



# Providence

## Medicare Advantage Plans

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### PROVIDENCE MEDICARE ADVANTAGE PLANS

### 2024 PRIOR AUTHORIZATION CRITERIA:

### ALIGN GROUP PLAN + RX (HMO)

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Last Updated 03/2024

For more recent information or other questions, please contact Providence Health Assurance Customer Service at 503-574-8000 or 1-800-603-2340 or, for TTY users, 711, seven days a week, between 8 a.m. and 8 p.m. (Pacific Time), or visit [ProvidenceHealthAssurance.com](https://www.ProvidenceHealthAssurance.com).

# ALBENDAZOLE/EMVERM

## Products Affected

- Emverm

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	One of the following must be met: 1. Diagnosis of pinworms ( <i>Enterobius vermicularis</i> ), or 2. For diagnosis other than pinworm, all the following must be met: a. Documentation of medically accepted diagnosis, defined as FDA approved or compendia-supported, b. Confirmation of parasite species through validated laboratory testing/identification. If laboratory confirmation is not possible, must be prescribed by or in consultation with an infectious disease specialist.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an infectious disease specialist unless diagnosis is pinworm, or diagnosis of parasite species has been confirmed through validated lab testing.
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for three (3) months.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# ALPHA-1 PROTEINASE INHIBITORS

## Products Affected

- Aralast NP
- Glassia
- Prolastin-C
- Zemaira intravenous recon soln 1,000 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For initial authorization, all of the following must be met:</p> <p>1. Documentation of one of the following: a. Serum alpha-1 antitrypsin (AAT) concentrations less than 11 micromol/L (approximately 50 mg/dL by nephelometry or 80 mg/dL by immunodiffusion), or b. Patient has one of the high-risk phenotypes by protease inhibitor (PI) typing: PI*ZZ, PI*Z(null), PI*(null,null), 2. Confirmed diagnosis of emphysema, AND 3. Documentation that dose does not exceed 60 mg/kg every seven (7) days. Criteria 1 and 2 will be waived in patients with concomitant necrotizing panniculitis. Reauthorization requires documentation of response to therapy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	<p>Initial authorization will be approved for 6 months.                      Reauthorization will be approved for one year.</p>
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# ANTI-CANCER AGENTS

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## Products Affected

- abiraterone oral tablet 250 mg
- Actimmune
- Akeega
- Alecensa
- Alunbrig
- Augtyro
- Ayvakit
- Balversa
- Besremi
- bexarotene
- Bosulif
- Braftovi
- Brukinsa
- Cabometyx
- Calquence
- Calquence (acalabrutinib mal)
- Caprelsa
- Cometriq
- Copiktra
- Cotellic
- Daurismo
- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- Erivedge
- Erleada
- erlotinib
- everolimus (antineoplastic)
- Exkivity
- Fotivda
- Fruzaqla
- Gavreto
- gefitinib
- Gilotrif
- Gleostine
- Ibrance
- Iclusig
- Idhifa
- imatinib
- Imbruvica oral capsule
- Imbruvica oral suspension
- Imbruvica oral tablet 140 mg, 280 mg, 420 mg
- Inlyta
- Inqovi
- Inrebic
- Iwilfin
- Jakafi
- Jaypirca
- Kisqali
- Kisqali Femara Co-Pack
- Koselugo
- Krazati
- lapatinib
- lenalidomide
- Lenvima
- Lonsurf
- Lorbrena
- Lumakras
- Lynparza
- Lytgobi
- Mekinist
- Mektovi
- metyrosine
- Nerlynx
- nilutamide
- Ninlaro

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- Nubeqa
- Odomzo
- Ogsiveo
- Ojjaara
- Onureg
- Orgovyx
- Orserdu
- Panretin
- pazopanib
- Pemazyre
- Piqray
- Pomalyst
- Qinlock
- Retevmo
- Revlimid
- Rezlidhia
- Rozlytrek
- Rubraca
- Rydapt
- Scemblix
- sorafenib
- Sprycel
- Stivarga
- sunitinib malate
- Synribo
- Tabrecta
- Tafenlar
- Tagrisso
- Talzenna
- Tassigna
- Tazverik
- Tepmetko
- Tibsovo
- toremifene
- tretinoin (antineoplastic)
- Truqap
- Tukysa
- Turalio oral capsule 125 mg
- Vanflyta
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Vitrakvi
- Vizimpro
- Vonjo
- Welireg
- Xalkori
- Xospata
- Xpovio oral tablet 100 mg/week (50 mg x 2), 40 mg/week (40 mg x 1), 40mg twice week (40 mg x 2), 60 mg/week (60 mg x 1), 60mg twice week (120 mg/week), 80 mg/week (40 mg x 2), 80mg twice week (160 mg/week)
- Xtandi
- Zejula
- Zelboraf
- Zolanza
- Zydelig
- Zykadia

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>One of the following for initiation of the requested agent:</p> <p>1. For Bosulif or Tasisna: Documentation of use of imatinib or dasatinib (Sprycel) for the requested indication, unless one of the following: a. The patient has an intolerance or hypersensitivity to imatinib OR dasatinib, b. The patient has an FDA labeled contraindication to imatinib or dasatinib, c. CMS-approved compendia do not support the use of imatinib or dasatinib for the requested indication, or d. The prescriber has provided information in support of use of Bosulif or Tasisna over imatinib or dasatinib for the requested indication.</p> <p>2. For Calquence: Documentation of use of Brukinsa or Imbruvica for the requested indication (if applicable), unless one of the following: a. The patient has an intolerance or hypersensitivity to Imbruvica or Brukinsa, b. The patient has an FDA labeled contraindication to Imbruvica or Brukinsa, c. CMS-approved compendia do not support the use of Imbruvica or Brukinsa for the requested indication, or d. The prescriber has provided information in support of use of Calquence over Imbruvica or Brukinsa for the requested indication.</p> <p>3. For everolimus tablets for suspension (generic for Afinitor Disperz): documentation of medical rationale for the use of this formulation over the available everolimus tablet formulation.</p> <p>4. For all other agents: Indication is supported by CMS-approved compendia.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>For cancer diagnoses, must be prescribed by or in consultation with an oncologist, transplant specialist, neurologist or, for abiraterone, a urologist. For diagnosis of systemic mast cell disease, allergist or immunologist are also acceptable.</p>

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# ANTIFUNGAL AGENTS

## Products Affected

- Cresemba oral capsule 186 mg
- Cresemba oral capsule 74.5 mg
- itraconazole oral solution
- posaconazole oral
- voriconazole

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>1. For oropharyngeal or esophageal candidiasis (itraconazole solution, posaconazole oral suspension (Noxafil), and voriconazole only):</p> <ul style="list-style-type: none"> <li>a. For itraconazole solution: Documented failure, intolerance, or contraindication to fluconazole</li> <li>b. For voriconazole or posaconazole oral suspension (Noxafil): Documented failure, intolerance, or contraindication to fluconazole and itraconazole solution.</li> </ul> <p>2. For the treatment of invasive aspergillosis or invasive candidiasis:</p> <ul style="list-style-type: none"> <li>a. Confirmed diagnosis (Fungal culture and other relevant laboratory studies [including histopathology] must be documented),</li> <li>b. voriconazole will be covered,</li> <li>c. for posaconazole or isavuconazonium: Documented failure, intolerance, or contraindication to voriconazole.</li> </ul> <p>3. For the treatment of blastomycosis or histoplasmosis: itraconazole will be covered,</p> <ul style="list-style-type: none"> <li>a. For voriconazole or posaconazole: Documented failure, intolerance, or contraindication to itraconazole</li> </ul> <p>4. For prophylaxis of invasive aspergillosis or invasive candidiasis: posaconazole or voriconazole will be covered in severely immunocompromised patients.</p>
<b>Age Restrictions</b>	

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PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an infectious disease specialist, hematologist, oncologist, transplant specialist, or pulmonologist for all indication except dermatomycosis
<b>Coverage Duration</b>	Aspergillus/Candida infection prophylaxis: initial/reauth 1 yr. Other uses: initial 3 mo/reauth 1 yr
<b>Other Criteria</b>	5. For dermatomycosis (itraconazole only): Documentation of trial and failure, intolerance, or contraindication to one topical therapy to treat the condition, or medical rationale for not using a topical agent (e.g., treatment area is large enough or in multiple locations such that it is not practically treated with topical agents). 6. For treatment of mucormycosis: isavuconazonium or posaconazole will be covered. 7. For empiric antifungal therapy in patients with febrile neutropenia: itraconazole, voriconazole or posaconazole will be covered. For reauthorization: Documentation supporting continued use of the requested agent for the intended diagnosis (such as continued active disease, length of therapy is supported by literature or guidelines, for prophylaxis patient continues to be severely immunocompromised).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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# ANTIPSYCHOTICS

## Products Affected

- Caplyta
- Fanapt
- Lybalvi
- Rexulti oral tablet
- Secuado
- Vraylar

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>1. For all requests, documentation of medically accepted diagnosis, defined as Food and Drug Administration (FDA) approved indication or compendia-supported use, AND 2. One of the following indication-specific criteria must be met: a. For adjunctive treatment of major depressive disorder, both of the following must be met: i. Documentation of current use of an antidepressant (e.g., citalopram, sertraline, paroxetine, duloxetine, mirtazapine, venlafaxine) AND ii. Documented trial and failure, intolerance, or contraindication to quetiapine and aripiprazole, b. For schizophrenia: Documented trial and failure, intolerance, or contraindication to two formulary, generic antipsychotics (e.g., quetiapine, olanzapine, ziprasidone, risperidone, aripiprazole, lurasidone), c. For bipolar disorder: Documented trial and failure, intolerance, or contraindication to two formulary, generic medications for bipolar disorder (e.g., lithium, quetiapine, lamotrigine, divalproex, aripiprazole, risperidone, olanzapine, lurasidone).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# ARCALYST

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## Products Affected

- Arcalyst

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For Cryopyrin-Associated Periodic Syndrome (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), all the following must be met: 1. Diagnosis confirmed by laboratory evidence of genetic mutation NLRP-3 (Nucleotide-binding domain, leucine rich family pyrin domain containing 3) or CIAS1 (Cold-induced autoinflammatory syndrome-1), AND 2. Classic symptoms associated with CAPS (such as urticaria-like rash, fever, cold/stress-triggered episodes, sensorineural hearing loss, chronic aseptic meningitis, and skeletal abnormalities). For Deficiency of Interleukin-1 Receptor Antagonist (DIRA), all the following must be met: 1. Confirmed by laboratory evidence of genetic mutation in IL1RN (encodes for interleukin-1 receptor antagonist), AND 2. Classic symptoms associated with DIRA (such as pustular psoriasis-like rashes, osteomyelitis without bacterial infection, and nail changes), AND 3. Current inflammatory remission of DIRA, AND 4. Weight of at least 10 kg. For recurrent pericarditis, all the following must be met: 1. Diagnosis of recurrent pericarditis (RP) confirmed by an acute episode of pericarditis followed by a 4-6 week symptom free period prior to the next episode without an identified cause, AND 2. Documentation of treatment trial and failure, contraindication or intolerance to NSAIDs or glucocorticoids. Reauthorization requires documentation of improvement of symptoms (such as fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis for CAPS).</p>
<b>Age Restrictions</b>	For CAPS (which includes FCAS, MWS) and RP: Approved for patients 12 years of age and older
<b>Prescriber Restrictions</b>	

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PA Criteria	Criteria Details
<b>Coverage Duration</b>	Initial authorization will be approved for six months. Reauthorization will be approved for one year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024



# AURYXIA

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## Products Affected

- Auryxia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use for iron deficiency anemia in chronic kidney disease (CKD) not on dialysis
<b>Required Medical Information</b>	For initial authorization, all the following must be met: 1. Diagnosis of hyperphosphatemia AND 2. Patient has chronic kidney disease (CKD) AND 3. Patient is on dialysis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan
<b>Other Criteria</b>	
<b>Indications</b>	Some FDA-approved Indications Only.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# BENLYSTA

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## Products Affected

- Benlysta subcutaneous

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	1. Severe active central nervous system lupus 2. Current use of other biologic immunomodulator

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PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>For Systemic Lupus Erythematosus (SLE) or active lupus nephritis: All of the following must be met: 1. Documented diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis by a rheumatologist or nephrologist AND 2. Documentation of laboratory test results indicating that patient has presence of auto-antibodies, defined as one (1) of the following: a. Positive Antinuclear antibody (ANA) b. Positive antidouble-stranded DNA (anti-dsDNA) on two (2) or more occasions, OR if tested by ELISA, an antibody level above laboratory reference range c. Positive anti-Smith (Anti-Sm) d. Positive anti-Ro/SSA and anti-La/SSB antibodies AND 3. Documented failure of an adequate trial of 30-day duration (such as inadequate control with ongoing disease activity and/or frequent flares), contraindication, or intolerance to at least one (1) of the following: a. For SLE without active lupus nephritis: oral corticosteroid(s), azathioprine, methotrexate, mycophenolate mofetil, hydroxychloroquine, chloroquine, or cyclophosphamide, b. For SLE with active lupus nephritis: mycophenolate for induction followed by mycophenolate for maintenance, OR cyclophosphamide for induction followed by azathioprine for maintenance. AND 4. Documentation that patient will continue to receive standard therapy (e.g., corticosteroids, hydroxychloroquine, mycophenolate, azathioprine, methotrexate). Reauthorization: 1. Documentation of positive clinical response to belimumab (e.g. improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications,</p>
	<p>decrease in the number of exacerbations since prior to start of belimumab, reduction in renal related events) AND 2. Patient currently receiving standard therapy for SLE or active lupus nephritis</p>

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PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a rheumatologist or nephrologist.
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for 6 months.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# BUDESONIDE ER

## Products Affected

- budesonide oral tablet, delayed and ext. release

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For mild to moderate, active ulcerative colitis: 1. Confirmed diagnosis of mild to moderate, active ulcerative colitis AND 2. Documented trial, failure, intolerance or contraindication to treatment with an aminosalicylate (e.g., sulfasalazine, mesalamine) AND 3. Documented trial, failure, intolerance or contraindication to one of the following oral corticosteroids: dexamethasone, hydrocortisone, methylprednisolone, prednisone or budesonide extended release capsule. For microscopic colitis: 1. Confirmed diagnosis of active, microscopic colitis. Further approval requires medical rationale why additional treatment is warranted for ulcerative colitis and microscopic colitis and if patient is not on maintenance therapy for ulcerative colitis why it is not appropriate.</p>
<b>Age Restrictions</b>	Approved for patients 18 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for 8 weeks.

