ambrisentan

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PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) - 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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
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
Prerequisite Therapy Required	No

## ANTINEOPLASTIC AGENTS

#### **Products Affected**

- abiraterone acetate oral tablet 250 mg, 500 mg
- ABIRTEGA
- AKEEGA
- ALECENSA
- ALUNBRIG ORAL TABLET 180 MG. 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY **PACK**
- AUGTYRO ORAL CAPSULE 160 MG, 40 MG
- AVMAPKI FAKZYNJA CO-PACK
- AYVAKIT
- BALVERSA
- bexarotene
- BOSULIF ORAL CAPSULE 100 MG, 50 IBTROZI MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG
- BRAFTOVI ORAL CAPSULE 75 MG
- BRUKINSA ORAL CAPSULE
- BRUKINSA ORAL TABLET
- CABOMETYX
- CALQUENCE ORAL TABLET
- 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
- DANZITEN
- dasatinib
- DAURISMO ORAL TABLET 100 MG, 25 MG
- ENSACOVE
- ERIVEDGE
- ERLEADA ORAL TABLET 240 MG, 60 MG

- erlotinib hcl oral tablet 100 mg, 150 mg, 25 mg
- EULEXIN
- 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
- **GOMEKLI**
- HERNEXEOS
- IBRANCE
- ICLUSIG
- IDHIFA
- imatinib mesylate oral tablet 100 mg, 400 mg
- imkeldi
- INLYTA ORAL TABLET 1 MG, 5 MG
- INQOVI
- INREBIC
- ITOVEBI
- IWILFIN
- JAYPIRCA ORAL TABLET 100 MG, 50
- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KISQALI FEMARA (400 MG DOSE)
- KISOALI FEMARA (600 MG DOSE)
- KOSELUGO ORAL CAPSULE
- KRAZATI
- lapatinib ditosylate
- LAZCLUZE
- lenalidomide
- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)

- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)
- LEUKERAN
- 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)
- MEKINIST ORAL SOLUTION RECONSTITUTED
- MEKINIST ORAL TABLET 0.5 MG, 2 MG
- MEKTOVI
- mercaptopurine oral suspension
- MODEYSO
- NERLYNX
- nilotinib d-tartrate oral capsule 150 mg, 200 mg, 50 mg
- nilotinib hcl oral capsule 150 mg, 200 mg,
   50 mg
- nilutamide
- NINLARO
- NUBEOA
- 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
- OINLOCK
- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

- REVLIMID
- REVUFORJ
- REZLIDHIA
- ROMVIMZA
- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PACKET
- RUBRACA
- RYDAPT
- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG
- SOLTAMOX
- sorafenib tosylate
- STIVARGA
- *sunitinib malate*
- TABLOID
- TABRECTA
- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET SOLUBLE
- TAGRISSO
- TALZENNA
- TAZVERIK
- TEPMETKO
- THALOMID ORAL CAPSULE 100 MG, 50 MG
- TIBSOVO
- toremifene citrate
- tretinoin oral
- TRUQAP
- 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
- VORANIGO
- 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 10 MG, 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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an oncologist or specialist for submitted diagnosis.
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
Prerequisite Therapy Required	No

## **APOMORPHINE**

### **Products Affected**

• apomorphine hcl subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with any 5-HT3 antagonist (e.g., ondansetron, alosetron, granisetron)
Required Medical Information	The member has a documented diagnosis of Parkinson's Disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Parkinson's disease - Initial: (1) tried and failed at least one other treatment for off episodes such as long-acting levodopa formulations or adjunct non-dopamineric treatment (e.g., amantadine) AND (2) currently receiving carbidopa/levodopa AND (3) experiencing off episodes (i.e. difficulty starting movements, muscle stiffness, and slow movement). Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **AQNEURSA**

### **Products Affected**

AQNEURSA

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	New starts will be authorized for 6 months. Cont of therapy or reauth until end of contract year.
Other Criteria	For new starts: 1) The member has a documented diagnosis of Niemann-Pick disease type C (NPC) AND 2) Documentation of genetic testing identifying disease-causing alleles in NPC1 or NPC2 AND 3) Documentation of disease-related neurological symptoms (e.g., developmental delay/regression, ataxia, cataplexy, seizures, motor-function decline, tremors, dysphagia) For reauthorization: Documentation that member has had positive response to therapy (e.g., stabilization in neurological status, decrease in functional Scale for Assessment and Rating of Ataxia [fSARA] score).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **ARCALYST**

### **Products Affected**

ARCALYST

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	CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont
Other Criteria	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 lest 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

## **ARIKAYCE**

### **Products Affected**

• ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Mycobacterium avium complex (MAC): (1) Documented diagnosis of MAC lung disease as verified by failure to acheive 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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or an infectious disease specialist
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
Prerequisite Therapy Required	No

## **ARISTADA**

#### **Products Affected**

• ARISTADA INITIO

441 MG/1.6ML, 662 MG/2.4ML, 882 MG/3.2ML

• ARISTADA INTRAMUSCULAR PREFILLED SYRINGE 1064 MG/3.9ML,

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	The member has a documented history of receiving oral aripiprazole without any clinically significant side effects.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **AUVELITY**

## **Products Affected**

• AUVELITY

PA Criteria	Criteria Details
Exclusion Criteria	Seizure disorder.
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	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **AZTREONAM LYSINE**

### **Products Affected**

• CAYSTON

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 pulmonologist, infectious diseases specialist, or other provider specializing in cystic fibrosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Patient has Pseudomonas aeruginosa in culture of the airway (i.e. bronchoalveolar lavage culture, oropharyngeal culture, sputum culture).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **BENLYSTA**

### **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	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.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **BESREMI**

## **Products Affected**

• BESREMI

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
Prerequisite Therapy Required	No

## **BOSENTAN**

### **Products Affected**

• bosentan oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
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
Prerequisite Therapy Required	No

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## **CABLIVI**

## **Products Affected**

• CABLIVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of medically accepted indication and date of last plasma exchange.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	Request will be authorized until 2 months after the date of the last plasma exchange.
Other Criteria	Cablivi is being used in combination with plasma exchange and immunosuppressive therapy (i.e. cyclosporine, cyclophosphamide, mycophenolate mofetil, systemic corticosteroids).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **CAMZYOS**

### **Products Affected**

• CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	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)

PA Criteria	Criteria Details
	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%.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **CARGLUMIC ACID**

#### **Products Affected**

• carglumic acid oral tablet soluble

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
Prerequisite Therapy Required	No

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## **CASPOFUNGIN**

## **Products Affected**

• caspofungin acetate

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Documentation of a consultation with an infectious disease specialist.
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
Prerequisite Therapy Required	No

## **CEPROTIN**

## **Products Affected**

• CEPROTIN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of congenital protein C deficiency as confirmed by lab values indicating low protein C activity.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hemotologist or specialist in genetic disorders.
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
Prerequisite Therapy Required	No

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## **CERDELGA**

### **Products Affected**

• CERDELGA

PA Criteria	Criteria Details
Exclusion Criteria	Patients with undetermined CYP2D6 metabolizer status.
Required Medical Information	Type 1 Gaucher Disease (GD1) - Initial: [Note: documentation required] (1) diagnosis confirmed by an enzyme assay demonstrating deficiency of beta-glucocerbrosidase 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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in treatment of Gaucher's disease.
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
Prerequisite Therapy Required	No

## **CHENODAL**

### **Products Affected**

• CHENODAL

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

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## **CHOLBAM**

### **Products Affected**

• CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Chenodal.
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with hepatologist, gastroenterologist, metabolic specialist.
Coverage Duration	Initial: 3 months. Continuation of therapy: end of contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **CIBINQO**

## **Products Affected**

• CIBINQO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a biologic, targeted disease modifying antirheumatic drug (DMARD), anti-interleukin monoclonal antibody, janus kinase inhibitors, immunomodulators, with other potent immunosuppressants.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Initial therapy only: prescribed by or in consultation with an allergist, dermatologist, or immunologist.
Coverage Duration	Initial: 3 months. Continuation of therapy: end of calendar year
Other Criteria	Atopic Dermatitis - Initial: (1) patient has had a 3-month trial of at least one traditional systemic therapy (i.e. azathioprine, cyclosporine, and mycophenolate mofetil) OR (2) patient has tried at least one traditional systemic therapy but was unable to tolerate a 3-month trial. Note: A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis.  Continuation of therapy: (1) patient has been receiving Cibinqo for at least 90 days AND (2) patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: (i) estimated body surface area affected, (ii) erythema, (iii) excoriations, (iv) induration/papulation/edema, (v) lichenification, and/or (vi) decreased requirement for other topical or systemic therapies for atopic dermatitis AND (3) compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom (i.e. decreased itching).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **CIMZIA**

