Providence
Medicare Advantage Plans

# PROVIDENCE MEDICARE ADVANTAGE PLANS

# 2025 PART D PRIOR AUTHORIZATION CRITERIA

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.

H9047_2025RX_PHA1045_C

# ANTI-CANCER AGENTS

## Products Affected

- abiraterone oral tablet 250 mg
- Actimmune
- Akeega
- Alecensa
- Alunbrig
- Augtyro
- Ayvakit
- Balversa
- Besremi
- bexarotene
- Bosulif
- Braftovi
- Brukinsa
- Cabometyx
- Calquence (acalabrutinib mal)
- Caprelsa
- Cometriq
- Copiktra
- Cotellic
- dasatinib
- 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 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

Last Updated: 10/01/2024

- Ninlaro
- Nubeqa
- Odomzo
- Ogsiveo
- Ojemda
- Ojjaara
- Onureg
- Orgovyx
- Orserdu
- Panretin
- pazopanib
- Pemazyre
- Piqray
- Pomalyst
- Qinlock
- Retevmo
- Revlimid
- Rezlidhia
- Rozlytrek
- Rubraca
- Rydapt
- Scemblix
- sorafenib
- Sprycel
- Stivarga
- sunitinib malate
- Tabrecta
- Tafinlar
- Tagrisso
- Talzenna
- Tasigna
- Tazverik
- Tepmetko
- Tibsovo
- toremifene
- Torpenz
- Trelstar intramuscular suspension for reconstitution
- tretinoin (antineoplastic)
- Truqap
- Tukysa
- Turalio oral capsule 125 mg
- Vanflyta
- Venclexta
- Venclexta Starting Pack
- Verzenio
- Vitrakvi
- Vizimpro
- Vonjo
- Welireg
- Xalkori
- Xospata
- Xpovio
- Xtandi
- Zejula oral tablet
- Zelboraf
- Zolinza
- Zydelig
- Zykadia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | One of the following for initiation of the requested agent: 1. For Bosulif or Tasigna: 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 Tasigna over imatinib or dasatinib for the requested indication. 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. 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. 4. For asciminib (Scemblix®) for Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine kinase inhibitors (TKIs) OR Ph+ CML-CP with the T315I |
| | mutation: Documented trial, failure, intolerance, or contraindication to ponatinib (Iclusig®), 5. For all other agents: Indication is supported by CMS-approved compendia. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | 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. |
| **Coverage Duration** | Authorization will be approved until no longer eligible with the plan. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# ANTIFUNGAL AGENTS

## Products Affected

- Cresemba oral
- itraconazole oral solution
- posaconazole oral
- voriconazole

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

Last Updated: 10/01/2024

# ANTIPSYCHOTICS

## Products Affected

- asenapine maleate
- Caplyta
- Fanapt
- Lybalvi
- Rexulti oral tablet
- Secuado

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- Vraylar oral capsule

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be approved until no longer eligible with the plan. |
| **Other Criteria** | |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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 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). |
| **Age Restrictions** | For CAPS (which includes FCAS, MWS) and RP: Approved for patients 12 years of age and older |
| **Prescriber Restrictions** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial authorization will be approved for six months. Reauth will be approved for one year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# BENLYSTA

## Products Affected

- Benlysta subcutaneous

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

Last Updated: 10/01/2024

# BUDESONIDE ER

## Products Affected

- budesonide oral tablet,delayed and ext.release

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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. |
| **Age Restrictions** | Approved for patients 18 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for 8 weeks. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | MICROSCOPIC COLITIS |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# CABLIVI

## Products Affected

- Cablivi injection kit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | For initial authorization, all the following criteria must be met: 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) For reauthorization for a new treatment cycle, all the following criteria must be met: 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, and 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). For reauthorization for treatment extension, all the following criteria must be met: 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 (less than 10% or 10 |
| | IU/dL), and 3. Documentation that length of therapy post plasma exchange will not exceed 58 days. |
| **Age Restrictions** | Approved for patients 18 years of age and older |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an oncologist or hematologist |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for 90 days. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# CFTR MODULATORS

## Products Affected

- Kalydeco
- Orkambi
- Symdeko
- Trikafta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis of cystic fibrosis with documentation of mutations consistent with FDA approved uses for the requested medication. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with a pulmonologist or provider at a Cystic Fibrosis Center. |
| **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: 10/01/2024