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	MICROSCOPIC COLITIS
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# CABLIVI

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## Products Affected

- Cablivi injection kit

PA Criteria	Criteria Details
Exclusion Criteria	

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PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>Initial Criteria: 1. Diagnosis of acquired thrombotic thrombocytopenic purpura 2. Documentation that therapy will be given in combination with plasma exchange therapy 3. Documentation that therapy will be given in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab) Reauthorization criteria: If the request is for a new treatment cycle: 1. Documentation of previous positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers) 2. Documentation that therapy will be given in combination with plasma exchange therapy and immunosuppressive therapy (i.e., glucocorticoids, rituximab) 3. Documentation that length of therapy post plasma exchange will not exceed 58 days 4. Documentation that patient has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on therapy with caplacizumab. Recurrence is defined as initial platelet normalization followed by a reduction in platelet count that necessitates re-initiation of plasma exchange. If request is for treatment extension: 1. Documentation of positive response to therapy (such as an improvement in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers) 2. Documentation that patient has signs of persistent underlying disease such as persistent severe ADAMTS13 deficiency 3. Documentation that length of therapy post plasma exchange will not exceed 58 days.</p>
<b>Age Restrictions</b>	Approved for patients 18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an oncologist or hematologist

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for 90 days.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# CAMZYOS

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## Products Affected

- Camzyos

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>Initial authorization requires documentation of all the following: 1. Clinical diagnosis of obstructive hypertrophic cardiomyopathy (HCM), defined as left ventricular hypertrophy (LVH) in the absence of another cardiac, systemic, or metabolic disease, capable of producing the magnitude of hypertrophy evident, and evidence of one of the following as measured by any imaging technique: a. Left ventricle wall thickness of 15 mm or greater OR b. Left ventricle wall thickness of 13 mm or greater with family history of HCM or in conjunction with a positive genetic test, 2. New York Heart Association (NYHA) class II, III, or IV, 3. Left ventricular ejection fraction (LVEF) 55% or greater, 4. Left ventricular outflow tract (LVOT) peak gradient 50 mmHg or greater at rest or with provocation, and 5. Documented trial and failure, intolerance, or contraindication to two of the following: A. a formulary generic non vasodilating beta blocker (such as propranolol, metoprolol, atenolol, bisoprolol), B. a formulary generic calcium channel blocker (verapamil or diltiazem), C. disopyramide. Reauthorization requires documentation of a positive clinical response, as evidenced by at least one of the following: 1. Improvement in symptoms (such as dyspnea, fatigue, chest pain, palpitations, dizziness, fainting) OR 2. NYHA class reduction.</p>
<b>Age Restrictions</b>	Approved for 18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist.
<b>Coverage Duration</b>	Initial auth will be approved for six months. Reauth will be approved for one year.

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# CFTR MODULATORS

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## Products Affected

- Kalydeco
- Orkambi
- Symdeko
- Trikafta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis with documentation of mutations consistent with FDA approved uses for the requested medication.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a pulmonologist or provider at a Cystic Fibrosis Center.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# CGRP-AIMOVIG

## Products Affected

- Aimovig Autoinjector

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	In combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis
<b>Required Medical Information</b>	For initial authorization for prevention of migraine headaches, all the following must be met: 1. Diagnosis of migraine headaches with at least four (4) headache days per month AND 2. One of the following: a. Trial and inadequate response to at least one (1) of the following prophylactic medications: divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, venlafaxine, OR b. Documented intolerance or contraindication to the above medications. Reauthorization requires clinical benefit with use, such as a reduction in the severity or frequency of headaches
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# CGRP-EMGALITY

## Products Affected

- Emgality Pen
- Emgality Syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	In combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis
<b>Required Medical Information</b>	For initial authorization for prevention of migraine headaches, all the following must be met: 1. Diagnosis of migraine headaches with at least four (4) headache days per month AND 2. One of the following: a. Trial and inadequate response to at least one (1) of the following prophylactic medications: divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, venlafaxine, OR b. Documented intolerance or contraindication to the above medications. For initiation authorization for cluster headaches, all the following must be met: 1. Diagnosis of episodic cluster headache with at least five (5) cluster headache attacks AND 2. The patient has had at least two cluster periods lasting at least seven (7) days and separated by pain-free remission periods of three months or more. Reauthorization requires clinical benefit with use, such as a reduction in the severity or frequency of headaches.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# CGRP-NURTEC ODT

## Products Affected

- Nurtec ODT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For initial authorization for prevention of migraine headaches, all the following must be met: 1. Diagnosis of migraine headaches with at least four (4) headache days per month AND 2. One of the following: a. Trial and inadequate response to at least one (1) of the following prophylactic medications: divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, venlafaxine, OR b. Documented intolerance or contraindication to the above medications, AND 3. The patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis. For initial authorization for the acute treatment of migraine headaches, all the following criteria must be met: 1. Patient has a diagnosis of migraine with or without aura, AND 2. The patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent, or intolerance, hypersensitivity or an FDA labeled contraindication to a triptan, AND 3. The patient will NOT be using the requested agent in combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP). Reauthorization requires clinical benefit with use, such as a reduction in the severity or frequency of headaches.</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# CGRP-QULIPTA

## Products Affected

- Qulipta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	In combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis
<b>Required Medical Information</b>	For initial authorization for prevention of migraine headaches, all the following must be met: 1. Diagnosis of migraine headaches with at least four (4) headache days per month AND 2. One of the following: a. Trial and inadequate response to at least one (1) of the following prophylactic medications: divalproex, valproate, topiramate, metoprolol, propranolol, timolol, amitriptyline, venlafaxine, OR b. Documented intolerance or contraindication to the above medications. Reauthorization requires clinical benefit with use, such as a reduction in the severity or frequency of headaches
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# CGRP-UBRELVY

## Products Affected

- Ubrelyvy

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	In combination with another acute migraine agent (e.g., triptan, 5HT-1F, ergotamine, acute CGRP)
<b>Required Medical Information</b>	For initial authorization for the acute treatment of migraine headaches, all the following criteria must be met: 1. Patient has a diagnosis of migraine with or without aura, AND 2. The patient has tried and had an inadequate response to a triptan (e.g., sumatriptan, rizatriptan) agent, or intolerance, hypersensitivity or an FDA labeled contraindication to a triptan. Reauthorization requires clinical benefit with use, such as a reduction in the severity or frequency of headaches.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# CORLANOR

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## Products Affected

- Corlanor

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024



PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For chronic heart failure in adults, all the following must be met: 1. Symptoms consistent with New York Heart Association (NYHA) Class II, III, or IV, 2. Left ventricular ejection fraction (LVEF) of 35% or less, 3. Documentation that patient is currently in normal sinus rhythm with resting heart rate of at least 70 bpm, 4. Documentation that the patient is currently using two (2) of the following therapies unless contraindicated or not tolerated: a. An ACE inhibitor (e.g., lisinopril, enalapril) or ARB (e.g., losartan, valsartan) at the maximally tolerated dose, b. One of the following beta-blockers, at the maximally tolerated dose, proven to reduce mortality in all stable patients of heart failure with reduced left ventricular ejection fraction: carvedilol, metoprolol succinate, or bisoprolol, c. A sodium-glucose cotransporter-2 inhibitor (SGLT-2 inhibitor) (empagliflozin or dapagliflozin), 5. Documentation that the patient has been hospitalized for worsening heart failure in the previous 12 months. For pediatric patients at least six months of age: 1. Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM), 2. Documentation that patient is currently in normal sinus rhythm with resting heart rate as follows: age 6-12 months: at least 105 bpm, age 1-3 years: at least 95 bpm, age 3-5 years: at least 75 bpm, age over 5 years: at least 70 bpm.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist or electrophysiologist.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# DIACOMIT

## Products Affected

- Diacomit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial authorization, all the following criteria must be met: 1. Documentation of seizures associated with Dravet Syndrome (DS), 2. Documentation of inadequate control on clobazam or valproate, unless contraindicated, 3. Documentation that stiripentol will be used in combination with clobazam 4. Dose will not exceed 50mg/kg (up to maximum 3,000 mg) per day
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an epilepsy specialist or a neurologist.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# DISPOSABLE INSULIN PUMPS

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## Products Affected

- Omnipod 5 G6 Intro Kit (Gen 5)
- Omnipod 5 G6 Pods (Gen 5)
- Omnipod Dash Intro Kit (Gen 4)
- Omnipod Dash Pods (Gen 4)

PA Criteria	Criteria Details
Exclusion Criteria	

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Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>Disposable insulin pumps will be covered for the treatment of insulin-dependent diabetes when one of the following criteria is met: 1. The request is for a patient with Type 1 diabetes, or 2. All the following: a. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and b. The patient has been on a program of multiple daily injections of insulin (at least two injections per day), and c. Documented history of inadequate glycemic control despite compliance with frequent self-monitoring (four or more blood glucose readings per day or use of continuous glucose monitor) and patient has any of the following problems controlling blood glucose level: i. Documented hypoglycemia unawareness, or ii. Documented recurring episodes (two or more events) of clinically significant hypoglycemia (less than 54 mg/dl) or fasting hyperglycemia (greater than 150 mg/dl), or iii. Glycosylated hemoglobin level (HbA1C) greater than 7%, or iv. History of recurring, symptomatic hypoglycemia, or v. Fasting blood sugars frequently exceeding 200 mg/dL, or vi. History of severe glycemic fluctuations, or vii. Documented need for more than five daily injections of insulin. Requests for additional pods may be covered when the patients' total daily dose of insulin is more than 65 units per day. The quantity will be limited to the appropriate number of pods per month based on insulin utilization (each pod can hold 200 units of insulin and must be changed every 72 hours)</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# DROXIDOPA

## Products Affected

- droxidopa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All of the following criteria must be met: 1. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) 2. Documentation that neurogenic orthostatic hypotension is caused by one of the following: a. Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure) b. Dopamine beta-hydroxylase deficiency c. Non-diabetic autonomic neuropathy 3. Documentation of a screen for treatable causes of orthostatic hypotension and currently being treated for the identified treatable cause of orthostatic hypotension 4. Documented trial, failure, intolerance or contraindication to both midodrine and fludrocortisone. Reauthorization: 1. Documented response to initial therapy (improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out) 2. Documentation that periodic evaluations are being done to assess continued efficacy and medical rationale for continuing therapy, as none of the clinical trials demonstrated continued efficacy beyond 2 weeks of treatment.
<b>Age Restrictions</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist or neurologist.
<b>Coverage Duration</b>	Initial authorization will be for three months. Reauthorization will be approved for 1 year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024



# DUPIXENT

## Products Affected

- Dupixent Pen
- Dupixent Syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
<b>Required Medical Information</b>	For initial authorization for moderate-to-severe asthma: 1. Diagnosis of eosinophilic asthma or oral corticosteroid dependent asthma, 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/ contraindication to standard asthma control therapy. Asthma control therapy may include inhaled corticosteroids (ICS), ICS with long-acting beta agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), and/or theophylline, 3. Documentation of severe asthma with inadequate control such as frequent exacerbations requiring oral corticosteroids or hospitalizations or a poor asthma control scores (An ACT score less than 20 or an ACQ greater than or equal to 1.5). Reauthorization for asthma requires: 1. Documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses and 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/ contraindication to standard asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline).