### **Products Affected**

• CIMZIA (2 SYRINGE)

- CIMZIA-STARTER
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG

WO	
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	Request will be authorized until the end of the contract year.
Other Criteria	For ankylosing spondylitis (AS): Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Enbrel, Cosentyx, an adalimumab product, or Xeljanz. For Crohn's Disease (CD): Trial of, medical reason for not using, or contraindication to 2 of the following therapies: an adalimumab product, or an ustekinumab 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: Tremfya, an ustekinumab product, Enbrel, or an adalimumab product. For Psoriatic arthritis (PsA): Trial of, medical reason for not using or contraindication to 2 of the following therapies: an ustekinumab product, Tremfya, Xeljanz, Enbrel, Cosentyx or an adalimumab product. For Rheumatoid arthritis (RA): Trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, an adalimumab product, or Xeljanz. Polyarticular juvenile idiopathic arthritis (pJIA) - Initial: trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, an adalimumab product, or Xeljanz. AS/CD/PS/PsA/RA/pJIA Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **CORLANOR**

#### **Products Affected**

- CORLANOR ORAL SOLUTION
- ivabradine hcl oral tablet 5 mg, 7.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	New starts for chronic heart failure must have all of the following: 1) LVEF of 35% or less 2) Sinus rhythm and have resting heart rate greater than or equal to 70 bpm. For pediatric patients with heart failure due to dilated cardiomyopathy: approve
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a cardiologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Trial of, contraindication to, or medical reason for not receiving a beta blocker.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## **CORTROPHIN**

### **Products Affected**

CORTROPHIN

#### • CORTROPHIN GEL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	MS exacerbation: 1 month. Other conditions: new start for 3 months and reauth end of contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **COSENTYX**

#### **Products Affected**

- COSENTYX (300 MG DOSE)
- COSENTYX INTRAVENOUS
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SENSOREADY PEN
- COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 150 MG/ML, 75 MG/0.5ML
- COSENTYX UNOREADY

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	Documented diagnosis of ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, psoriatic arthritis, enthesitis-related arthritis, rheumatoid arthritis or hidradenitis suppurativa.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **CRESEMBA**

### **Products Affected**

• CRESEMBA ORAL

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

## **CRYSVITA**

### **Products Affected**

• CRYSVITA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with oral phosphate or active vitamin D analogs. Use in patients with severe renal impairment or end stage renal disease (ESRD).
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, nephrologist or endocrinologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Documentation of low serum phosphate concentration.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **CYSTAGON**

### **Products Affected**

• CYSTAGON

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Procysbi.
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist or nephrologist.
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
Prerequisite Therapy Required	No

# **CYSTARAN**

### **Products Affected**

• CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or metabolic disease specialist.
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
Prerequisite Therapy Required	No

### **DALFAMPRIDINE ER**

#### **Products Affected**

• dalfampridine er

PA Criteria	Criteria Details
Exclusion Criteria	History of seizure or moderate/severe renal impairment (CrCl less than or equal to 50 mL/min).
Required Medical Information	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.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
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
Prerequisite Therapy Required	No

## **DEFERASIROX**

#### **Products Affected**

• deferasirox

• deferasirox granules

PA Criteria	Criteria Details
Exclusion Criteria	Creatinine clearance less than 40 mL/min or platelet counts less than 50,000/mm3.
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	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **DEFERIPRONE**

### **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
Prerequisite Therapy Required	No

## **DEFLAZACORT**

### **Products Affected**

deflazacort

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	1) Member has a documented diagnosis of Duchenne Muscular Dystrophy as evidenced by one of the following: a) documented mutation of dystrophin gene OR b) muscle biopsy indicating absence of the dystrophin protein AND 2) Patient has trial and failure with, contraindication to or medical reason for not taking prednisone.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or specialist for submitted diagnosis.
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
Prerequisite Therapy Required	Yes

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### **DIACOMIT**

#### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Initial therapy only: 6 months 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: 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **DIHYDROERGOTAMINE NASAL**

#### **Products Affected**

• dihydroergotamine mesylate nasal

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	New starts will be authorized for 6 months. Cont of therapy or reauth until end of contract year.
Other Criteria	Trial of, contraindication to, or medical reason (e.g. intolerance or hypersensitivity) for not using a triptan (e.g., rizatriptan, sumatriptan).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **DOPTELET**

### **Products Affected**

• DOPTELET

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
Prerequisite Therapy Required	Yes

# **DOXEPIN CREAM**

#### **Products Affected**

• doxepin hcl external

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 for 14 days.
Other Criteria	(1) Trial of, contraindication to, or medical reason (i.e. treatment on axilla, face or groin) for not using a topical corticosteroid [potency of medium or higher] OR (2) topical calcineurin inhibitor.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **DROXIDOPA**

#### **Products Affected**

• droxidopa oral capsule 100 mg, 200 mg, 300 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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 autoionic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND (2) patient has tried and failed midodrine.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a neurologist.
Coverage Duration	Request will be authorized for 3 months.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **DUPIXENT**

#### **Products Affected**

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

# **EGRIFTA**

### **Products Affected**

• EGRIFTA SV

### • EGRIFTA WR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of active antiretroviral therapy for at least 8 weeks.
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
Prerequisite Therapy Required	No

# **EMGALITY**

### **Products Affected**

• EMGALITY

• EMGALITY (300 MG DOSE)

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
Prerequisite Therapy Required	Yes

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# **EMSAM**

### **Products Affected**

• EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with SSRIs, SNRIs, clomipramine and imipramine, meperidine, tramadol, methadone, pentazocine, and propoxyphene, and the antitussive agent dextromethorphan or carbamazepine
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	Initial: (1) trial of, contraindication to, or medical reason for not using two generic antidepressants OR (2) patient is unable to swallow oral formulations.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **ENBREL**

#### **Products Affected**

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

Criteria Details
UNDER CMS REVIEW
No
Yes

### **ENDARI**

### **Products Affected**

• l-glutamine oral packet

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

# **ENTYVIO**

### **Products Affected**

• ENTYVIO PEN

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
Prerequisite Therapy Required	Yes

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## **EPIDIOLEX**

### **Products Affected**

• EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	1 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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **EPRONTIA**

### **Products Affected**

• topiramate oral solution

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

### **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, 2000
- UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML
- PROCRIT
- 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

10000 UN11/ML, 2000 UN11/ML, 20000	
PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized for 6 months.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **ERZOFRI**

#### **Products Affected**

• ERZOFRI INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE 117 MG/0.75ML, 156 MG/ML, 234 MG/1.5ML, 351 MG/2.25ML, 39 MG/0.25ML, 78 MG/0.5ML

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
Prerequisite Therapy Required	Yes

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# **EUCRISA**

### **Products Affected**

• EUCRISA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a dermatologist, immunologist or an allergist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Trial of, contraindication to, or medical reason for not using topical pimecrolimus. For patients less than 2 years of age: approve.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **EVRYSDI**

#### **Products Affected**

- EVRYSDI ORAL SOLUTION RECONSTITUTED
- EVRYSDI ORAL TABLET

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
Prerequisite Therapy Required	No

### **FABHALTA**

### **Products Affected**

• FABHALTA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another complement inhibitor (i.e. Empaveli, Soliris, or Ultomiris).
Required Medical Information	PNH - Initial: patient has documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by (1) flow cytometry analysis confirming presence of PNH clones AND (2) patient has signs and symptoms of PNH (i.e. anemia, abdominal pain, dyspnea, kidney disease, pulmonary hypertension, hemolysis/hemoglobinuria, etc.). Continuation of therapy: patient has documented positive clinical response to treatment (i.e. decrease in LDH, increased or stabilization of hemoglobin levels, reduction in transfusions, increased reticulocyte count, etc.). Reduction of proteinuria in adults with immunoglobulin A (IgA) nephropathy - Initial: patient has documented diagnosis of IgA nephropathy AND IgA nephropathy at risk of rapid disease progression (i.e. clinical evidence of rapid disease progression generally a urine protein-to-creatinine ratio or UPCR greater or equal to 1.5g/g OR other clinically relevant tests). Continuation of therapy: patient has documented positive clinical response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, nephrologist or oncologist.
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
Prerequisite Therapy Required	No