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PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: 1. Asthma: asthma specialist (such as a pulmonologist, immunologist, or allergist), 2. AD: dermatologist, allergist, or immunologist, 3. EOE: allergist or gastroenterologist, 4. CRSwNP: otolaryngologist, allergist, or pulmonologist.</p>
<b>Coverage Duration</b>	<p>AD/PN/EOE/CRSwNP:Initial 6 mo/reauth 1 yr.  Asthma:Initial 1 yr/reauth until no longer elig with plan</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial authorization for atopic dermatitis (AD): 1. Diagnosis of moderate to severe atopic dermatitis, 2. Documented inadequate response to one of the following: a. Moderate to high potency topical corticosteroids (e.g., clobetasol 0.05%, betamethasone dipropionate 0.05%, triamcinolone 0.5%) or b. Topical calcineurin inhibitor (e.g., tacrolimus ointment). Reauthorization for AD: Documentation of reduction or stabilization from baseline of flares, pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, lichenification, or affected BSA.</p> <p>For initial authorization for eosinophilic esophagitis (EoE): 1. Eosinophil-predominant inflammation on esophageal biopsy with greater than or equal to 15 eosinophils per high power field (HPF), 2. Symptoms of esophageal dysfunction such as dysphagia, chest pain, stomach pain, heartburn, regurgitation, and vomiting, 3. Documented trial and failure, contraindication, or hypersensitivity to both of the following treatment modalities: a. Proton pump inhibitors (e.g. omeprazole, pantoprazole) AND b. Topical glucocorticoids (e.g. fluticasone, budesonide). Reauthorization for EoE: Documentation of response to therapy or disease stabilization.</p> <p>For initial authorization for prurigo nodularis (PN): 1. Presence of firm, nodular lesions, 2. Documentation of itching which has lasted for at least six weeks, 3. Patient has had an inadequate response to at least two weeks of moderate to high potency topical corticosteroids (such as clobetasol, betamethasone dipropionate, triamcinolone).</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
	<p>Reauthorization for PN: Documentation of positive clinical response to therapy, such as reduced number of PN nodules and decreased severity of itching. For initial authorization for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP): 1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan and 2. Inadequate response to a three-month trial of intranasal corticosteroids (e.g., fluticasone) or has an intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid. Reauthorization for CRSwNP requires documentation of positive clinical response to therapy.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# EPIDIOLEX

## Products Affected

- Epidiolex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial Authorization: 1. Documentation that patient has one of the following: a. Seizures associated with Lennox-Gastaut syndrome (LGS) b. Seizures associated with Dravet syndrome (DS) c. Tuberous sclerosis complex (TSC) 2. Documented trial, failure, intolerance or contraindication to two of the following for the seizure type: a. For DS: clobazam, valproate/ valproic acid or topiramate, b. For LGS: clobazam, lamotrigine, valproate/ valproic acid, topiramate or rufinamide, c. For TSC: clobazam, and valproate/ valproic acid 3. Baseline liver function tests must be documented, 4. Dose will not exceed: a. 20 mg/kg/day in Lennox-Gastaut syndrome or Dravet Syndrome b. 25mg/kg/day in tuberous sclerosis complex
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an epilepsy specialist or neurologist.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# ERYTHROPOIESIS STIMULATING AGENTS

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## Products Affected

- Retacrit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients with uncontrolled hypertension, Anemia induced from hepatitis C therapy, Anemia of cancer not related to cancer treatment, Prophylactic use to prevent chemotherapy-induced anemia, Prophylactic use to reduce tumor hypoxia

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PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>1. All diagnoses with the exception of 2d (preoperative use in anemic patients scheduled for elective noncardiac, nonvascular surgery) must have documented hemoglobin (HGB) levels of less than or equal to 10 g/dl or hematocrit (HCT) levels of less than or equal to 30% within 30 days prior to initiation of therapy, AND 2. Must meet the following indication-specific criteria: a. For anemia in Chronic Kidney Disease (not on dialysis): Documentation of adequate iron stores as indicated by current (within the last three months) serum ferritin level greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20%, b. For anemia due to chemotherapy in cancer and related neoplastic conditions (see exclusion criteria for non-covered indications): i. Adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20%, AND, ii. Documentation that anemia is secondary to myelosuppressive chemotherapy in solid tumors, multiple myeloma, lymphoma, or lymphocytic leukemia, c. Anemia associated with zidovudine-treated HIV-infection patients: Documented endogenous serum erythropoietin level less than or equal to 500 mU/ml and zidovudine dose less than or equal to 4200 mg/week.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.

Last Updated: 03/19/2024



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>d. Preoperative use in anemic patients scheduled for elective hip or knee surgery: i. Documentation of preoperative anemia with pretreatment HGB between 10 and 13 g/dL., ii. The procedure has a high risk of perioperative blood loss (e.g., expected to lose more than 2 units of blood), AND iii. Patient is unwilling or unable to donate autologous blood pre-operatively. e. For anemia secondary to myelodysplastic syndrome (MDS) or myelofibrosis, both of the following criteria must be met: i. Documentation of adequate iron stores as indicated by current (within the last three months) serum ferritin level more than or equal to 100 mcg/L or serum transferrin saturation more than or equal to 20% and ii. Documented current (within last three months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL. Reauthorization requires: 1. Documentation of continued medical necessity AND 2. Documented HGB levels of less than or equal to 12 g/dl within previous 30 days.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# ESBRIET/OFEV

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## Products Affected

- Ofev
- pirfenidone

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>Initial authorization: For Idiopathic Pulmonary Fibrosis (IPF) 1. Diagnosis of Idiopathic Pulmonary Fibrosis a. Note: Confirmed by exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, drug toxicity, or connective tissue disease AND 2. Presence of a histological pattern associated with usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) or histological pattern of probable or indeterminate UIP and diagnosis is supported by lung biopsy. For Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (nintedanib only): 1. Confirmed diagnosis of systemic sclerosis AND 2. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography. For other chronic fibrosing interstitial lung diseases with a progressive phenotype (nintedanib only): 1. Presence of ILD confirmed by evidence of pulmonary fibrosis on HRCT tomography AND 2. One (1) of the following criteria: a. Relative decline in FVC of at least 10% of predicted value (as reported by spirometry performed on two different dates within the last two years) b. Relative decline in FVC of at least 5% of predicted value combined with worsening of respiratory symptoms c. Relative decline in FVC of at least 5% of predicted value combined with increased extent of fibrotic changes on chest imaging d. Increased extent of fibrotic changes on chest imaging combined with worsening of respiratory symptoms e. Increased fibrotic changes on HRCT.</p> <p>Reauthorization: Documentation of positive clinical</p>
	<p>response to therapy, such as slowed rate or lack of declining lung function (e.g., FVC, DLCO) and improved or stable respiratory symptoms (e.g., cough, dyspnea).</p>

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	For SSc-ILD only: Must be prescribed by or in consultation with a pulmonologist or rheumatologist. For all other indications: Must be prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# FENTANYL CITRATE

## Products Affected

- fentanyl citrate buccal lozenge on a handle

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of all the following: 1. Treatment of breakthrough cancer pain (prescriber MUST submit chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer), 2. Failure of or intolerance to ONE short-acting opioid formulary agent used for breakthrough pain (e.g. morphine sulfate, oxycodone, oxymorphone, hydromorphone), AND 3. Pain is not controlled with ONE long-acting opioid formulary agent (e.g. morphine sulfate ER, Xtampza ER, hydrocodone ER). Reauthorization: 1. Documentation that patient continues to have breakthrough cancer pain (prescriber MUST submit recent chart notes or other documentation supporting a diagnosis of cancer related pain AND list type of cancer) AND 2. Documentation of successful response to the medication.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an oncologist or pain specialist
<b>Coverage Duration</b>	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# FINTEPLA

## Products Affected

- Fintepla

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome
<b>Required Medical Information</b>	Initial authorization: 1. Documentation that patient has seizures associated with Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS) AND 2. Documented trial, failure, intolerance or contraindication to one of the following: valproate/valproic acid, clobazam, or topiramate
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an epilepsy specialist or neurologist.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# FIRDAPSE

## Products Affected

- Firdapse

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with a history of seizures
<b>Required Medical Information</b>	For initial authorization, all the following must be met: 1. Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS), 2. Documentation of confirmatory diagnostic test results including: a. Repetitive Nerve Stimulation (RNS) testing showing reproducible post-exercise increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared with pre-exercise baseline value or a similar increment on high-frequency repetitive nerve stimulation without exercise OR b. Positive anti-P/Q type voltage-gated calcium channel antibody test, 3. Documentation of symptomatic disease, such as dyspnea or muscle weakness, 4. Member has been evaluated for malignancy and treated for malignancy, if present. Note: LEMS symptoms associated with malignancy may resolve after treatment directed at malignancy. Reauthorization requires documentation of improvement or stabilization of muscle weakness from baseline.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial approval will be approved for 3 months. Reauthorization will be approved for 12 months.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# GAMMA GLOBULIN - IgG

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## Products Affected

- Bivigam
- Flebogamma DIF
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C
- Octagam
- Panzyga
- Privigen

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>Primary immune deficiency disorders (e.g., agammaglobulinemia, hypogammaglobulinemia, common variable immunodeficiency, hyperIgM, or Wiskott-Aldrich syndrome) are covered by Medicare Part B only. For secondary immunodeficiency (e.g., due to drugs, underlying disease): 1. Documentation of recurrent infections AND 2. Evidence of immunoglobulin (IgG) deficiency defined one of the following: a. Agammaglobulinemia (total pre-treatment IgG less than 200 mg/dL) or b. Hypogammaglobulinemia (total IgG less than 700 mg/dl, or at least two standard deviations (SDs) below normal), OR c. Deficiency in producing antibodies in response to vaccination. For Kawasaki syndrome: documentation that use is for acute treatment (within 10 days of symptom onset) in combination with aspirin. For children with Idiopathic or Immune Thrombocytopenic Purpura (ITP): Documentation of one of the following: a. Platelet count less than 20,000 and significant mucous membrane bleeding, b. Platelet count less than 10,000 and minor purpura, c. Rapid increase in platelets required (e.g., planned surgery, dental extractions, or other procedures likely to cause blood loss). For pregnant women with ITP: Documentation of one of the following: a. Platelet count is less than 100,000 b. History of splenectomy c. History of delivered infant with autoimmune thrombocytopenia. For adult patients with ITP: 1. Documentation of one of the following: a. Platelet count of less than 30,000, b. Platelet count less than 50,000 with acute bleeding or high-risk of bleeding, c. To</p>

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<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>defer or avoid splenectomy, d. Rapid increase in platelets required (e.g., planned surgery, dental extractions, or other procedures likely to cause blood loss) AND 2. Documentation that product will be used in combination with corticosteroid therapy, unless contraindicated. For Guillain-Barre Syndrome: 1. Documentation of symptom onset within 2 weeks or severe symptoms and 2. Documented inadequate response or contraindication to plasma exchange.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Must be prescribed by, or in consultation with, an appropriate specialist (e.g., a neurologist for multiple sclerosis or a hematologist for autoimmune hemolytic anemia)</p>
<b>Coverage Duration</b>	<p>Initial authorization for 6 months. Reauthorization for 12 months.</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For prevention of infections in patients with chronic B-cell CLL: 1. Hypogammaglobulinemia (as defined above) OR 2. History of recurrent, severe infections (e.g., need for antibiotics, hospitalization). For dermatomyositis and polymyositis: 1. Documented trial and failure, intolerance, or contraindication to systemic corticosteroids and immunosuppressants, 2. Documentation of severe symptoms despite therapy with above agents. For multifocal motor neuropathy: 1. Motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities AND 2. Documentation of severe disease/disability. For MS: 1. Documentation of relapsing/remitting disease AND 2. Documented trial and failure, intolerance, or contraindication to at least 2 conventional therapies. For Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients: 1. Therapy is requested for use within 100 days of transplantation (transplantation date must be documented) OR 2. Hypogammaglobulinemia (as defined above). For chronic inflammatory demyelinating polyneuropathy (CIDP): 1. Documentation of severe disability and 2. One of the following: a. Documented trial and failure, intolerance or contraindication to systemic corticosteroids or b. Documentation of pure motor CIDP. For autoimmune hemolytic anemia: 1. Documented trial and failure, intolerance or contraindication to systemic corticosteroids AND another conventional therapy (e.g., cyclophosphamide, azathioprine, cyclosporine). For</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
	<p>myasthenia gravis: One of the following: a. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month: difficulty swallowing, acute respiratory failure, major functional disability responsible for the discontinuation of physical activity or b. Evidence of refractory disease defined as the following: 1. Documentation of severely impaired function AND 2. Documented trial and failure, intolerance, or contraindication to at least 2 of the following conventional therapies: acetylcholinesterase inhibitors, corticosteroids or immunosuppressive agents. For autoimmune mucocutaneous blistering disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatrical) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]: 1. Biopsy proven disease AND 2. Documented trial and failure, intolerance, or contraindication to systemic corticosteroids and immunosuppressive treatment.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Hematopoietic stem cell transplant recipients, acute Guillain-Barre syndrome, dermatomyositis, relapsing-remitting type multiple sclerosis, myasthenia gravis, autoimmune hemolytic anemia, autoimmune mucocutaneous blistering disease, B-cell CLL, multifocal motor neuropathy, and polymyositis.
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# GATTEX

## Products Affected

- Gattex 30-Vial
- Gattex One-Vial

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initiation of therapy in short bowel syndrome (SBS), all the following must be met: 1. An initial nutritional assessment has been completed by a registered dietitian who has determined that oral/enteral nutrition is not sufficient to meet nutritional goals, AND 2. Patient is stable and dependent on parenteral support (fluids, electrolytes and/or nutrients) delivered at least three times per week, AND 3. The medication has been made part of a treatment plan established by a gastroenterologist or a hospital Metabolic Support Team that includes: a. Member evaluation indicates the possibility of success with treatment b. Defined parameters to measure response to therapy, AND 4. Dose does not exceed 0.05 mg/kg once daily. For patients already established on therapy, the following must be met: Documentation that parenteral nutrition support requirement has decreased since initiation of therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a gastroenterologist.

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial approval will be approved for 6 months. Reauthorization will be approved for 12 months.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024



# GLP-1 AGONISTS

## Products Affected

- Bydureon BCise mg/dose (8 mg/3 mL)
- Mounjaro • Rybelsus
- Ozempic subcutaneous pen • Trulicity  
injector 0.25 mg or 0.5 mg (2 mg/3 mL), 0.25 mg or 0.5 mg(2 mg/1.5 mL), 1 mg/dose (4 mg/3 mL), 2
- Victoza 2-Pak
- Victoza 3-Pak

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All the following must be met: 1. The requested agent will NOT be used for weight loss alone, AND 2. The patient has a diagnosis of type 2 diabetes mellitus
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# HEPATITIS C

## Products Affected

- ledipasvir-sofosbuvir
- Mavyret
- sofosbuvir-velpatasvir
- Vosevi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Criteria will be applied consistent with current American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious disease specialist, or providers experienced in Hepatitis C management.
<b>Coverage Duration</b>	8 to 24 weeks based on medication, indication and established treatment guidelines
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# HEREDITARY ANGIOEDEMA THERAPY

## Products Affected

- Cinryze
- Haegarda
- icatibant
- Orladeyo
- Sajazir
- Takhzyro

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of more than one agent used for prophylaxis
<b>Required Medical Information</b>	All of the following must be met: 1. Diagnosis of Hereditary Angioedema (HAE) Type I, II or III, 2. One of the following: a. For HAE Type I and Type II, documentation of a complement study that shows: i. C4 less than normal AND ii. One of the following: C1-Inhibitor (C1-INH) protein or C1-INH function less than normal. b. For HAE with normal C1-INH or HAE Type III, one of the following: i. Confirmed Factor 12 (FXII) ANGPT1, PLG, KNG1 gene mutation OR ii. Positive family history for HAE and attacks that lack response to high dose antihistamines or corticosteroids, and 3. Dosing regimens are within FDA labeled dosing outlined in package insert or sufficient evidence-based rationale is provided for increased dosing and/or frequency. 4. For coverage of Cinryze: Documentation of trial and failure or contraindication to Haegarda. Reauthorization requires documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an immunologist or allergist.

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial prior authorization will be approved for 3 months. Reauthorization may be approved for 1 yr.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# HETLIOZ

## Products Affected

- Hetlioz LQ
- tasimelteon

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Sleep disorders other than Non-24 and nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
<b>Required Medical Information</b>	For Non-24-Hour Sleep-Wake Disorder (Non-24): All of the following criteria must be met: 1. Member is totally blind (i.e. no light perception), 2. Documented diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as characterized by all of the following: a. Distinct pattern of sleeping and waking that drifts by a consistent time period every night AND b. History of periods of insomnia, excessive sleepiness, or both, which alternate with short asymptomatic periods, 3. Documented sleep study to exclude other sleep disorders. Reauthorization requires documentation of entrainment to the 24-hour circadian period. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): All of the following criteria must be met: 1. Documented diagnosis of SMS, as characterized by: a. Confirmation of the deletion or mutations of retinoic acid-induced 1 (RAI1) gene, 2. Documented sleep study to exclude other sleep disorders, 3. Documentation of at least one of the following: a. difficulties falling asleep, b. shortened sleep cycles, c. frequent and prolonged nocturnal awakenings, d. excessive daytime sleepiness or e. daytime napping. Reauthorization requires documentation of improvement in sleep quality or total sleep time.

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a sleep specialist or neurologist
<b>Coverage Duration</b>	Initial authorization will be approved for 6 months. Reauthorization will be approved for 1 year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# HUMAN GROWTH HORMONES

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## Products Affected

- Omnitrope

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>For initial authorization for Growth Hormone Deficiency (GHD) in adults due to congenital defects, genetic defects, organic hypothalamic-pituitary disease, must meet one of the following criteria: 1. At least three pituitary hormone deficiencies (other than GH) or 2. Less than three pituitary hormone deficiencies, or IGF-1 below normal for age/sex, and one of the following confirmatory stimulation tests: a. Insulin Tolerance Test (ITT) with peak GH less than/equal to 5 micrograms per liter (mcg/L), b. Glucagon Stimulation Test (GST) with low peak GH based on body mass index (BMI), as follows: i. BMI less than 25: Peak GH less than/equal to 3 mcg/L, ii. BMI 25-30: Peak GH less than/equal to 1 mcg/L (patients with high clinical suspicion of GHD, peak GH less than 3 mcg/L will be covered), iii. BMI greater than/equal to 30: Peak GH less than/equal to 1 mcg/L, c. Macimorelin with peak GH less than/equal to 2.8 mcg/L. For initial authorization for GHD in adults (adult-onset) and history of destructive lesions of the hypothalamic region (such as hypothalamic-pituitary tumors, surgery, cranial irradiation, traumatic brain injury): 1. IGF-1 below normal for age/sex, 2. One of the following confirmatory stimulation tests: a. Insulin Tolerance Test (ITT) with peak GH less than/equal to 5 mcg/L, b. Glucagon Stimulation Test (GST) with low peak GH based on body mass index (BMI), as follows: i. BMI less than 25: Peak GH less than/equal to 3 mcg/L, ii. BMI 25-30: Peak GH less than/equal to 1 mcg/L. For patients with high clinical suspicion of GHD in this range, coverage will be approved with peak GH less than 3</p>

Last Updated: 03/19/2024



<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>mcg/L., iii. BMI greater than/equal to 30: Peak GH less than/equal to 1 mcg/L, c. Macimorelin with peak GH less than/equal to 2.8 mcg/L. For reauthorization for GHD in adults: evidence of improved quality of life, good tolerability, and annual documentation of IGF-1 with appropriate dosage adjustments (GH requirements often decrease with age).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Must be prescribed by, or in consultation with, an endocrinologist.</p>
<b>Coverage Duration</b>	<p>SBS: 4 weeks. AIDS wasting: 12 months. All other uses: initial/reauth for 12 months.</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial authorization for GHD in children, must meet one of the following: 1. Newborn with hypoglycemia and both of the following: a. Serum GH level less than/equal to 5 mcg/L and b. One of the following: i. An additional pituitary hormone deficiency (other than GH), or ii. Classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk), 2. Extreme short stature (height more than 3 SDS below the mean for chronological age/sex), all the following: a. IGF-1 level at least 2 SDS below normal, b. Insulin-like growth factor binding protein-3 (IGFBP-3) at least 2 SDS below normal, or c. Delayed bone age (2 SDs below the mean for chronological age), 3. Pituitary abnormality (secondary to a congenital anomaly, tumor, or irradiation) and both of the following criteria: a. Additional pituitary hormone deficiency (other than GH), and b. Evidence of short stature/growth failure (GF) by one of the following: i. Height more than 3 SDS below the mean for chronological age/sex, ii. Height below 3rd percentile (or greater than 2 SD below the mean) AND untreated growth velocity (GV) is below the 25th percentile, iii. Severe growth rate deceleration (GV over one year of more than 2 SD below the mean for age/sex), 4. Suspected GHD and all the following: a. Evidence of short stature/GF using criteria above, b. Biochemical GHD by one of the following: i. Two GH stimulation tests (using arginine, clonidine, glucagon, insulin, or levodopa) with peak GH concentrations less than 10 ng/mL or ii. One GH stim test with peak GH less than 15 ng/ml and</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
	<p>IGF-1 and IGFBP-3 levels below normal. For Prader-Willi Syndrome, Turner Syndrome, Short stature homeobox-containing (SHOX) deficiency: 1. Confirmed diagnosis by genetic testing and 2. Evidence of short stature/GF using criteria above. For Noonan Syndrome: 1. Confirmed diagnosis by genetic testing or made by an endocrinologist based on clinical features AND 2. Evidence of short stature/GF using criteria above. For GF due to chronic kidney disease: 1. Other causes of GF have been ruled out, AND 2. Evidence of short stature/GF using criteria above. For Small for Gestational Age: 1. Birth weight or length at least 2 SDs below the mean AND 2. Failure to reach catch-up growth by two years of age (height at least two SDS below the mean for age/sex). For Reauthorization for children (all diagnoses): 1. Evidence of improved growth AND 2. Evidence of open epiphyses</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# INCRELEX

## Products Affected

- Increlex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Subjects with secondary forms of IGF-1 deficiency (e.g., GH deficiency, malnutrition, hypothyroidism, chronic treatment with pharmacologic doses of anti-inflammatory steroids). Concurrent use of growth hormone therapy. Malignant neoplasia
<b>Required Medical Information</b>	For severe primary IGF-1 deficiency all of the following criteria must be met: 1. Height standard deviation score of less than or equal to -3.0, 2. Basal IGF-1 standard deviation score of less than or equal to -3.0, 3. Normal or elevated growth hormone (GH) levels, AND 4. Documentation of open epiphyses by bone radiograph. For GH gene deletion: 1. Documentation of open epiphyses by bone radiograph AND 2. Patient has developed neutralizing antibodies to growth hormone. Reauthorization will require evidence that the medication remains effective, growth velocity is above 2.0 cm/year, evidence of open epiphyses, and documentation of expected adult height goal that is not yet obtained.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# ISTURISA/SIGNIFOR

## Products Affected

- Isturisa
- Signifor

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial authorization all of the following criteria must be met: 1. Diagnosis of endogenous Cushing's Disease AND 2. Documentation of one of the following: a. Patient has failed pituitary surgery OR b. Patient is not a candidate for surgery. Reauthorization requires documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# JUXTAPID

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## Products Affected

- Juxtapid

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Diagnosis of Heterozygous familial hypercholesterolemia or other hyperlipidemia disorders

Last Updated: 03/19/2024



PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For initial authorization, all the following must be met: 1. Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) as evidenced by either genetic or clinical confirmation, as outlined below: a. Genetic confirmation: biallelic functional mutations in the low density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin/kexin type 9 (PCSK9) or LDL receptor adapter protein 1 (LDLRAP1) genes, b. Clinical confirmation defined as untreated total cholesterol greater than 500 mg/dL or treated LDL-C greater than or equal to 300 mg/dL and one of the following: i. Presence of xanthomas before the age of 10 years, or ii. Evidence of heterozygous familial hypercholesterolemia in both parents such as documented history of elevated LDL-C greater than or equal to 190 mg/dL prior to lipid-lowering therapy, AND 2. Current use of TWO (2) of the following therapies: a. High-intensity statin therapy, defined as atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily, unless contraindicated or documented statin intolerance, b. Ezetimibe, unless contraindicated or prior intolerance, c. PCSK-9 inhibitor (such as, evolocumab), unless contraindicated or prior intolerance, AND 3. Documentation of LDL cholesterol levels (taken within the last six months) of greater than 100 mg/dL despite at least six (6) months of use of the therapies outlined above. Initial reauthorization requires documentation of at least a 30% reduction in LDL cholesterol levels from pre-treatment levels.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board certified lipidologist

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial auth approved for 1 year. Reauth will be approved until no longer eligible with the plan
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# KERENDIA

## Products Affected

- Kerendia

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initiation of therapy, all the following must be met: 1. Patient has a diagnosis of type 2 diabetes, AND 2. Patient has evidence of diabetic nephropathy, AND 3. Documentation that patient is on a maximally tolerated Angiotensin Converting Enzyme inhibitor (such as lisinopril) or an Angiotensin Receptor Blocker (such as losartan), unless all agents in these classes are contraindicated, AND 4. Documentation of trial, contraindication, or intolerance to a Sodium Glucose Co-transporter-2 inhibitor (such as empagliflozin or dapagliflozin).
<b>Age Restrictions</b>	Approved for patients 18 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

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

Last Updated: 03/19/2024

# KORLYM

## Products Affected

- Korlym

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Current pregnancy
<b>Required Medical Information</b>	Initial authorization: 1. Documentation that the patient has hyperglycemia secondary to endogenous Cushing's Syndrome (defined as hypercortisolism that is not a result of chronic administration of high dose glucocorticoids), AND 2. Documentation that the patient has type 2 diabetes mellitus or glucose intolerance, AND 3. Documentation that the patient has failed surgery or is not a candidate for surgery. Reauthorization: Documentation that the patient has improved or stable glucose tolerance.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an endocrinologist.
<b>Coverage Duration</b>	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# LIDOCAINE PATCH

## Products Affected

- DermacinRx Lidocan
- lidocaine topical adhesive patch, medicated 5 %
- Lidocan III

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of post-herpetic neuralgia, cancer-related neuropathic pain, or diabetic peripheral neuropathy
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Diabetic peripheral neuropathy and cancer-related neuropathic pain.
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# LONG-ACTING OPIOIDS

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## Products Affected

- Belbuca
- buprenorphine
- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr
- levorphanol tartrate oral tablet 2 mg
- methadone oral solution
- methadone oral tablet
- Xtampza ER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	As needed (prn) use. For treatment of acute pain such as recent injury, sprain, strain or surgery.