### **FASENRA**

#### **Products Affected**

• FASENRA PEN

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of medically-accepted indication.
Age Restrictions	N/A
Prescriber Restrictions	Initial therapy only: prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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. New starts 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 AND trial of, contraindication to, or medical reason for not using one of the following medications: cyclophosphamide or methotrexate. 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).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **FILSPARI**

### **Products Affected**

• FILSPARI

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
Prerequisite Therapy Required	Yes

### **FINTEPLA**

### **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
Prerequisite Therapy Required	Yes

### **FIRDAPSE**

### **Products Affected**

• FIRDAPSE

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
Prerequisite Therapy Required	No

# **FLUCYTOSINE**

### **Products Affected**

• flucytosine oral

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

# **FULVESTRANT**

### **Products Affected**

• fulvestrant intramuscular solution prefilled syringe

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
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
Prerequisite Therapy Required	No

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# **GALAFOLD**

### **Products Affected**

• GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Fabrazyme (agalsidase beta).
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease.
Coverage Duration	Request will be authorized to the end of the contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **GATTEX**

### **Products Affected**

• GATTEX

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
Prerequisite Therapy Required	Yes

### **GLP-1 AGONISTS**

#### **Products Affected**

- liraglutide
- 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

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
Prerequisite Therapy Required	Yes

### **GNRH AGONISTS**

#### **Products Affected**

- ELIGARD
- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG
- *leuprolide acetate (3 month)*
- leuprolide acetate injection

- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUTRATE DEPOT
- TRELSTAR MIXJECT

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	Fibroids and endometriosis: 6 months. All other indications: end of contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **GOCOVRI**

#### **Products Affected**

• GOCOVRI ORAL CAPSULE EXTENDED RELEASE 24 HOUR 137 MG, 68.5 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 neurologist.
Coverage Duration	Initial: 3 months. Continuation of therapy: end of contract year.
Other Criteria	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).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **GROWTH HORMONES**

#### **Products Affected**

- GENOTROPIN MINIQUICK SUBCUTANEOUS PREFILLED SYRINGE
- GENOTROPIN SUBCUTANEOUS CARTRIDGE
- NGENLA
- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED
- SKYTROFA SUBCUTANEOUS CARTRIDGE 11 MG, 13.3 MG, 3 MG, 3.6 MG, 4.3 MG, 5.2 MG, 6.3 MG, 7.6 MG, 9.1 MG

SOLUTION CA	AKTRIDGE
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
Prerequisite Therapy Required	No

### **HEREDITARY ANGIOEDEMA AGENTS**

#### **Products Affected**

- BERINERT
- CINRYZE

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist, hematologist, immunologist, rheumatologist, or a provider that specializes in the treatment of HAE or related disorders.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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), angiopoietin-1, 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), angiopoietin-1, 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.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **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

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
Prerequisite Therapy Required	Yes

### **HIGH RISK MEDICATION**

#### **Products Affected**

- amitriptyline hcl oral
- amoxapine
- benztropine mesylate oral
- clomipramine hcl oral
- cyproheptadine hcl oral
- diphenoxylate-atropine oral liquid
- diphenoxylate-atropine oral tablet 2.5-0.025 mg
- dipyridamole oral
- doxepin hcl oral capsule

- doxepin hcl oral concentrate
- ergotamine-caffeine
- hydroxyzine hcl oral syrup
- hydroxyzine hcl oral tablet
- hydroxyzine pamoate oral
- imipramine hcl oral
- imipramine pamoate oral capsule 100 mg, 125 mg, 150 mg, 75 mg
- nifedipine oral
- promethazine-phenylephrine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For patients 65 years old and older the prescriber has documented: the benefits of treatment with the drug outweigh the potential risks
Age Restrictions	Prior authorization only applies to members 65 years old or older.
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
Prerequisite Therapy Required	No

# **HIGH RISK MEDICATION - PROTECTED CLASS DRUGS**

### **Products Affected**

- phenobarbital oral elixir 20 mg/5ml
   phenobarbital oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For patients 65 years old and older the prescriber has documented: the benefits of treatment with the drug outweigh the potential risks
Age Restrictions	Prior authorization only applies to members 65 years old or older.
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
Prerequisite Therapy Required	No

# HIGH RISK MEDICATION, BUTALBITAL

#### **Products Affected**

- BAC (BUTALBITAL-ACETAMIN-CAFF)
- 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 solution
- butalbital-apap-caffeine oral tablet 50-325-40 mg
- butalbital-asa-caff-codeine
- butalbital-aspirin-caffeine oral capsule

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

# HIGH RISK MEDICATION, MEGESTROL

#### **Products Affected**

- megestrol acetate oral suspension 40 mg/ml, 400 mg/10ml, 625 mg/5ml
- megestrol acetate oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	Prior authorization only applies to members 65 years old or older.
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
Prerequisite Therapy Required	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

mg	
PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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 anticholingeric 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.
Age Restrictions	Prior authorization only applies to members 65 years old or older.
Prescriber Restrictions	N/A
Coverage Duration	New starts will be authorized for 30 days. Continuation of therapy or reauth will be for 90 days.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# HIGH RISK MEDICATION, SLEEP AGENTS

#### **Products Affected**

- eszopiclone
- temazepam
- zaleplon

- zolpidem tartrate er
- zolpidem tartrate oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	Prior authorization only applies to members 65 years old or older.
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
Prerequisite Therapy Required	Yes

# **HYFTOR**

### **Products Affected**

HYFTOR

PA Criteria	Criteria Details
Exclusion Criteria	Concurrently receiving systemic mTOR inhibitor therapy such as everolimus.
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
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
Prerequisite Therapy Required	No

# **ICATIBANT**

#### **Products Affected**

• icatibant acetate subcutaneous solution prefilled syringe

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, rheumatologist. Or provider that specializes in the treatment of HAE or related disorders.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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, angiopoietin-1, heparan sulfate glucosamine 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **ILARIS**

### **Products Affected**

• ILARIS SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation was submitted indicating that the member was evaluated for active or latent TB infection (i.e. tuberculin skin test)
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 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **ILUMYA**

### **Products Affected**

• ILUMYA

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	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) AND (3) patient has history of failure or medical reason for not using at least one of the following products: an adalimumab product, Enbrel, Tremfya or an ustekinumab product. Continuation of therapy: patient has positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **IMBRUVICA**

#### **Products Affected**

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

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

# **IMPAVIDO**

### **Products Affected**

• IMPAVIDO

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

# **INCRELEX**

### **Products Affected**

INCRELEX

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

### **JAKAFI**

### **Products Affected**

JAKAFI

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

# **JUXTAPID**

### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist or lipid specialist
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **KALYDECO**

### **Products Affected**

• KALYDECO

DA Cuitoris	Critorio Dotoila
PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Orkambi, Symdeko, or Trikafta.
Required Medical Information	Documentation of CFTR gene that is responsive to ivacaftor treatment.
Age Restrictions	1 month of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a provider specializing in treatment of CF.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Cystic Fibrosis - Initial: (1) patient must have a mutation in the CFTR gene that is considered to be a pathogenic or likely pathogenic variant (ex: E56K, P67L, M952T, etc.), AND (2) patient has positive newborn screening test, OR family history of cystic fibrosis OR clinical presentation consistent with signs and symptoms of cystic fibrosis (ex: pulmonary function tests consistent with obstructive airways, excess sputum production, etc.), AND (3) patient has evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by elevated sweat chloride test, OR abnormal nasal potential difference, OR two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations. Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **KERENDIA**

### **Products Affected**

KERENDIA

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
Prerequisite Therapy Required	Yes

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# **KEVZARA**

### **Products Affected**

KEVZARA

PA Criteria	Criteria Details
Exclusion	N/A
Criteria	
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, an adalimumab product, 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, an adalimumab product, 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
Prerequisite Therapy Required	Yes

### **KINERET**

### **Products Affected**

• KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Rheumatoid Arthritis (RA) - Initial: trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, an adalimumab product, or Xeljanz. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **LEQSELVI**