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Last Updated: 03/19/2024



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Required Medical Information</b>	<p>For ALL requests, a treatment plan must exist that outlines current treatment regimen (including all opioids with daily dose and frequency, all non-opioid therapy, and/or non-pharmacological therapy), appropriate patient medical history, and pertinent physical examination findings. In addition, patient must meet all the criteria under one of the patient-specific conditions listed below:</p> <p>A. For patients initiating long-acting opioid therapy for cancer pain, palliative care with a terminal diagnosis, sickle cell disease, or severe burns: 1. Documentation of active pain directly related to the condition(s) mentioned above, AND 2. Documentation that patient has inadequate response to "around-the-clock" short-acting opioid therapy within the past 30 days, AND 3. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy.</p> <p>B. For patients established on long-acting opioid therapy for cancer pain, palliative care with a terminal diagnosis, sickle cell disease, or severe burns: 1. Improvement from baseline in pain control/level of functioning, no worsening of pain control, or patient is switching long-acting opioid products due to adverse effect or inadequate response, 2. Documentation of continued active pain directly related to the condition(s) mentioned above.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.

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PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>C. For patients initiating long-acting opioid therapy for chronic pain (other than cancer pain, palliative care, sickle cell disease, or severe burns): 1. Documentation of chronic pain (lasting longer than 3 months) that is severe enough to require around-the-clock analgesic therapy, 2. Documentation that within the past 30 days patient has had inadequate response to at least two weeks of consistent use of short-acting opioids, totaling at least 60 morphine milligram equivalents (MME) per day, 3. Documentation that the pain is not caused by a condition for which opioids are not recommended, including: fibromyalgia, abdominal pain, diabetic neuropathy, temporomandibular joint, headaches, migraines, pelvic pain syndrome, 4. No contraindications to opioids, including but not limited to: untreated substance use disorder, significant respiratory depression, hypercapnia, or central apnea GI obstruction or paralytic ileus, 5. Documentation of trial and failure, contraindication, or intolerance to long-acting morphine sulfate therapy, 6. There is a pain management agreement and/or treatment/monitoring plan between the prescriber and patient that includes monitoring plans and functional goals that has been reviewed within the previous six months, 7. Prescription Drug Monitoring Program (PDMP) has been reviewed and no concerns for initiating long-acting opioid therapy were identified, AND 8. For fentanyl patch: Patient must be opioid-tolerant, defined as using at least 60 MME per day. D. For patients established on long-acting opioid therapy for chronic pain (other than</p>

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<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>cancer pain, palliative care, sickle cell disease, or severe burns) all of the following criteria must be met: 1. Improvement from baseline in pain control/level of functioning, no worsening of pain control, or patient is switching long-acting opioid products due to adverse effect or inadequate response, 2. Appropriate monitoring (including review of PDMP) with no concerns for adverse events (such as no unmonitored dose escalation, no excess sedation, no signs of developing substance use disorder), 3. There is a pain management agreement and/or treatment/monitoring plan between the prescriber and patient that includes monitoring plans and functional goals that has been reviewed within the previous six months.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# LUPRON DEPOT

## Products Affected

- leuprolide (3 month)
- leuprolide subcutaneous kit
- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Lupron Depot-Ped (3 month) intramuscular syringe kit 11.25 mg
- Lupron Depot-Ped intramuscular kit 7.5 mg (Ped)
- Lupron Depot-Ped intramuscular syringe kit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For oncological indications: Use must be for a FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher. For non-oncological indications: documentation of confirmed diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Approved until no longer elig with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

Last Updated: 03/19/2024

# MEDICATIONS FOR RARE INDICATIONS

## Products Affected

- carglumic acid
- Cerdelga
- miglustat
- Ravicti
- sodium phenylbutyrate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Initial authorization: 1. Confirmation of FDA-labeled indication AND 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information). Reauthorization: 1. Documentation of successful response to therapy AND 2. Dosing is within FDA-labeled guidelines OR documentation has been submitted in support of therapy with a higher dose for the intended diagnosis (e.g., high-quality peer reviewed literature, guidelines, other clinical information).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Must be prescribed by, or in consultation with, an endocrinologist, geneticist, hematologist, or metabolic disorder specialist.</p>
<b>Coverage Duration</b>	<p>Initial authorization and reauthorization will be approved for one year.</p>
<b>Other Criteria</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# NEXLETOL/NEXLIZET

## Products Affected

- Nexletol
- Nexlizet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For Initial Authorization, all of the following must be met:</p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or familial hypercholesterolemia,</li> <li>2. Fasting LDL-C greater than or equal to 70 mg/dL despite treatment with therapies below,</li> <li>3. One of the following:               <ol style="list-style-type: none"> <li>a. Current use of high-intensity statin therapy for at least 3 months, defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily or</li> <li>b. Documented intolerance, FDA labeled contraindication or hypersensitivity to a statin,</li> </ol> </li> <li>4. Current use of a formulary PCSK-9 inhibitor (such as Repatha®) for at least three (3) months, or documented intolerance/contraindication to its use. Reauthorization requires documented response to therapy, as defined by a reduction in fasting LDL-C.</li> </ol>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial auth approved for one year. Reauth will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	

Last Updated: 03/19/2024



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# NUEDEXTA

## Products Affected

- Nuedexta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Current use, or use within the past 14 days, of monoamine oxidase inhibitors (MAOIs) and patients diagnosed with a prolonged QT interval, congenital long QT syndrome, or a history suggesting torsades de pointes.
<b>Required Medical Information</b>	Initial authorization: 1. Diagnosis of pseudobulbar affect (PBA) AND 2. Documentation of a neurologic disease or brain injury (such as traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis [ALS], or Parkinson's disease). Reauthorization: Documentation of response to therapy, defined as a reduction in episodes of laughing, crying, and/or emotional lability.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# NUPLAZID

## Products Affected

- Nuplazid

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial authorization, all the following must be met: 1. Diagnosis of Parkinson's disease with hallucinations and/or delusions causing clinically significant distress, with dementia-related psychosis ruled out AND 2. Patient able to self-report symptoms (such as hallucinations or distress) AND 3. Documented trial and failure, intolerance, or contraindication to clozapine.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist, psychiatrist, or geriatrician.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# OCALIVA

## Products Affected

- Ocaliva

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Non-alcoholic steatohepatitis (NASH). Decompensated cirrhosis (such as Child-Pugh Class B or C) or a prior decompensated event. Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
<b>Required Medical Information</b>	For the diagnosis of primary biliary cholangitis, all the following must be met: 1. Confirmed diagnosis of primary biliary cholangitis as evidenced by two (2) of the following criteria: a. Elevated alkaline phosphatase (ALP) [above the upper limit of normal (ULN) as defined by laboratory reference values] b. Presence of antimitochondrial antibody (AMA) c. Histologic evidence of primary biliary cirrhosis from liver biopsy AND 2. Both of the following: a. Use of ursodiol for a minimum of 12 months and has had an inadequate response according to prescribing physician AND b. Documentation that the medication will be used in combination with ursodiol, unless patient is unable to tolerate ursodiol. For reauthorization, all the following must be met: 1. Maintenance of biochemical response (e.g. improvement or stabilization of ALP or total bilirubin levels), AND 2. Documentation that ursodiol will be continued, if tolerated, AND 3. Hepatic function is assessed at least annually.
<b>Age Restrictions</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.
<b>Coverage Duration</b>	Initial authorization will be approved for 4 months. Reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# OPZELURA

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## Products Affected

- Opzelura

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For initial authorization for atopic dermatitis, all the following criteria must be met: 1. Diagnosis of mild to moderate atopic dermatitis despite therapies outlined in criterion number 2. Mild to moderate atopic dermatitis may be defined by all the following: a. Patient has a body surface area (BSA) involvement of 3% to 20% b. Chronic condition, affecting patient for at least two years 2. Documented trial and failure, contraindication, or hypersensitivity to both of the following: a. A moderate to high potency topical corticosteroid for at least two weeks and b. A topical calcineurin inhibitor (such as tacrolimus ointment) applied twice daily for at least one month. For reauthorization for atopic dermatitis: Documentation of reduction or stabilization from baseline of flares, pruritis, erythema, edema, xerosis, erosions/excoriation, oozing/crusting, lichenification or affected BSA. For initial authorization for nonsegmental vitiligo, all the following criteria must be met: 1. Diagnosis of nonsegmental vitiligo with depigmented areas affecting less than or equal to 10% total BSA, 2. Inadequate response to both of the following: a. A topical calcineurin inhibitor (such as tacrolimus) and b. A moderate to high potency topical corticosteroid (such as clobetasol or fluocinolone). For reauthorization for nonsegmental vitiligo: Documentation of positive clinical response to therapy, such as reduction in depigmented BSA.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
<b>Coverage Duration</b>	Initial authorization will be approved for six months. Reauthorization will be approved for one year

Last Updated: 03/19/2024



PA Criteria	Criteria Details
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 03/19/2024

# ORENCIA

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## Products Affected

- Orencia
- Orencia ClickJect

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient is currently being treated with another therapeutic immunomodulator or apremilast

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Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Required Medical Information</b>	<p>For patients already established on the requested therapy: 1. Documentation of response to therapy (i.e. slowing of disease progression or decrease in symptom severity and/or frequency) and 2. One of the following: a. Patient is not currently being treated with another biologic immunomodulator OR b. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator. For patients being initiated on therapy, all of the following criteria must be met: 1. Patient must have an FDA labeled indication for the requested agent, 2. One of the following: a. Patient is not currently being treated with another biologic immunomodulator OR b. Patient is currently being treated with another biologic immunomodulator AND will discontinue the other biologic immunomodulator prior to starting the requested agent, 3. Documentation of trial and failure, intolerance, or contraindication to preferred biologic agents, as follows: Use of TWO preferred agents (secukinumab, etanercept, adalimumab, upadacitinib, risankizumab, ustekinumab, tofacitinib) is required for diagnosis of psoriatic arthritis. Use of TWO preferred agents (etanercept, adalimumab, upadacitinib, tofacitinib) is required for diagnosis of rheumatoid arthritis. Use of TWO preferred agents (etanercept, adalimumab, tofacitinib) is required for diagnosis of juvenile idiopathic arthritis. NO preferred agent is required for diagnosis of prophylaxis of acute graft vs host disease.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a dermatologist, rheumatologist, or transplant specialist.

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# OSTEOANABOLIC AGENTS

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## Products Affected

- teriparatide subcutaneous pen injector 20 mcg/dose (620mcg/2.48mL)
- Tymlos

PA Criteria	Criteria Details
Exclusion Criteria	

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Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For the treatment or prevention of osteoporosis, must meet ONE of the following criteria (a-e): a. Patient has a history of multiple or severe vertebral fractures, or history of fragility fractures, b. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -3.0, c. Patient has a spine or hip bone mineral density (BMD) T-score less than or equal to -2.5 to -3.0 and high risk for fracture, defined as one of the following: i. Age more than 80 years, ii. Chronic glucocorticoid use, iii. Documented increased fall risk, d. Patient has a spine or hip BMD T-score less than or equal to -2.5 to -3.0 and one of the following: 1. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while on therapy, or 2. Documented contraindication or intolerance to both denosumab and bisphosphonate therapies, OR e. Patient has a spine or hip BMD T-score between -1.0 and -2.5 and BOTH of the following (i. and ii.): i. Fracture Risk Assessment (FRAX) probability score for hip fracture of at least 3% or, for other major osteoporosis fracture, of at least 20%, ii. One of the following: 1. Documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates). Failure is defined as a new fracture or worsening BMD while on therapy, 2. Documented contraindication or intolerance to both denosumab and bisphosphonate therapies</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an endocrinologist or rheumatologist
<b>Coverage Duration</b>	Auth for up to 2 yrs in lifetime. No reauth, unless meets clinical criteria for teriparatide.

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For authorization for teriparatide use exceeding two years in a lifetime, must meet both of the following criteria: 1. Documentation that previous treatment with teriparatide showed clinical improvement, defined as absence/decrease in frequency of new fragility fracture or stable/increased BMD T-score while on teriparatide 2. One of the following: a. Patient continues to be at very high risk for fracture, defined as one of the following while on teriparatide: i. BMD T-score continues to be less than or equal to -3.0 ii. New vertebral or fragility fracture b. Documentation of worsening disease, defined as one of the following: i. A repeat BMD after discontinuation of therapy demonstrates a decline in BMD ii. New onset fragility fracture after discontinuation</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# PCSK-9 INHIBITORS

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## Products Affected

- Repatha Pushtonex
- Repatha SureClick
- Repatha Syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with another PCSK9 inhibitor.