### **Products Affected**

• LEQSELVI

PA Criteria	Criteria Details
Exclusion Criteria	Absolute lymphocyte count less than 500 cells/mm3, absolute neutrophil count less than 1,000 cells/mm3 or hemoglobin level less than 8 g/dl.
Required Medical Information	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. Enbrel, Cimzia, Simponi, Orencia, an adalimumab product, Xeljanz) OR (ii) potent immunosuppressant. Continuation of therapy: documentation of positive clinical response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	Documentation of confirmed diagnosis and other causes of hair loss have been ruled out.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **LITFULO**

### **Products Affected**

• LITFULO

PA Criteria	Criteria Details
Exclusion Criteria	Absolute lymphocyte count less than 500 cells/mm3 or platelet count less than 100,000 cells/mm3.
Required Medical Information	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. Enbrel, Cimzia, Simponi, Orencia, an adalimumab product, Xeljanz) OR (ii) potent immunosuppressant. Continuation of therapy: documentation of positive clinical response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	Documentation of confirmed diagnosis and other causes of hair loss have been ruled out.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **LIVMARLI**

### **Products Affected**

• LIVMARLI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Initial: (1) documented diagnosis of Alagille Syndrome (ALGS) with molecular genetic testing confirming mutations in the JAG1 or NOTCH2 gene AND (2) documentation of one of the following, (i) total serum bile acid greater than 3x the upper limit of normal (ULN) OR (ii) conjugated bilirubin greater than 1mg/dL OR (iii) Gammaglutamyl transpeptidase (GGT) greater than 3x ULN OR (iv) unexplainable fat soluble vitamin deficiency AND(3) patient is experiencing moderate to severe cholestatic pruritus AND (4) patient has had an inadequate response to one of the following treatments used for the relief of pruritus: antihistamine, ursodeoxycholic acid (i.e. Ursodiol), rifampin, bile acid sequestrants (i.e. Questran, Welchol). For new starts for Progressive Familial Intrahepatic Cholestasis (PFIC): (1) PFIC type 1, 2, 3, 4 or 6, with confirmed beallelic mutations via genetic testing AND (2) Documentation that patient does not have an ABCB11 variant that results in non-functional or complete absence of bile salt export pump protein. Continuation of therapy: (1) clinical improvement in pruritis AND (2) reduction in serum bile acid level from baseline AND (3) attestation of monitoring of hepatic enzymes for decompensation.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or gastroenterologist.
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	For new starts: 1) Trial of, contraindication to, or medical reason for not using both of the following: cholestyramine AND rifampin. 2) Prescriber attests that the member has cholestasis 3) Baseline serum bile acid level is provided. 4) Documentation of patients weight. For continuation of therapy or reauthorization: 1) Documentation submitted indicating the member has had all of the following: an improvement in pruritis (e.g. improved observed scratching, decreased sleep disturbances/nighttime awakenings

PA Criteria	Criteria Details
	due to scratching, etc.) AND reduction in serum bile acid level from baseline. 2) Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.). 3) Documentation of patients weight.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## **LIVTENCITY**

### **Products Affected**

• LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Cytomegalovirus (CMV): (1) Documented diagnosis of CMV infection AND (2) Member is a recipient of one of the following: (a) hematopoietic stem cell transplant, (b) solid organ transplant AND (3) patient has tried and failed, has contraindication to or is intolerant to treatment with valganciclovir, ganciclovir, cidofivir, or foscarnet AND (4) patient weighs greater than or equal to 35 kg.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a transplant specialist, infectious disease specialist, oncologist, hematologist or other appropriate specialist.
Coverage Duration	Request will be authorized for 8 weeks.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **LODOCO**

### **Products Affected**

• LODOCO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## **LUCEMYRA**

### **Products Affected**

• lofexidine hcl

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 for 14 days.
Other Criteria	Patient must have trial of, contraindication to, or medical reason for not using clonidine.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **LUPKYNIS**

### **Products Affected**

• LUPKYNIS

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
Prerequisite Therapy Required	Yes

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### **LYBALVI**

### **Products Affected**

• LYBALVI

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with opioids.
Required Medical Information	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.
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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

## **MAVYRET**

#### **Products Affected**

• MAVYRET ORAL PACKET

#### MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized for 8-16 weeks as per AASLD-IDSA guidance.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

## METHOTREXATE ORAL SOLUTION

### **Products Affected**

• JYLAMVO

#### • XATMEP

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

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## **METHYLTESTOSTERONE**

#### **Products Affected**

• methyltestosterone oral

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
Prerequisite Therapy Required	Yes

## **METYROSINE**

### **Products Affected**

• metyrosine

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a provider who specializes in the management of pheochromocytoma.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Initial: patient has tried a selective alpha blocker (i.e. doxazosin, prazosin or terazosin). Continuation of therapy: approve.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## **MIFEPRISTONE**

#### **Products Affected**

• mifepristone oral tablet 300 mg

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with simvastatin, lovastatin, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a provider who specializes in the treatment of Cushing's syndrome.
Coverage Duration	Cushing's Syndrome: end of contract yr.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **MIGLUSTAT**

### **Products Affected**

• miglustat

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in treatment of Gaucher's disease.
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### MULTIPLE SCLEROSIS AGENTS

#### **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	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	Request will be authorized until the end of the contract year.
Other Criteria	Requests for Bafiertam, Betaseron, Kesimpta, Mavenclad, Mayzent, Ponvory, Rebif, Tascenso - Initial: patient has tried and failed, contraindication or medical reason for not using at least two of the

PA Criteria	Criteria Details
	following: dalfampridine ER, dimethyl fumarate, fingolimod, glatiramer, glatopa, or teriflunomide.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **MYFEMBREE**

### **Products Affected**

• MYFEMBREE

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
Prerequisite Therapy Required	Yes

### **NASAL ANTISEIZURE AGENTS**

#### **Products Affected**

- NAYZILAM
- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE NASAL LIQUID THERAPY PACK 2 X 7.5 MG/0.1ML
- VALTOCO 20 MG DOSE NASAL LIQUID THERAPY PACK 2 X 10 MG/0.1ML
- VALTOCO 5 MG DOSE

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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
Prerequisite Therapy Required	No

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## **NITISINONE**

#### **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
Prerequisite Therapy Required	No

## NON-AMPHETAMINE CENTRAL NERVOUS **SYSTEM AGENTS**

### **Products Affected**

- 250 mg, 50 mg
- armodafinil oral tablet 150 mg, 200 mg, modafinil oral tablet 100 mg, 200 mg

250 mg, 50 mg	
PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **NUCALA**

#### **Products Affected**

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

DA Cuitania	Catania Data II.
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
Prerequisite Therapy Required	Yes

## **NUEDEXTA**

### **Products Affected**

• NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	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.
Required Medical Information	Confirmation diagnosis is for Part D indication.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or psychiatrist.
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
Prerequisite Therapy Required	No

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### **NUPLAZID**

#### **Products Affected**

• NUPLAZID ORAL CAPSULE

NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
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
Prerequisite Therapy Required	No

# **NURTEC ODT**

### **Products Affected**

• NURTEC

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
Prerequisite Therapy Required	Yes

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# **OCALIVA**

### **Products Affected**

• OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	Members with decompensated cirrhosis, a prior decompensation event, compensated cirrhosis who have evidence of portal hypertension, or complete biliary obstruction.
Required Medical Information	For new starts: 1) Lab results for baseline ALT/AST, alkaline phosphatase (ALP), and bilirubin within 90 days of request AND 2) patient has no evidence of cirrhosis OR patient has compensated cirrhosis without evidence of portal hypertension.
Age Restrictions	Initial therapy only: 18 years of age or older.
Prescriber Restrictions	Initial therapy only: prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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) AND patient has no cirrhosis OR patient has compensated cirrhosis without evidence of portal hypertension.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

# **OCREVUS**

### **Products Affected**

• OCREVUS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years of age and older.
Prescriber Restrictions	Specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **OCTREOTIDE**

#### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Continuation of therapy or reauthorization: documentation of clinical improvement with therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **OFEV**

### **Products Affected**

• OFEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	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.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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

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

## **OPSUMIT**

### **Products Affected**

• OPSUMIT

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

### **ORAL ANTIPSYCHOTICS**

#### **Products Affected**

- CAPLYTA
- COBENFY
- COBENFY STARTER PACK
- FANAPT
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B ORAL TABLET
- FANAPT TITRATION PACK C ORAL TABLET
- OPIPZA ORAL FILM 10 MG, 2 MG, 5 MG
- VRAYLAR ORAL CAPSULE

TABLET	
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	For schizophrenia, manic or mixed episodes associated with bipolar I disorder, major depressive disorder associated with bipolar I or II disorder, adjunctive treatment of major depressive disorder, irritability associated with autistic disorder or treatment of Tourette's 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

### **ORENCIA**

#### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Polyarticular juvenile idiopathic arthritis (pJIA): trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, an adalimumab product, or Xeljanz. Continuation of therapy: patient has positive clinical response to treatment. Psoriatic arthritis (PsA): trial of, medical reason for not using, or contraindication to 2 of the following therapies: an ustekinumab product, Cosentyx, Tremfya, Xeljanz, Enbrel or an adalimumab product. Continuation of therapy: patient has positive clinical response to treatment. Rheumatoid arthritis (RA) - Initial: trial of, medical reason for not using, or contraindication to 2 of the following: Enbrel, an adalimumab product or Xeljanz. Continuation of therapy: patient has positive clinical response to treatment. Acute graft versus host disease: attestation member is taking in combination with a calcineurin inhibitor and methotrexate. Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

### **ORIAHNN**

### **Products Affected**

• ORIAHNN

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
Prerequisite Therapy Required	Yes

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# **ORILISSA**

### **Products Affected**

ORILISSA

PA Criteria	Criteria Details
Exclusion Criteria	Patient has history of osteoporosis or hepatic impairment.
Required Medical Information	Initial: (1) documented diagnosis of moderate to severe pain associated with endometriosis AND (2) patient is premenopausal AND (3) patient has history of trial and failure (i.e. inadequate pain relief), contraindication or intolerance to a trial of at least one analgesic (i.e. ibuprofen, meloxicam, naproxen) AND (4) patient has history of trial and failure, contraindication, or intolerance after a trial of at least one of the following: hormonal contraceptives, progestins, gonadotropin-releasing hormone (GnRH) agonists (i.e. Lupron Depot), OR danazol. Continuation of therapy: (1) treatment does not exceed the eligible maximum lifetime treatment duration of 2 years for 150mg tablet or 6 months for 200mg tablet AND (2) documentation of patient experiencing positive clinical positive response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an OB, gynecologist or reproductive endocrinologist.
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	Trial of, contraindication to, or medical reason for not using the following concurrently for endometriosis: analgesic pain reliever (e.g. NSAIDs, COX-2 inhibitors) AND either combined estrogen-progestin oral contraceptive, progestin (e.g. medroxyprogesterone acetate, norethindrone), gonadotropin-releasing hormone (GnRH) agonists (e.g. Lupron Depot), OR danazol. 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 for 150mg tablet or 6 months for 200mg tablet, and 2) Documentation has been provided that the member has obtained clinical benefit from the medication.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **ORKAMBI**

#### **Products Affected**

• ORKAMBI ORAL PACKET

#### ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Kalydeco, Symdeko, or Trikafta.
Required Medical Information	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.
Age Restrictions	1 year of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a provider who specializes in treatment of CF.
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
Prerequisite Therapy Required	No

### **OTEZLA**

### **Products Affected**

• OTEZLA ORAL TABLET

• OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with a Biologic or with a Targeted Synthetic Disease Modifying Antirheumatic Drugs (DMARD).
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Psoriasis, moderate to severe - Initial: trial of, medical reason for not using, or contraindication to 2 of the following therapies: an ustekinumab product, Tremfya, Enbrel, or an adalimumab product. 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: an ustekinumab product, Tremfya, Xeljanz, Enbrel or an adalimumab product. Continuation of therapy: patient has positive clinical response to treatment. Bechet's Syndrome or mild psoriasis: Approve.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **OXERVATE**

### **Products Affected**

• OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	Treatment duration greater than 16 weeks per affected eye(s).
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by an ophthalmologist or an optometrist.
Coverage Duration	Initial: 8 weeks. Continuation of therapy: additional 8 weeks.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **OXYCODONE ER**

#### **Products Affected**

• OXYCONTIN ORAL TABLET ER 12 HOUR ABUSE-DETERRENT 10 MG, 15  $\begin{array}{c} MG,\,20\ MG,\,30\ MG,\,40\ MG,\,60\ MG,\,80\\ MG \end{array}$ 

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	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.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **PCSK9 INHIBITORS**

### **Products Affected**

• REPATHA

#### • REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis and labs.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or a provider who focuses in the treatment of CV risk management and/or lipid disorders.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Heterozygous familial hypercholesterolemia (HeFH) - Initial: (1) HeFH diagnosis AND (2) tried or has contraindication to high intensity statin (i.e. minimum of atorvastatin 40 mg daily or rosuvastatin 20 mg daily or higher) AND (3) LDL 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). Hyperlipidemia with ASCVD - Initial: (1) pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina, history of TIA, PAD, undergone a coronary or other arterial revascularization procedure AND (2) tried or has contraindication to high intensity statin (defined above) AND (3) ezetimibe concomitantly and LDL-C remains greater than or equal to 55 mg/dL unless the patient is determined to be statin intolerant (defined above). Homozygous familial hypercholesterolemia (HoFH) - Initial: (1) diagnosis confirmed w/ genetic test (i.e. two mutant alleles at the APOB, LDLR, LDLRAP1 or PCSK9 gene locus) OR (2) pretreatment LDL greater than 400 mg/dL OR (3) treated LDL greater than or equal to 300 mg/dL (note: pretreatment not including Repatha, Praluent, Juxtapid, Nexletol or Nexlizet) OR (4) patient has clinical manifestations of HoFH (i.e. arcus cornea, cutaneous xanthomas, tendon xanthomas, tuberous xanthomas and/or xanthelasma)

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PA Criteria	Criteria Details
	AND (5) tried or has contraindication to high intensity statin (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH) - Initial: (1) tried or has contraindication to high intensity statin (defined above) AND (2) LDL remains 100 mg/dL or higher unless statin intolerant (defined above). Continuation for all indications: patient has positive clinical response to treatment due to elevated LDLs.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **PEGINTERFERON**

#### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a gastroenterologist, hepatologist, infectious disease doctor or transplant specialist.
Coverage Duration	Request will be authorized for 24 to 48 weeks as defined by compendia.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **PENICILLAMINE**

### **Products Affected**

• penicillamine oral tablet

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	Request will be authorized until the end of the contract year.
Other Criteria	Rheumatoid arthritis (RA) - Initial: patient has trial, intolerance or medical reason for not using at least 2 of the following: Enbrel, an adalimumab product, or Xeljanz. 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **PERSERIS**

### **Products Affected**

• PERSERIS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	The member has a documented history of receiving oral risperidone without any clinically significant side effects.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **PHENOXYBENZAMINE**

#### **Products Affected**

• phenoxybenzamine hcl oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Initial: (1) patient has documented diagnosis of pheochromocytoma AND (2) patient has trial, failure, intolerance or contraindication to at least one alpha-1 selective adrenergic receptor blocker (i.e. doxazosin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, endocrine surgeon, hematologist, or oncologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Trial of, contraindication to, or medical reason for not using doxazosin.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **PIRFENIDONE**

#### **Products Affected**

• pirfenidone oral capsule

• pirfenidone oral tablet 267 mg, 534 mg, 801 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist.
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
Prerequisite Therapy Required	No

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# **POSACONAZOLE**

#### **Products Affected**

- posaconazole oral suspension
- posaconazole oral tablet delayed release

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	Prophylaxis of Invasive Aspergillus and Candida Infections: 2 years of age or older. Treatment of Invasive Aspergillosis: 13 years of age or older.
Prescriber Restrictions	Documentation of a consultation with an infectious disease specialist, a transplant specialist, or an oncologist.
Coverage Duration	Request will be authorized for 6 months.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **PRETOMANID**

### **Products Affected**

• pretomanid

PA Criteria	Criteria Details
Exclusion Criteria	MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy
Required Medical Information	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.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with infectious disease specialist, pulmonologist, or provider specializing in treatment of tuberculosis.
Coverage Duration	Request will be authorized for 26 weeks.
Other Criteria	Documentation of prior trial of or medical reason for not using first-line TB regimen containing isoniazid and rifampin.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **PREVYMIS**

### **Products Affected**

• PREVYMIS ORAL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, oncologist, infectious disease, or transplant specialist.
Coverage Duration	Request will be authorized for 7 months.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **PROMACTA**