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Last Updated: 03/19/2024



PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>For initial authorization, both criteria 1 and 2 must be met:</p> <p>1. One of the following: a. The patient has an inadequate response to a high-intensity statin (rosuvastatin 20-40 mg or atorvastatin 40-80 mg), b. The patient has an intolerance to TWO different statins, or c. The patient has an FDA labeled contraindication to a statin, AND 2. Must meet listed criteria below for each specific diagnosis: a. Diagnosis of familial hypercholesterolemia and one of the following: i. Genetic confirmation of a mutation at the LDLR, Apo-B, PCSK9, or 1/LDLRAP1 gene, ii. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment), iii. The patient has clinical manifestations of familial hypercholesterolemia (such as cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma), iv. The patient has "definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria, v. The patient has a Dutch Lipid Clinic Network criteria score of greater than 5, vi. The patient has a treated low-density lipoprotein cholesterol (LDL-C) level 100 mg/dL or greater after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy, b. Diagnosis of established cardiovascular disease [angina pectoris, coronary heart disease, myocardial infarction, transient ischemic attacks, cerebrovascular disease, peripheral vascular disease (PVD), history of coronary revascularization or carotid endarterectomy] AND the requested agent will be used to reduce the risk of myocardial infarction, stroke, and coronary revascularization, OR c. A diagnosis of primary</p>
	<p>hyperlipidemia (not associated with familial hypercholesterolemia or established cardiovascular disease). Reauthorization requires provider attestation of response to therapy, defined as a decrease in LDL-C levels from pre-treatment levels.</p>

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Medications must be prescribed by, or in consultation with a cardiologist, endocrinologist, and/or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders
<b>Coverage Duration</b>	Initial authorization for one year. Reauth will be approved until no longer eligible with plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# PREVYMIS

## Products Affected

- Prevymis oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	One of the following criteria must be met: 1. Patient is using for prophylaxis of cytomegalovirus (CMV) infection after allogeneic hematopoietic stem cell transplant (HSCT) and all of the following: a. Patient is CMV seropositive and b. Attestation that therapy will be started within 28 days post-transplantation, or 2. Patient is using for prophylaxis of CMV disease after kidney transplant and all of the following: a. Patient is at high risk, defined as CMV seropositive Donor in a Recipient that is CMV seronegative (D+/R-) and b. Attestation that therapy will be started within seven (7) days post-transplantation.
<b>Age Restrictions</b>	Approved for patients 18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a hematologist, oncologist, transplant specialist, or infectious disease specialist.
<b>Coverage Duration</b>	Authorization will be approved for up to 200 days post-transplantation.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# PROMACTA

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## Products Affected

- Promacta

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For initiation of therapy, must meet the following indication-specific criteria: 1. For myelodysplastic syndromes (MDS): use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher, 2. For Immune Thrombocytopenia (ITP), all the following criteria (a-c) must be met: a. Diagnosis of chronic immune thrombocytopenia (ITP), b. Platelet count of less than 30,000 cells per microliter, AND c. Treatment with at least one of the following therapies was ineffective or not tolerated, unless all are contraindicated: i. Systemic corticosteroids, ii. Immune globulin, iii. Splenectomy, iv. Rituximab, 3. For Severe Aplastic Anemia, documentation that the patient is at risk for bleeding with a platelet count of less than 30,000 cells per microliter, 4. Thrombocytopenia due to chronic Hepatitis C. For patients established on therapy, must meet indication-specific criteria below: 1. For MDS: documentation of improved platelet levels from baseline, 2. For ITP, severe aplastic anemia or Hepatitis C: a. Documentation of improved platelet levels from baseline AND b. Documentation the continued therapy is medically necessary to maintain a platelet count of at least 50,000 cells per microliter.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Must be prescribed by, or in consultation with an oncologist, hematologist, infectious disease specialist, gastroenterologist, or hepatologist.</p>
<b>Coverage Duration</b>	<p>Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months.</p>

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myelodysplastic syndromes.
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# PULMONARY ANTIHYPERTENSIVES

## Products Affected

- Adempas tablet
- Alyq • tadalafil (pulm. hypertension)
- ambrisentan • Tracleer oral tablet for suspension
- bosentan • Tyvaso DPI
- Opsumit • Uptravi oral
- sildenafil (pulm.hypertension) oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For initial authorization the following criteria must be documented: 1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization, as defined by all of the following: a. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest, b. Pulmonary capillary wedge pressure (PCWP) or left ventricular end diastolic pressure (LVEDP) less than or equal to 15 mmHg, AND c. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU), 2. Patient has documentation of one of the following i. World Health Organization (WHO) Group 1 classification PAH (or WHO Group 4 classification CTEPH for Adempas® only) with WHO/New York Heart Association (NYHA) functional class II, III, or IV, ii. For Tyvaso® DPI only, pulmonary hypertension associated with interstitial lung disease (WHO Group 3 classification PH-ILD). 3. For Opsumit, Uptravi, Tracleer tablets for suspension, patient has had a therapeutic failure to generic bosentan or ambrisentan. Reauthorization requires documentation of response to therapy including lack of disease progression or improvement in WHO functional class.</p>

Last Updated: 03/19/2024



PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# PYRUKYND

## Products Affected

- Pyrukynd

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial authorization, all the following criteria must be met: 1. Diagnosis of pyruvate kinase deficiency (PKD) (ICD-10 d55.21). Must include evidence supporting diagnosis, such as: a. Documentation of markers of chronic hemolytic anemia (such as low hemoglobin, low haptoglobin, elevated bilirubin, and elevated reticulocytes) and evidence of family history of PKD), OR b. Documentation of pyruvate kinase enzyme activity below the lower limit of normal per the laboratory standard (actual laboratory results must be included), OR c. Documentation of at least two mutant alleles in the PKLR gene AND 2. Hemoglobin less than or equal to 10 mg/dL taken within the previous three months. For reauthorization: Documentation of positive clinical response (such as an increase in hemoglobin level, reduction in transfusion burden from prior to treatment).
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a hematologist
<b>Coverage Duration</b>	Initial authorization for six months, reauthorization for one year.

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# RADICAVA

## Products Affected

- Radicava
- Radicava ORS
- Radicava ORS Starter Kit Susp

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1. For initiation of therapy, all of the following criteria must be met: a. Documentation of definite or probable amyotrophic lateral sclerosis (ALS) within the previous two years per the El Escorial (Airlie House) Criteria b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with at least 2 points in each individual item c. Forced vital capacity (FVC) of at least 80% (taken within the past three months) d. Dosing is in accordance with the FDA approved labeling 2. For patients established on therapy: a. Documentation of a clinical benefit from therapy such as slowing of disease progression or stabilization of functional ability and maintenance of activities of daily living (ADLs) b. Dosing is in accordance with the FDA approved labeling
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist with expertise in ALS.
<b>Coverage Duration</b>	Initial authorization will be approved for six months. Reauthorization will be approved for one year
<b>Other Criteria</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# REGRANEX

## Products Affected

- Regranex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial authorization, all the following must be met: 1. Documentation of lower extremity diabetic neuropathic ulcer, AND 2. Documentation that treatment will be given in combination with standard ulcer care (such as debridement, adequate nutritional status, infection control). There is no medical evidence to justify ongoing treatment after 180 days.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be approved for 6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 03/19/2024

# RELISTOR

## Products Affected

- Relistor oral
- Relistor subcutaneous solution
- Relistor subcutaneous syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial authorization all of the following criteria must be met: 1. Patient is on chronic opioid therapy, AND 2. Documentation of less than three (3) spontaneous bowel movements per week, AND 3. Documentation of trial and failure (at least two weeks of therapy), intolerance, or contraindication to routine laxative therapy with lactulose, AND 4. One of the following: A. Opioid-induced constipation in adult patients with advanced illness, OR B. For opioid-induced constipation in patients with chronic noncancer pain, documentation of trial and failure (at least two weeks of therapy), intolerance, or contraindication to one of the following: a. naloxegol (Movantik), b. lubiprostone (Amitiza), or c. naldemedine (Symproic). Reauthorization requires documentation of response to therapy (e.g., less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for 1 year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024



# RELYVRIO

## Products Affected

- Relyvrio

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1. For initiation of therapy, all the following criteria must be met: a. Documentation of diagnosis of amyotrophic lateral sclerosis (ALS), b. Documentation of baseline ALS Functional Rating Scale-Revised (ALSFRS-R), c. Slow vital capacity (SVC) greater than 60% of predicted (taken within the past three months), d. Documentation that patient is not dependent on invasive ventilation or tracheostomy. 2. For patients established on therapy, documentation of a clinical benefit from therapy, such as stabilization of disease or slowing of disease progression from pre-treatment baseline ALSFRS-R scores.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist with expertise in ALS
<b>Coverage Duration</b>	Initial authorization will be approved for six months, reauthorization will be approved for one year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# RESCUE MEDICATION FOR EPILEPSY

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## Products Affected

- Nayzilam
- Valtoco

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist
Coverage Duration	Authorization will be approved until no longer eligible with the plan
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 03/19/2024

# RESPIRATORY AGENTS-FASENRA

## Products Affected

- Fasenra Pen

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
<b>Required Medical Information</b>	For initial authorization for asthma, all the following criteria must be met: 1. Diagnosis of severe eosinophilic asthma, 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/contraindication to standard asthma control therapy. Asthma control therapy may include inhaled corticosteroids (ICS), ICS with long-acting beta agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), and/or theophylline. 3. Documentation of severe asthma with inadequate control such as frequent exacerbations requiring oral corticosteroids or hospitalizations or a poor asthma control scores (An ACT score less than 20 or an ACQ greater than or equal to 1.5). Reauthorization for asthma: 1. Documentation of positive clinical response to therapy, such as attainment and maintenance of remission or decrease in number of relapses, 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/contraindication to standard asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline).

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an asthma specialist (such as a pulmonologist, immunologist, or allergist)
<b>Coverage Duration</b>	Initial authorization for one year. Reauthorization until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# RESPIRATORY AGENTS-NUCALA

## Products Affected

- Nucala

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
<b>Required Medical Information</b>	For initial authorization for asthma, all the following criteria must be met: 1. Diagnosis of severe eosinophilic asthma, 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/contraindication to standard asthma control therapy. Asthma control therapy may include inhaled corticosteroids (ICS), ICS with long-acting beta agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), and/or theophylline. 3. Documentation of severe asthma with inadequate control such as frequent exacerbations requiring oral corticosteroids or hospitalizations or a poor asthma control scores (An ACT score less than 20 or an ACQ greater than or equal to 1.5). Reauthorization for asthma: 1. Documentation of positive clinical response to therapy, such as attainment and maintenance of remission or decrease in number of relapses, 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/contraindication to standard asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline).

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: 1. Asthma: asthma specialist (such as a pulmonologist, immunologist, or allergist), 2. EGPA: pulmonologist, neurologist, or rheumatologist, 3. HES: hematologist, immunologist, pulmonologist, cardiologist, or neurologist, 4. CRSwNP: otolaryngologist, allergist, or pulmonologist.</p>
<b>Coverage Duration</b>	<p>EGPA/HES/CRSwNP: Initial 6 mo/reauth 1 yr. Asthma: Initial 1 yr/reauth until no longer elig with plan</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<p><b>Other Criteria</b></p>	<p>For initial authorization for hypereosinophilic syndrome (HES): 1. Diagnosis of HES (blood eosinophil count of 1,000 cells/microliter or higher for at least six months), without an identifiable non-hematologic secondary cause (such as parasitic infections, solid tumors, or T cell lymphoma), 2. The patient is currently being treated with maximally tolerated oral corticosteroid, unless intolerance/contraindication to oral corticosteroids. Reauthorization for HES: 1. Documentation of positive clinical response to therapy and 2. The patient is currently being treated with maximally tolerated oral corticosteroid, unless intolerance/contraindication to oral corticosteroids. For initial authorization for eosinophilic granulomatosis with polyangiitis (EGPA): 1. Diagnosis of EGPA defined as blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells/microliter, 2. The patient is currently being treated with maximally tolerated oral corticosteroid, unless intolerance/contraindication to oral corticosteroids. Reauthorization for EGPA: 1. Documentation of positive clinical response to therapy and 2. The patient is currently being treated with maximally tolerated oral corticosteroid, unless intolerance/contraindication to oral corticosteroids. For initial authorization for Chronic Rhinosinusitis with Nasal Polyp (CRSwNP): 1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan and 2. Inadequate response to a three-month trial of intranasal corticosteroids (e.g., fluticasone) or has an intolerance,</p>
	<p>FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid. Reauthorization for CRSwNP requires documentation of positive clinical response to therapy.</p>

Last Updated: 03/19/2024



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# RESPIRATORY AGENTS-XOLAIR

## Products Affected

- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
<b>Required Medical Information</b>	<p>For asthma, must meet all the following criteria: 1. Diagnosis of moderate or severe persistent asthma, 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/ contraindication to standard asthma control therapy. Asthma control therapy may include inhaled corticosteroids (ICS), ICS with long-acting beta agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), and/or theophylline, 5.</p> <p>Documentation of severe asthma with inadequate control such as frequent exacerbations requiring oral corticosteroids or hospitalizations or a poor asthma control scores (An ACT score less than 20 or an ACQ greater than or equal to 1.5). Reauthorization for asthma requires: 1. Documentation of response to therapy, such as attainment and maintenance of remission or decrease in number of relapses and 2. The patient is currently being treated with, and will continue asthma control therapy in combination with the requested agent, or has an intolerance/ contraindication to standard asthma control therapy (e.g., ICS, ICS/LABA, LRTA, LAMA, theophylline).</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis. 1. Asthma: asthma specialist (such as a pulmonologist, immunologist, or allergist), 2. Urticaria: dermatologist, allergist, or immunologist, 3. nasal polyps: otolaryngologist, allergist, or pulmonologist.
<b>Coverage Duration</b>	Urticaria/nasal polyp: Init 6mo/reauth 1yr. Asthma: Init 1yr/reauth until no longer elig with plan
<b>Other Criteria</b>	For initial authorization for chronic idiopathic urticaria, must meet all of the following criteria: 1. Documentation that the condition is idiopathic and that secondary causes of urticaria (e.g. offending allergens, physical contact, etc.) have been ruled out, 2. Inadequate response, intolerance, or contraindication to H1 antihistamine. Reauthorization for urticaria will require documentation of response to therapy (e.g. reduction in flares or oral steroid dose). Reauthorization for urticaria requires documentation of positive clinical response to therapy. For initial authorization for nasal polyps, all of the following: 1. Evidence of nasal polyposis by direct examination, endoscopy or sinus CT scan, 2. Inadequate response to a three-month trial of intranasal corticosteroids (e.g., fluticasone) or has an intolerance, FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid. Reauthorization for nasal polyps: Documentation of positive clinical response to therapy
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# SANDOSTATIN LAR

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## Products Affected

- Sandostatin LAR Depot  
intramuscular  
suspension,extended rel recon

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For initiation of therapy (new starts), must meet one of the following indication-specific criteria below: 1. For acromegaly, all the following must be met: a. Confirmed diagnosis of acromegaly b. Documentation that the patient has persistent disease (such as biochemical or clinical) following surgical resection or is not a candidate for surgical resection, 2. For carcinoid tumors or carcinoid syndromes: documentation of severe diarrhea or flushing, 3. For vasoactive intestinal peptide tumors: documentation of severe diarrhea, 4. For chemotherapy induced diarrhea, all the following must be met: a. Documentation that patient has severe diarrhea caused by chemotherapy, b. Documentation of an inadequate response or contraindication to loperamide, c. Documentation of good response and tolerability to short-acting octreotide, 5. For AIDS-related diarrhea, all the following must be met: a. Documentation that patient has severe diarrhea, b. Documentation of an inadequate response or contraindication to loperamide and diphenoxylate/atropine (Lomotil®) c. Documentation of good response and tolerability to short-acting octreotide, 6. For oncologic diagnoses, use must be for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# SAPROPTERIN

## Products Affected

- Javygtor
- sapropterin

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Doses greater than 20mg/kg/day will not be approved. Use in combination with pegvalise-pqpz (Palynziq).
<b>Required Medical Information</b>	Initial authorization: 1. Diagnosis of phenylketonuria (PKU) AND 2. Documentation that the patients pre-treatment phenylalanine blood levels measured within 90 days prior to starting therapy is above 6 mg/dL (360 micromol/L) in children less than 12 years of age, or above 10 mg/dL (600 micromol/L) for ages 12 and older. Reauthorization requires improvement in average blood Phe level from pretreatment baseline.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a specialist in metabolic disorders
<b>Coverage Duration</b>	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

Last Updated: 03/19/2024



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

Last Updated: 03/19/2024

# SOMAVERT

## Products Affected

- Somavert

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial authorization all of the following criteria must be met: 1. Diagnosis of acromegaly, 2. Documentation that the patient has persistent disease (e.g., biochemical or clinical) following surgical resection or patient is ineligible for surgery, AND 3. Documentation of trial and failure, intolerance or contraindication to octreotide injection therapy. Reauthorization requires documentation of a positive response to therapy, such as a decrease or normalization of insulin like growth factor (IGF)-1.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# SPRAVATO

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## Products Affected

- Spravato nasal spray, non-aerosol  
56 mg (28 mg x 2), 84 mg (28 mg x 3)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with another dissociative agent, specifically phencyclidine (PCP), ketamine, or dextromethorphan• Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation• History of intracerebral hemorrhage• Current or prior DSM-5 diagnosis of a psychotic disorder or MDD with psychosis, bipolar or related disorders, comorbid obsessive-compulsive disorder, intellectual disability, autism spectrum disorder, borderline personality disorder, antisocial personality disorder, histrionic personality disorder, or narcissistic personality disorder• Current or recent history (i.e. within the last six months) of moderate or severe substance or alcohol use disorder

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>For initiation of therapy, all the following criteria (1-4) must be met:</p> <ol style="list-style-type: none"> <li>1. Confirmed diagnosis of one of the following:               <ol style="list-style-type: none"> <li>a. For treatment-resistant depression (TRD), clinical documentation must be provided that outlines the patient evaluation. TRD is defined as use of the following regimens (i and ii) for the current depressive episode:                   <ol style="list-style-type: none"> <li>i. Inadequate response to at least three oral antidepressants in two different therapeutic classes for at least eight weeks of treatment at a therapeutic dose for major depressive disorder (MDD).</li> <li>ii. Inadequate response to augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly).</li> </ol> </li> <li>b. For MDD with acute suicidal ideation or behavior, documentation must be provided that patient has current suicidal ideation with intent defined as both of the following:                   <ol style="list-style-type: none"> <li>i. Patient has thoughts, even momentarily, of self-harm with at least some intent or awareness that they may die as a result, or member thinks about suicide,</li> <li>and ii. Patient intends to act on thoughts of killing themselves.</li> </ol> </li> </ol> </li> <li>2. Baseline score from one of the following standardized depression rating scales confirming severe depression:               <ol style="list-style-type: none"> <li>a. Patient Health Questionnaire-9 (PHQ-9) score of at least 20</li> <li>b. Hamilton Depression Scale (HAM-D17) score of at least 24</li> <li>c. Quick Inventory of Depressive Symptomatology, Clinician-Rated (QIDS-C16) score of at least 16</li> <li>d. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28</li> </ol> </li> </ol>
	<p>Documentation that esketamine (Spravato®) will be used in combination with oral antidepressant therapy</p> <p>4. Dosing is in accordance with the United States Food and Drug Administration approved labeling</p>

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	Approved for 18 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a psychiatrist or a psychiatric nurse practitioner.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# SYNAREL

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## Products Affected

- Synarel

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial authorization will be approved with documentation of confirmed diagnosis of endometriosis or central precocious puberty. Reauthorization is not allowed in endometriosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Endometriosis: 6 months. CPP: initial/re-auth approved for one year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 03/19/2024

# TADALAFIL

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## Products Affected

- tadalafil oral tablet 2.5 mg, 5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use for sexual dysfunction without comorbid diagnosis of benign prostatic hypertrophy (BPH)
<b>Required Medical Information</b>	Documentation of confirmed diagnosis of benign prostatic hyperplasia (BPH).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024



# TAFAMIDIS

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## Products Affected

- Vyndamax
- Vyndaqel

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>Initial authorization, all the following must be met: 1. Confirmation of amyloid deposits showing cardiac involvement by ONE of the following: a. A positive radionuclide imaging scan, defined as showing Grade 2 or 3 cardiac uptake using one of the following radiotracers: i. 99m technetium-Pyrophosphate (99mTc-PYP), ii. 99m technetium (Tc)-labeled 3,3-diphosphono-1,2-propanodicarboxylic acid (99mTc-DPD), iii. 99m Tc-labeled hydroxymethylene diphosphonate (HMDP), b. A positive cardiac biopsy for ATTR amyloid, OR c. A positive non-cardiac biopsy for ATTR amyloid and evidence of cardiac involvement by end-diastolic interventricular septal wall thickness greater than 12 mm (by echocardiogram or MRI) or suggestive cardiac MRI findings, AND 2. Documentation of patient's NYHA functional class (functional class IV is excluded from coverage), AND 3. Documentation of clinical signs or symptoms of cardiomyopathy and/or heart failure such as dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema, elevated BNP or NT-BNP levels. Reauthorization requires documentation of a positive clinical response. Appropriate documentation may include evidence of slowing of clinical decline, reduced number of cardiovascular hospitalizations, or improvement or stabilization of the 6-minute walk test.</p>
<b>Age Restrictions</b>	Approved for patients 18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist or a physician who specializes in the treatment of amyloidosis
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# THERAPEUTIC IMMUNOMODULATORS

## Products Affected

- Cosentyx (2 Syringes)
- Cosentyx Pen
- Cosentyx Pen (2 Pens)
- Cosentyx subcutaneous
- Cosentyx UnoReady Pen
- Enbrel Mini
- Enbrel subcutaneous solution
- Enbrel subcutaneous syringe
- Enbrel SureClick
- Hadlima
- Hadlima PushTouch
- Hadlima(CF)
- Hadlima(CF) PushTouch
- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 40 mg/0.8 mL
- Humira(CF)
- Humira(CF) Pedi Crohns Starter
- Humira(CF) Pen
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Pediatric UC
- Humira(CF) Pen Psor-Uv-Adol HS
- Otezla
- Otezla Starter oral tablets, dose pack 10 mg (4)-20 mg (4)-30 mg (47)
- Rinvoq
- Skyrizi subcutaneous pen injector
- Skyrizi subcutaneous syringe 150 mg/mL
- Skyrizi subcutaneous wearable injector
- Stelara subcutaneous
- Tremfya
- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient is currently being treated with another therapeutic immunomodulator or apremilast

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For patients already established on the requested therapy: 1. Documentation of response to therapy (i.e. slowing of disease progression or decrease in symptom severity and/or frequency), AND 2. One of the following: a. Patient is not currently being treated with another therapeutic immunomodulator, OR b. Patient is currently being treated with another therapeutic immunomodulator AND will discontinue the other therapeutic immunomodulator. For patients being initiated on therapy, all of the following criteria must be met: 1. Patient must have an FDA labeled indication for the requested agent, AND 2. For Rinvoq/Xeljanz/Xeljanz XR: Documentation of trial and failure, intolerance, or contraindication to a preferred TNF agent (see notes below), AND 3. Documentation of trial and failure, intolerance, or contraindication to conventional therapy prerequisite(s) for the requested indication (see notes below), AND 4. One of the following: a. Patient is not currently being treated with another therapeutic immunomodulator, OR b. Patient is currently being treated with another therapeutic immunomodulator AND will discontinue the other therapeutic immunomodulator prior to starting the requested agent.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial auth approved for 1 year. Reauth will be approved until no longer eligible with the plan

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Notes: Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, and juvenile idiopathic arthritis. Use of TWO conventional prerequisite agents is required for atopic dermatitis, specifically ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor. NO conventional prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, ulcerative colitis, Crohn's disease, enthesitis related arthritis, non-radiographic axial spondyloarthritis, or uveitis. For Rinvoq: Use of ONE preferred TNF (etanercept or adalimumab) is required for diagnoses of ankylosing spondylitis, rheumatoid arthritis, or psoriatic arthritis. Only preferred TNF adalimumab is required for diagnosis of ulcerative colitis or Crohn's disease. For Xeljanz/Xeljanz XR: Use of ONE preferred TNF (etanercept or adalimumab) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, or ankylosing spondylitis. Only preferred TNF adalimumab is required for diagnosis of ulcerative colitis.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# TOLVAPTAN

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## Products Affected

- Jynarque
- tolvaptan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hepatic impairment, anuria, hypovolemia, for Tolvaptan (Jynarque): Patients with eGFR of less than 25 mL/min.

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>For autosomal dominant polycystic kidney disease (ADPKD), tolvaptan (Jynarque) can be covered when all of the following criteria are met: 1. Diagnosis of ADPKD confirmed by ultrasound, MRI or CT scan. Note: genetic testing may also be used to help confirm the diagnosis , AND 2. The patient must have a confirmed diagnosis of rapidly progressing ADPKD by at least one of the following criteria: a. eGFR decline of at least 5 mL/min/1.73 meter squared per year over 1 year, b. eGFR decline of at least 2.5 mL/min/1.73 meter squared per year over a period of 5 years, c. Total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart, d. Height-adjusted total kidney volume (htTKV) compatible with Mayo class 1D or 1E disease, e. htTKV compatible with Mayo class 1C disease AND additional evidence of rapid disease progression such as a predicting renal outcomes in ADPKD (PROPCKD) score greater than six, early hypertension or urological manifestations, truncating PKD1 mutation or family history of early onset dialysis related to ADPKD , AND 3. Patient does not have significant renal disease other than ADPKD (e.g., renal cancer, acute kidney injury). Reauthorization requires documentation of a positive response to therapy (such as a slowing in patients decline in kidney function). For hypervolemic and euvolemic hyponatremia, tolvaptan (Samsca) can be covered when all of the following criteria are met: 1. One of the following: a. Serum sodium of less than 125 mEq/L, b.</p>

Last Updated: 03/19/2024



PA Criteria	Criteria Details
	Less marked hyponatremia (less than 135 mEq/L), but symptomatic, AND 2. Evidence that initiation and re-initiation of therapy in a hospital setting where serum sodium can be monitored closely, AND 3. Patient does not have an urgent need to raise serum sodium acutely (such as acute/transient hyponatremia associated with head trauma)
<b>Age Restrictions</b>	Approved for patients 18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a nephrologist, cardiologist or endocrinologist.
<b>Coverage Duration</b>	Tolvaptan (Samsca): approved for 30 days. Tolvaptan (Jynarque): initial/reauth approved for 1 year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# TOPICAL RETINOID PRODUCTS

## Products Affected

- adapalene topical cream
- Altreno
- tazarotene topical cream
- tazarotene topical gel
- Tazorac topical cream 0.05 %
- tretinoin
- tretinoin microspheres topical gel
- tretinoin microspheres topical gel with pump 0.04 %, 0.1 %

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cosmetic use
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# TRIENTINE

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## Products Affected

- trientine oral capsule 250 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Cystinuria or rheumatoid arthritis
<b>Required Medical Information</b>	Confirmed diagnosis of Wilson's Disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a gastroenterologist, medical geneticist, or hepatologist.
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# VERKAZIA