#### **Products Affected**

- eltrombopag olamine oral packet 12.5 mg, eltrombopag olamine oral tablet 12.5 mg, 25 mg
  - 25 mg, 50 mg, 75 mg

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
Prerequisite Therapy Required	Yes

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# **PYRIMETHAMINE**

#### **Products Affected**

• pyrimethamine oral

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	Request will be authorized until the end of the contract year.
Other Criteria	Toxoplasma gondii Encephalitis (Chronic Maintenance): patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary): patient is immunosuppressed.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **PYRUKYND**

### **Products Affected**

• PYRUKYND

#### • PYRUKYND TAPER PACK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year. Denial: 14 days for dose tapering.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

# **QULIPTA**

### **Products Affected**

• QULIPTA

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
Prerequisite Therapy Required	Yes

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# **RADICAVA**

#### **Products Affected**

• RADICAVA ORS

#### • RADICAVA ORS STARTER KIT

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 neurologist, a neuromuscular disease specialist, or a provider who specializes in the treatment of ALS.
Coverage Duration	Request will be authorized for 6 months.
Other Criteria	Amyotrophic lateral sclerosis (ALS) - Initial: (1) patient has definitive or probable ALS diagnosis (based on the application of the El Escorial or the revises 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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **RAVICTI**

### **Products Affected**

• RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Provider is a geneticist, metabolic specialist, gastroenterologist, hepatologist, or liver transplant specialist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Trial of, contraindication to, or medical reason for not using sodium phenylbutyrate.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **RECORLEV**

### **Products Affected**

RECORLEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with specialist for submitted diagnosis.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Trial of, contraindication to, or medical reason for not using ketoconazole tablets.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **RELISTOR**

#### **Products Affected**

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

MG/0.4ML	,
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
Prerequisite Therapy Required	Yes

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# **REVCOVI**

### **Products Affected**

• REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient has diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one of the following: 1) documentation of deficiency or absense of adenosine deaminase OR 2) genetic testing revealing mutations in both alleles of the ADA1 gene AND/OR (3) biochemical testing showing less than 1% of ADA catalytic activity in red blood cells or in extracts of dried blood spots
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an immunologist, geneticist, hematologist, oncologist, or provider who specializes in the treatment of ADA-SCID or related disorders.
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
Prerequisite Therapy Required	No

# **REXULTI**

### **Products Affected**

• REXULTI

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
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	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 due to dementia: 1) patient has documented diagnosis of Alzheimer's disease AND 2) medication will not be used on an "as needed" basis
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **REZDIFFRA**

### **Products Affected**

• REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	Patients with decompensated cirrhosis.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastreoenterologist, endocrinologist or specialist in the treatment of liver disease.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Initial therapy: (1) documented diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis, (2) documentation of stage F2 to F3 fibrosis as confirmed by a biopsy or a non-invasive test (NIT), (3) the drug is being prescribed at an FDA approved dose according to the member's weight and (4) prescriber attestation to providing lifestyle counseling on nutrition, exercise and avoiding excessive alcohol intake. For reauthorization: (1) the member has shown clinical benefit from the medication (e.g., the resolution of steatohepatitis and no worsening of liver fibrosis, or at least one stage improvement in liver fibrosis and no worsening of steatohepatitis), (2) the member continues to have a fibrosis stage of 3 or less and (3) the drug continues to be prescribed at an FDA approved dose according to the member's weight.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

# **REZUROCK**

### **Products Affected**

• REZUROCK

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
Prerequisite Therapy Required	Yes

# **RUFINAMIDE**

#### **Products Affected**

- rufinamide oral suspension
- rufinamide oral tablet

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

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# **RYKINDO**

### **Products Affected**

• RYKINDO

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

# **RYLAZE**

### **Products Affected**

• RYLAZE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an oncologist, hematologist, or specialist for submitted diagnosis.
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
Prerequisite Therapy Required	No

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# **SAPROPTERIN**

#### **Products Affected**

- sapropterin dihydrochloride oral packet sapropterin dihydrochloride oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Initial therapy only: prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases.
Coverage Duration	Initial: 12 weeks. Continuation of therapy: end of contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **SECUADO**

### **Products Affected**

• SECUADO

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	(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.).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **SEROSTIM**

### **Products Affected**

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

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
Prerequisite Therapy Required	Yes

# **SIGNIFOR**

### **Products Affected**

• SIGNIFOR

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
Prerequisite Therapy Required	No

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### SILDENAFIL ORAL

### **Products Affected**

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

reconstitutea	
PA Criteria	Criteria Details
Exclusion Criteria	Documentation of concurrent nitrate or Adempas use.
Required Medical Information	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. Secondary Raynaud's phenomenon - Initial: [Note: documentation required] (1) diagnosis of secondary Raynaud's phenomenon AND (2) diagnosis of primary condition which Raynaud's phenomenon is secondary to (e.g., lupus, scleroderma, rheumatoid arthritis, Sjogren's syndrome, thyroid disease). Continuation of therapy: patient has positive clinical response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, pulmonologist, or a rheumatologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	For sildenafil suspension: Documentation of trial of, contraindication to, or medical reason for not using sildenafil tablet.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **SILIQ**

### **Products Affected**

• SILIQ

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 4 months. Cont of therapy or reauth until end of contract year.
Other Criteria	Psoriasis - Initial: trial of, medical reason for not using, or contraindication to 2 of the following therapies: an ustekinumab product, Tremfya, Enbrel or an adalimumab product. Continuation of therapy: patient has been receiving Siliq for a minimum of 4 months and has positive response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **SIMPONI**

#### **Products Affected**

- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML, 50 MG/0.5ML
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 50 MG/0.5ML

Criteria Details
N/A
N/A
N/A
Specialist for submitted diagnosis.
Request will be authorized until the end of the contract year.
For ankylosing spondylitis: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Enbrel, Cosentyx, an adalimumab product 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: an ustekinumab product, Tremfya, Xeljanz, Enbrel, or an adalimumab product, 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, an adalimumab product, 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: an adalimumab product, an ustekinumab product, Tremfya, or Xeljanz or 2) If utilized within the past 120 days, approve for continuation of therapy.
All Medically-accepted Indications.
N/A
No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

# **SIRTURO**

### **Products Affected**

• SIRTURO

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
Prerequisite Therapy Required	No

# **SODIUM OXYBATE**

### **Products Affected**

• sodium oxybate

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
Prerequisite Therapy Required	Yes

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# SODIUM PHENYLBUTYRATE

### **Products Affected**

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

gmvisp	
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
Prerequisite Therapy Required	No

# SOFOSBUVIR/VELPATASVIR

### **Products Affected**

• sofosbuvir-velpatasvir

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized for 12-24 weeks based on AASLD-IDSA guidelines
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **SOMAVERT**

### **Products Affected**

• SOMAVERT

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

# **SOTYKTU**

### **Products Affected**

• SOTYKTU

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	Request will be authorized until the end of the contract year.
Other Criteria	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) AND (3) patient has history of failure or medical reason for not using at least one of the following products: an adalimumab product, Enbrel, Tremfya or an ustekinumab product. Continuation of therapy: patient has been receiving Sotyktu for a minimum of 4 months and has positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **SUCRAID**

### **Products Affected**

• SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	(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 sucrase 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) sucrase (normal reference: greater than 25 U/g protein).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, geneticist, metabolic disorder specialist, or a provider who specializes in the treatment of congenital diarrheal disorders.
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
Prerequisite Therapy Required	No

# **SYMDEKO**

### **Products Affected**

• SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Kalydeco, Orkambi or Trikafta. Patients with unknown CFTR gene mutations.
Required Medical Information	Documentation of CFTR gene that is responsive to tezacaftor-ivacaftor treatment.
Age Restrictions	6 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a provider who specializes in CF.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **SYNAREL**

### **Products Affected**

• SYNAREL

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	Endometriosis - Initial: (1) patient has been diagnosed with endometriosis AND (2) patient has tried, intolerant or has medical reason for not using two of the following: (i) oral contraceptive, (ii) oral or injectable depot medroxyprogesterone, or (iii) analgesic pain reliever (i.e. NSAIDs). Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **TADALAFIL**

### **Products Affected**

• tadalafil (pah)

### • TADLIQ

PA Criteria	Criteria Details
Exclusion Criteria	Documentation of concurrent nitrate or Adempas use.
Required Medical Information	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 2 Wood units AND (5) documentation of diagnosis via chart notes. Continuation of therapy: patient has positive clinical response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	For Tadliq: Documentation of trial of, contraindication to, or medical reason for not using tadalafil tablets.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# TADALAFIL, BPH

### **Products Affected**

• tadalafil oral tablet 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	Diagnosis of erectile dysfunction
Required Medical Information	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).
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
Prerequisite Therapy Required	Yes

### **TALTZ**

### **Products Affected**

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

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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	Request will be authorized until the end of the contract year.
Other Criteria	For ankylosing spondylitis: Either 1) Trial of, medical reason for not using, or contraindication to 2 of the following therapies: Enbrel, Cosentyx, an adalimumab product, or Xeljanz, or 2) If utilized within the past 120 days, approve for continuation of therapy. For non-radiographic axial spondyloarthritis: Trial of, medical reason for not using, or contraindication to Cosentyx. 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: an ustekinumab product, Tremfya, Enbrel, or an adalimumab product, 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: an ustekinumab product, Tremfya, Xeljanz, Enbrel, or an adalimumab product, 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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

### **TARPEYO**

### **Products Affected**

• TARPEYO

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
Prerequisite Therapy Required	Yes

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# **TASIMELTEON**

### **Products Affected**

HETLIOZ LQ

• tasimelteon

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 sleep specialist or neurologist.
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **TAVNEOS**

### **Products Affected**

TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Initial: [Note: documentation required] (1) diagnosis of severe active antineutrophil 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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, nephrologist, pulmonologist, rheumatologist or vascular medicine specialist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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

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

### **TEPEZZA**

### **Products Affected**

TEPEZZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of moderate to severe active thyroid eye disease (TED) as evidenced by one or more of the following: a) eyelid retraction greater than or equal to 2 mm, b) moderate or severe soft tissue involvement, c) exophthalmos greater than or equal to 3 mm above normal for race and sex or d) periodic or constant diplopia OR Documentation of chronic TED with one or more of the following: a) a 3 mm or greater increase in exophthalmos from before diagnosis of TED, b) exophthalmos greater than or equal to 3 mm above normal for race and sex.
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an ophthalmologist or endocrinologist
Coverage Duration	Request will be authorized for 6 months.
Other Criteria	For active TED: member has had a trial and failure, contraindication to, or medical reason for not using oral or IV glucocorticoids.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **TERIPARATIDE**

### **Products Affected**

BONSITY

• teriparatide subcutaneous solution peninjector 560 mcg/2.24ml

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
Prerequisite Therapy Required	Yes

# **TESTOSTERONE CYPIONATE**

### **Products Affected**

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

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: patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines. 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
Prerequisite Therapy Required	No

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### TESTOSTERONE ENANTHATE

### **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: patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines. 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
Prerequisite Therapy Required	No

# **THIOLA**

### **Products Affected**

• tiopronin oral

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	(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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with nephrologist, urologist or provider specializing in treatment of cystinuria.
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
Prerequisite Therapy Required	No

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# **TIGECYCLINE**

### **Products Affected**

• tigecycline

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
Prerequisite Therapy Required	Yes

# TOBI PODHALER

### **Products Affected**

• TOBI PODHALER

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Patient has documented diagnosis of both: 1) cystic fibrosis AND 2) pseudomonas aeruginosa
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with pulmonologist, infectious disease specialist, or a provider who specializes in treatment of CF.
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
Prerequisite Therapy Required	No

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### **TOLVAPTAN**

### **Products Affected**

- tolvaptan (hyponatremia)
- tolvaptan oral tablet 15 mg, 30 mg
- tolvaptan oral tablet therapy pack

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
Prerequisite Therapy Required	No

# TOPICAL ANTINEOPLASTIC RETINOIDS

### **Products Affected**

• bexarotene

### • PANRETIN

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 dermatologist, oncologist or specialist for submitted diagnosis
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
Prerequisite Therapy Required	No

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# 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
Exclusion Criteria	Patient has history of prostate cancer or breast cancer.
Required Medical Information	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.
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: patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines. 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
Prerequisite Therapy Required	No

# TRANSDERMAL LIDOCAINE

### **Products Affected**

• lidocaine external patch 5 %

• ZTLIDO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documented diagnosis of a medically-accepted indication.
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 the product ZTlido, must provide medical reason for not being able to use generic lidocaine 5% patch
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **TREMFYA**

#### **Products Affected**

- TREMFYA CROHNS INDUCTION
- TREMFYA ONE-PRESS SUBCUTANEOUS SOLUTION PEN-INJECTOR
- TREMFYA PEN SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML, 200 MG/2ML
- TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 200 MG/2ML
- TREMFYA-CD/UC INDUCTION

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
Prerequisite Therapy Required	Yes

### **TRIENTINE**

### **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
Prerequisite Therapy Required	Yes

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### **TRIKAFTA**

### **Products Affected**

• TRIKAFTA ORAL TABLET THERAPY • TRIKAFTA ORAL THERAPY PACK PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with Kalydeco, Orkambi, or Symdeko. Patients with unknown CFTR gene mutations.
Required Medical Information	Documentation of CFTR gene that is responsive to elexacaftor-tezacaftor-ivacaftor treatment.
Age Restrictions	2 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a provider who specializes in treatment of CF.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **TYMLOS**

### **Products Affected**

• TYMLOS

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
Prerequisite Therapy Required	Yes

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### **TYVASO**

#### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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. Pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO Group 3) - Initial [Note: documentation required] (1) documented diagnosis of PH-ILD, WHO Group 3 confirmed by right heart catheterization AND (2) patient has connective tissue disease with baseline forced vital capacity less than 70% AND (3) patient has evidence of diffuse parenchymal lung disease on computed tomography of the chest. Continuation of therapy: patient has positive clinical response to treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	For the treatment of pulmonary arterial hypertension (PAH): 1) documentation of PAH WHO Group I classification and PAH Functional Class and 2) trial of, contraindication to, or medical reason for not using a generic phosphodiesterase inhibitor and a generic endothelin receptor antagonist. For the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO Group 3): documentation of PH-ILD and PAH Functional Class.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **UBRELVY**

### **Products Affected**

• UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **UPTRAVI**

### **Products Affected**

• UPTRAVI ORAL

### • UPTRAVI TITRATION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Trial of, contraindication to, or medical reason for not using a generic phosphodiesterase inhibitor and a generic endothelin receptor antagonist.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **USTEKINUMAB**

#### **Products Affected**

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

- STEQEYMA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90 MG/ML
- ustekinumab subcutaneous solution
- ustekinumab subcutaneous solution prefilled syringe 45 mg/0.5ml, 90 mg/ml
- ustekinumab-aekn subcutaneous solution prefilled syringe 45 mg/0.5ml, 90 mg/ml
- YESINTEK INTRAVENOUS
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90 MG/ML

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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

### **UZEDY**

#### **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
Exclusion Criteria	N/A
Required Medical Information	The member has a documented history of receiving oral risperidone without any clinically significant side effects.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **VALCHLOR**

### **Products Affected**

• VALCHLOR

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

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# **VEMLIDY**

### **Products Affected**

• VEMLIDY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For new starts: attestation that member has been tested for HIV infection. If member is HIV-positive, Vemlidy is not used alone.
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
Prerequisite Therapy Required	No

# **VEOZAH**

### **Products Affected**

VEOZAH

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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)
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
Prerequisite Therapy Required	Yes

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# **VIGABATRIN**

#### **Products Affected**

• vigabatrin

#### • VIGAFYDE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	For diagnosis of refractory complex partial seizures - initial: 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. Continuation of therapy: patient has positive clinical response to treatment (i.e., reduced seizure severity, frequency, or duration). For diagnosis of infantile spasm - initial: requested medication is being used as monotherapy. Continuation of therapy: patient has positive clinical response to treatment.
Age Restrictions	Refractory complex partial seizures: 2 years of age or older. Infantile spasms: less than or equal to 2 years of age.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Initial- infantile spasms: 6 mos, refractory partial seizures: 3 mos. Contend of contract yr.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **VIJOICE**

### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	2 years of age or older.
Prescriber Restrictions	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).
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **VMAT-2 INHIBITORS**

#### **Products Affected**

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE • tetrabenazine
- THERAPY PACK 12 & 18 & 24 & 30 MG
- INGREZZA ORAL CAPSULE
- INGREZZA ORAL CAPSULE **SPRINKLE**
- INGREZZA ORAL CAPSULE THERAPY PACK