## Products Affected

- Verkazia

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Initial authorization requires documentation of all the following: 1. Clinical diagnosis of vernal keratoconjunctivitis (H16.26) and 2. Documentation of inadequate response to a trial (defined as at least three weeks of consistent use) of two (2) of the following topical mast cell stabilizer eye drops: azelastine, epinastine, cromolyn, or Iodoxamide (Alomide®). Reauthorization requires documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial auth will be approved for six months. Reauth will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# VERQUVO

## Products Affected

- Verquvo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic heart failure, all of the following criteria must be met:1. Documentation of symptomatic heart failure (NYHA Class II-IV) with a left ventricular ejection fraction (LVEF) less than 45% 2. On maximally tolerated guideline-directed therapy including both of the following, unless contraindicated or not tolerated: a. Beta-blocker (specifically carvedilol, metoprolol succinate, or bisoprolol)b. One of the following:i. Angiotensin-converting enzyme (ACE) inhibitor (such as lisinopril, enalapril)ii. Angiotensin II receptor blocker (ARB) (such as losartan, valsartan)iii. Angiotensin receptor-neprilysin inhibitor (ARNI) (sacubitril/valsartan), unless not tolerated or contraindicated, 3. Documentation of clinical worsening of heart failure, defined as one of the following, despite maximal therapy as outlined above: a. Hospitalization for heart failure within the previous six months b. Need for outpatient intravenous diuretic therapy within the previous three months
<b>Age Restrictions</b>	Approved for adults 18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# VIBERZI

## Products Affected

- Viberzi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients without a gallbladder.
<b>Required Medical Information</b>	For initial authorization, all the following must be met: 1. Diagnosis of Irritable Bowel Syndrome with Diarrhea (IBS-D), AND 2. Documentation of trial and failure, contraindication, or intolerance to loperamide.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a gastroenterologist.
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024



# VIJOICE

## Products Affected

- Vijoje

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Initial authorization requires criteria 1-3 to be met: 1. Confirmed diagnosis of PIK3CA-related overgrowth spectrum (PROS) as defined by meeting criteria A-D: A. Presence of somatic PIK3CA mutation B. Congenital or early childhood onset C. Overgrowth sporadic or mosaic (other terms: patchy, irregular) D. Clinical features as described in either a or b: a. Spectrum (require two or more of the following): i. Overgrowth (adipose, muscle, nerve, skeletal) ii. Vascular malformations (capillary, venous, arteriovenous malformations, lymphatic) iii. Epidermal nevus b. Isolated features (one of the following): i. Large isolated lymphatic malformation ii. Isolated macrodactyly OR overgrown splayed feet/hands, overgrown limbs iii. Truncal adipose overgrowth iv. Hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia v. Epidermal nevus vi. Seborrheic keratoses vii. Benign lichenoid keratoses large, AND 2. Patient has at least one target lesion identified on imaging, AND 3. Patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician. Reauthorization requires documentation of positive response to therapy such as reduction in the sum of measurable target lesion volume.</p>

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	Approved for patients 2 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a specialist in treating PROS.
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for six months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# VMAT-2 INHIBITORS

## Products Affected

- Austedo
- Austedo XR
- Austedo XR Titration Kt(Wk1-4)
- Ingrezza
- Ingrezza Initiation Pack
- tetrabenazine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For chorea associated with Huntington disease, the following criteria must be met: 1. Diagnosis of Huntington disease as defined by all of the following: a. DNA testing showing CAG expansion of 36 or higher, b. Family history (if known), and c. Classic presentation (choreiform movements, psychiatric problems, and dementia), and 2. For coverage of deutetrabenazine (Austedo), documented trial (of at least 8 weeks) and failure or intolerance of tetrabenazine. For tardive dyskinesia, all of the following criteria must be met: 1. Diagnosis of tardive dyskinesia secondary to therapy with a dopamine receptor blocking agent (e.g. first or second generation antipsychotics, metoclopramide), 2. Documentation of moderate to severe tardive dyskinesia that is causing functional impairment, 3. For coverage of deutetrabenazine (Austedo®) and valbenazine (Ingrezza®): Documented trial (of at least 8 weeks) and failure or intolerance of tetrabenazine. Reauthorization requires documentation of positive clinical response to therapy, such as improved function.</p>
<b>Age Restrictions</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist or psychiatrist
<b>Coverage Duration</b>	Initial authorization will be approved for 3 months. Reauthorization will be approved for 1 year.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# WAKEFULNESS PROMOTING AGENT-SUNOSI

## Products Affected

- Sunosi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Idiopathic central nervous system hypersomnia
<b>Required Medical Information</b>	For Type 2 narcolepsy (excessive daytime sleepiness in narcolepsy without cataplexy), all the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one third of the normative values with the same standardized assay), 2. Documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, 3. Other causes of sleepiness have been ruled out or treated (such as shift work, effects of substances or medications or their withdrawal, other sleep disorders), 4. For adult patients: documentation of a 30-day trial and failure, intolerance, or contraindication to modafinil or armodafinil. For excessive sleepiness due to Obstructive Sleep Apnea (OSA), all the following criteria must be met: 1. Diagnosis of OSA as confirmed by sleep study and 2. Documented trial and failure, intolerance or contraindication of armodafinil or modafinil. Reauthorization for all indications requires documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness.
<b>Age Restrictions</b>	

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a sleep specialist, neurologist, pulmonologist, or psychiatrist
<b>Coverage Duration</b>	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# WAKEFULNESS PROMOTING AGENT-WAKIX

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## Products Affected

- Wakix

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For Type 1 narcolepsy (narcolepsy with cataplexy), all the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay), 2. Documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, 3. Documentation of at least three (3) weekly cataplexy attacks. For Type 2 narcolepsy (excessive daytime sleepiness in narcolepsy without cataplexy), all the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one third of the normative values with the same standardized assay), 2. Documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, 3. Other causes of sleepiness have been ruled out or treated (such as obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders), 4. For adult patients: documentation of a 30-day trial and failure, intolerance, or contraindication to modafinil or armodafinil. Reauthorization for all indications requires documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks, if applicable.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a sleep specialist, neurologist, pulmonologist, or psychiatrist

Last Updated: 03/19/2024



PA Criteria	Criteria Details
<b>Coverage Duration</b>	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# WAKEFULNESS PROMOTING AGENT- XYWAV/SODIUM OXYBATE

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## Products Affected

- sodium oxybate
- Xywav

PA Criteria	Criteria Details
Exclusion Criteria	

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Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For Type 1 narcolepsy (narcolepsy with cataplexy), all the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay), 2. Documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, 3. Documentation of at least three (3) weekly cataplexy attacks, 4. For adult patients: documentation of a 30-day trial and failure, intolerance, or contraindication to pitolisant (Wakix). For Type 2 narcolepsy (excessive daytime sleepiness in narcolepsy without cataplexy), all the following criteria must be met: 1. Diagnosis of narcolepsy as confirmed by sleep study or low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one third of the normative values with the same standardized assay), 2. Documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, 3. Other causes of sleepiness have been ruled out or treated (such as obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders), 4. For adult patients: documentation of a 30-day trial and failure, intolerance, or contraindication to modafinil or armodafinil.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	<p>Must be prescribed by, or in consultation with, a sleep specialist, neurologist, pulmonologist, or psychiatrist</p>
<b>Coverage Duration</b>	<p>Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.</p>

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<b>Other Criteria</b>	For idiopathic hypersomnia, Xywav will be approved when all the following criteria are met: 1. Diagnosis of idiopathic hypersomnia confirmed by sleep study, 2. Documentation that sleepiness is not due to another medical, behavioral, or psychiatric disorder condition, including but not limited to: insufficient sleep (less than seven hours per night), depression, sedating medications, and sleep-related breathing disorders, 3. Documentation of daily periods of irrepressible need to sleep/daytime lapses into sleep occurring for at least three (3) months, AND 4. Documentation of a 30-day trial and failure, intolerance or contraindication to modafinil. Reauthorization for all indications requires documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks, if applicable.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# XERMELO

## Products Affected

- Xermelo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial authorization, all the following criteria must be met: 1. Diagnosis of carcinoid syndrome diarrhea, 2. Inadequately controlled diarrhea despite use, for at least three months, of a long-acting somatostatin analog therapy such as octreotide LAR (Sandostatin LAR®) or lanreotide (Somatuline®) 3. Documentation that long-acting somatostatin analog therapy will be used in combination with the requested medication. Reauthorization will require documentation of positive clinical response to therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an oncologist or gastroenterologist.
<b>Coverage Duration</b>	Initial authorization and reauthorization will be approved for one year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.

Last Updated: 03/19/2024

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

Last Updated: 03/19/2024

# XIAFLEX

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## Products Affected

- Xiaflex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	• PD involving the urethra. • More than three total injections per affected cord for DC. • More than eight total injections per lifetime for PD.

Last Updated: 03/19/2024

PA Criteria	Criteria Details
<p><b>Required Medical Information</b></p>	<p>For Dupuytren's contracture (DC):1. Both of the following diagnostic criteria:a. Finger flexion contracture of at least 20° with a palpable cord in a metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) jointb. Documentation of a positive "table top test," defined as the inability to simultaneously place the affected finger(s) and palm flat against a table top2. Documentation that affected joint has not had surgical intervention within the previous 90 days</p> <p>For Peyronie's disease (PD):1. Patient's disease is stable, defined as unchanged degree of curvature for at least three months2. Patient has a curvature of the penis that is between 30 and 90 degrees with a palpable cord, or a cord that is documented through ultrasound3. Patient has intact erectile function, with or without the use of medications4. Documentation of a functional impairment that is expected to improve with treatment (e.g., inability to have intercourse despite intact erectile function, due to curvature)5. Documentation showing the patient does not have any of the following:a. Significant pain with palpation of the plaqueb. Lack of full erectile response to prostaglandin E1 during curvature measurementc. Ventral curved. Calcified plaquee. Plaque located proximal to the base of the penis6. Documentation that the patient has been counseled on expectations of treatment (e.g., expected average curvature reduction is 17 degrees without reduction in pain or erectile dysfunction, potential for adverse effects)</p> <p>Reauthorization Criteria:For DC:1. Documentation of fewer than three total injections in affected cord.For</p>
	<p>PD1. Documentation that the curvature of the penis remains greater than 15 degrees. Limited to eight total injections per lifetime.</p>

Last Updated: 03/19/2024



PA Criteria	Criteria Details
<b>Age Restrictions</b>	Approved for 18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	DC: Init/reauth 3 mo (limit 3 inj, NTE 6 inj/cord), PD: Init/reauth 3/6 mo (limit 4 inj, NTE 8 inj)
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# XIFAXAN

## Products Affected

- Xifaxan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	More than 3 treatment courses in a rolling 6-month period for IBS-D
<b>Required Medical Information</b>	For traveler's diarrhea (200 mg tablets): Diagnosis of traveler's diarrhea caused by noninvasive strains of Escherichia coli. Rifaximin is not covered if documentation shows diarrhea that is complicated by fever or blood in stool. For hepatic encephalopathy (HE) (550 mg tablets): Documentation of trial and failure, contraindication or intolerance to lactulose. For irritable bowel syndrome with diarrhea (IBS-D) (550 mg tablets) with or without small intestinal bacterial growth (SIBO): Documentation of trial and failure, contraindication, or intolerance to a tricyclic antidepressant (e.g. amitriptyline). Reauthorization in IBS-D requires documentation of initial response to treatment with rifaximin and recurrence of IBS-D symptoms. Limited to three (3) total 14-day course treatments (initial treatment and two reauthorizations).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	For irritable bowel syndrome with diarrhea (IBS-D): Must be prescribed by, or in consultation with, a gastroenterologist.

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	Traveler's diarrhea: 3 days, IBS-D: 14 days, HE: until no longer eligible with the plan
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# ZTALMY

## Products Affected

- Ztalmy

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initiation of therapy, all the following criteria must be met:1. Diagnosis of CDKL5 deficiency disorder (CDD) as confirmed with genetic testing2. Documented trial and failure with two or more antiepileptic drugs3. Documentation that it will be used as adjunctive therapy with other antiepileptic drugs
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an epilepsy specialist or neurologist
<b>Coverage Duration</b>	Authorization will be approved until no longer eligible with the plan.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024

# ZURZUVAE

## Products Affected

- Zurzuvae

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	<ul style="list-style-type: none"> <li>• Past medical history of bipolar disorder, schizophrenia, or schizoaffective disorder</li> <li>• Current pregnancy</li> </ul>
<b>Required Medical Information</b>	<p>Initial Authorization:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of moderate to severe major depressive disorder with documentation or provider attestation that depressive symptoms began between the third trimester of pregnancy to the first four weeks following delivery</li> <li>2. Patient is within the first twelve months postpartum</li> <li>3. Submission of validated screening tool results (for example, HAM-D, PHQ-9, MADRS) confirming diagnosis</li> <li>4. Member has not received prior treatment with Zurzuvae® for the current pregnancy</li> <li>5. Patient has tried and failed a formulary generic selective serotonin reuptake inhibitor (SSRI) or serotonin and norepinephrine reuptake inhibitor (SNRI) for the current episode of postpartum depression (after 4-6 weeks at an adequate dose), or has an intolerance/contraindication to all SSRIs/SNRIs. This may be waived in cases of severe postpartum depression.</li> </ol>
<b>Age Restrictions</b>	Ages 18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One month (one 14-day fill) per pregnancy

Last Updated: 03/19/2024

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

Last Updated: 03/19/2024