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
Prerequisite Therapy Required	No

# **VOQUEZNA**

### **Products Affected**

- VOQUEZNA
- VOQUEZNA DUAL PAK
- VOQUEZNA TRIPLE PAK

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
Prerequisite Therapy Required	Yes

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# **VORICONAZOLE**

#### **Products Affected**

• voriconazole intravenous

• voriconazole oral

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 for 6 months.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **VOSEVI**

### **Products Affected**

VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Request will be authorized for 12 weeks as per AASLD-IDSA guidance.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **VOWST**

### **Products Affected**

• VOWST

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

# **VYNDAMAX**

### **Products Affected**

• VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or prescriber specializing in treatment of amyloidosis.
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
Prerequisite Therapy Required	No

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# **WEGOVY**

#### **Products Affected**

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

WIG/0.5WIE, 0.5 WIG/0.5WIE, 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
Prerequisite Therapy Required	No

### WHITE BLOOD CELL STIMULATORS

#### **Products Affected**

- FULPHILA
- FYLNETRA
- LEUKINE INJECTION SOLUTION RECONSTITUTED
- NEULASTA ONPRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Documentation of medically accepted indication.
Age Restrictions	N/A
Prescriber Restrictions	Specialist for submitted diagnosis.
Coverage Duration	New starts will be authorized for 4 months. Cont of therapy or reauth until end of contract year.
Other Criteria	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 and Fylnetra: documentation of trial of, contraindication to, or medical reason for not using Fulphila. Continuation of therapy or reauthorization criteria: diagnosis of chronic neutropenia or a medical reason for continued need for GCSF.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# WINREVAIR

### **Products Affected**

WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1)- 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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	Documented trial and failure of, or contraindication to combination therapy including one PDE-5 inhibitor AND one endothelin receptor antagonist. Documentation of platelet count of greater than 50,000/mm3.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **XDEMVY**

### **Products Affected**

• XDEMVY

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
Prerequisite Therapy Required	No

# **XELJANZ**

#### **Products Affected**

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET

XELJANZ XR

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
Prerequisite Therapy Required	Yes

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# **XERMELO**

### **Products Affected**

• XERMELO

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
Prerequisite Therapy Required	No

# **XIAFLEX**

### **Products Affected**

XIAFLEX

PA Criteria	Criteria Details
Exclusion Criteria	Peyronie's plaques that involve the penile urethra.
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	Dupuytren's Contracture: 3 months. Peyronie's Disease: 6 months.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **XIFAXAN**

#### **Products Affected**

• XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	For HE: gastroenterologist or hepatologist. For IBS-D: gastroenterologist.
Coverage Duration	HE: 6 mos. IBS-D: 14 days. Travelers' Diarrhea: 3 days.
Other Criteria	For irritable bowel syndrome with diarrhea (IBS-D): (1) patient has not previously received treatment with the requested drug OR (2) patient has previously received treatment with the requested drug AND (i) the patient is experiencing a recurrence of symptoms AND (ii) the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with Xifaxan.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **XOLAIR**

### **Products Affected**

• XOLAIR

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
Prerequisite Therapy Required	Yes

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# **XOLREMDI**

### **Products Affected**

• XOLREMDI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be an immunologist, dermatologist, or a hematologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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).
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# XYWAV

### **Products Affected**

• XYWAV

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PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a sleep specialist, pulmonologist or a neurologist.
Coverage Duration	Initial authorization: 3 months. Reauthorization: 6 months.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **YORVIPATH**

### **Products Affected**

YORVIPATH

PA Criteria	Criteria Details
Exclusion Criteria	Diagnosis of acute post-surgical hypoparathyroidism.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	New starts will be authorized for 6 months. Cont of therapy or reauth until end of contract year.
Other Criteria	For new starts: 1) Documented diagnosis of chronic hypoparathyroidism AND 2) Provider attestation that patient is currently receiving or has medical reason for not receiving calcium supplementation and active vitamin D treatment AND 3) An albumin-corrected serum calcium level of 7.8 mg/dL or greater. For reauthorization: Documentation of improvement in albumin-corrected serum calcium from baseline.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **YUTREPIA**

### **Products Affected**

• YUTREPIA

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 cardiologist or a pulmonologist.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	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 PAH WHO Group I classification and PAH Functional Class AND (6) trial of, contraindication to, or medical reason for not using a generic phosphodiesterase inhibitor and a generic endothelin receptor antagonist. Continuation of therapy: patient has positive clinical response to treatment. Pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO Group 3) - Initial [Note: documentation required] (1) documented diagnosis of PH-ILD, WHO Group 3 confirmed by right heart catheterization AND (2) patient has connective tissue disease with baseline forced vital capacity less than 70% AND (3) patient has evidence of diffuse parenchymal lung disease on computed tomography of the chest AND (4) documentation of PAH functional class. Continuation of therapy: patient has positive clinical response to treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **ZAVZPRET**

### **Products Affected**

ZAVZPRET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Continuation of therapy: end of contract year.
Other Criteria	N/A
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **ZEPBOUND**

#### **Products Affected**

• ZEPBOUND SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	The member has an indication of only weight reduction or maintenance for overweight or obesity. The member has concurrent use of any GLP-1 receptor agonist. The member has a personal history of medullary thyroid carcinoma. The member has Multiple Endocrine Neoplasia syndrome type 2.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a sleep disorder specialist, pulmonologist, ENT, or other provider specializing in obstructive sleep apnea.
Coverage Duration	Request will be authorized until the end of the contract year.
Other Criteria	For new starts: The member has an indication for moderate to severe obstructive sleep apnea (OSA) in adults with obesity. Documentation of diagnosis of OSA through polysomnography (sleep study) with an apneahypopnea index of 15 or more events per hour, or five or more events per hour in the presence of symptoms (e.g., cognitive impairment, fatigue, insomnia, loud snoring) or cardiovascular comorbidities (e.g., hypertension, ischemic heart disease, previous stroke). Documentation is provided that the patient is obese (defined as a BMI of greater than or equal to 30 kg/m2). For continuation of therapy: Documentation of positive response to treatment. Documentation member has achieved and/or maintained a decrease in weight since baseline.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

## **ZEPOSIA**

### **Products Affected**

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

PA Criteria	Criteria Details
Exclusion Criteria	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 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 to 1 of the following: an ustekinumab product or an adalimumab product 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
Prerequisite Therapy Required	Yes

# **ZILBRYSQ**

### **Products Affected**

• ZILBRYSQ SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 16.6

MG/0.416ML, 23 MG/0.574ML, 32.4 MG/0.81ML

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

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## **ZTALMY**

## **Products Affected**

• ZTALMY

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
Prerequisite Therapy Required	Yes

## **ZURZUVAE**

### **Products Affected**

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

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
Prerequisite Therapy Required	No

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### PART B VERSUS PART D

#### **Products Affected**

- 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 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
- calcium acetate (phos binder) oral capsule 667 mg
- calcium acetate (phos binder) oral tablet 667 mg
- 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
- 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
- GAMMAGARD INJECTION SOLUTION 1 GM/10ML, 10 GM/100ML, 2.5 GM/25ML, 20 GM/200ML, 30 GM/300ML, 5 GM/50ML
- GAMMAGARD S/D LESS IGA INTRAVENOUS SOLUTION RECONSTITUTED 10 GM, 5 GM
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- GENGRAF ORAL CAPSULE 100 MG, 25 MG
- 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

- lanthanum carbonate oral tablet chewable 1000 mg, 500 mg, 750 mg
- 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
- 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
- pentamidine isethionate inhalation solution reconstituted 300 mg
- PLENAMINE INTRAVENOUS SOLUTION 15 %
- PREHEVBRIO INTRAMUSCULAR SUSPENSION 10 MCG/ML
- PRIVIGEN INTRAVENOUS SOLUTION 10 GM/100ML, 20 GM/200ML, 40 GM/400ML, 5 GM/50ML

- PROGRAF INTRAVENOUS SOLUTION 5 MG/ML
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PULMOZYME INHALATION SOLUTION 2.5 MG/2.5ML
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5ML
- RECOMBIVAX HB INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/ML, 5 MCG/0.5ML
- sevelamer carbonate oral packet 0.8 gm,
  2.4 gm
- sevelamer carbonate oral tablet 800 mg
- sirolimus oral solution 1 mg/ml
- sirolimus oral tablet 0.5 mg, 1 mg, 2 mg
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#### **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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