# CGRP-AIMOVIG

## Products Affected

- Aimovig Autoinjector

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | In combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis |
| **Required Medical Information** | 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 |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# CGRP-EMGALITY

## Products Affected

- Emgality Pen
- Emgality Syringe

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | In combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | Initial approval will be for 1 year. Reauth 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: 10/01/2024

# CGRP-NURTEC ODT

## Products Affected

- Nurtec ODT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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-use CGRP. For reauthorization, all of the following must be met: 1. Clinical benefit with use, such as a reduction in the severity or frequency of headaches, AND 2. One of the following: a. For prevention of migraine headache: The patient will NOT be using the requested agent in combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis, b. For acute treatment of migraine headaches: The patient will |
| | NOT be using the requested agent in combination with another acute-use CGRP. |
| **Age Restrictions** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial approval will be for 1 year. Reauth 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: 10/01/2024

# CGRP-QULIPTA

## Products Affected

- Qulipta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | In combination with another calcitonin gene-related peptide (CGRP) agent for migraine prophylaxis |
| **Required Medical Information** | 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 |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# CGRP-UBRELVY

## Products Affected

- Ubrelvy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | In combination with an acute-use CGRP |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial approval will be for 1 year. Reauth will be approved until no longer eligible with the plan. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# CORLANOR

## Products Affected

- Corlanor oral solution
- ivabradine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a cardiologist or electrophysiologist. |
| **Coverage Duration** | Authorization will be approved until no longer eligible with the plan. |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# DIACOMIT

## Products Affected

- Diacomit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initial authorization, all the following criteria must be met: 1. Documentation of seizures associated with Dravet Syndrome (DS), 2. Documentation that stiripentol will be used in combination with clobazam, 3. Dose will not exceed 50mg/kg (up to maximum 3,000 mg) per day |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, an epilepsy specialist or 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: 10/01/2024

# DISPOSABLE INSULIN PUMPS

## 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** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# DROXIDOPA

## Products Affected

- droxidopa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# DUPIXENT

## Products Affected

- Dupixent Pen mL
- Dupixent Syringe subcutaneous syringe 200 mg/1.14 mL, 300 mg/2

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

Last Updated: 10/01/2024

# EPIDIOLEX

## Products Affected

- Epidiolex

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

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# ERYTHROPOIESIS STIMULATING AGENTS

## Products Affected

- Retacrit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | 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 |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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 45 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | 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 preoperative use in anemic patients scheduled for cardiac surgery: i. Documentation that the patient will be undergoing cardiac surgery, ii. Documentation that anemia is due to chronic disease, AND iii. One of the following criteria: 1) Patient has preoperative anemia, defined as HGB less than 13g/dL for adult males or less than 12 g/dL for adult females, 2) Patient refused blood transfusions, 3). Patient is deemed high-risk for postoperative anemia. f. 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 45 days. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# FENTANYL CITRATE

## Products Affected

- fentanyl citrate buccal lozenge on a handle

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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 (such as morphine sulfate, oxycodone, oxymorphone, hydromorphone), AND 3. Pain is not controlled with ONE long-acting opioid formulary agent (such as morphine sulfate ER, tramadol ER, Xtampza 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an oncologist or pain specialist |
| **Coverage Duration** | Initial authorization will be approved for 6 months. Reauthorization will be approved for one year. |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# FINTEPLA

## Products Affected

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome |
| **Required Medical Information** | 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 |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, an epilepsy specialist or neurologist. |
| **Coverage Duration** | Authorization will be approved until no longer eligible with the plan |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# GAMMA GLOBULIN - IgG

## Products Affected

- Bivigam
- Flebogamma DIF intravenous solution 5 %
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked
- Gammaplex (with sorbitol)
- Gammaplex intravenous solution 10 %
- Gamunex-C
- Octagam
- Panzyga intravenous solution 10 %
- Privigen

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

Last Updated: 10/01/2024

# GLP-1 AGONISTS

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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 |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **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: 10/01/2024

# HEPATITIS C

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Criteria will be applied consistent with current American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 8 to 24 weeks based on medication, indication and established treatment guidelines |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# HEREDITARY ANGIOEDEMA THERAPY

## Products Affected

- icatibant
- Orladeyo
- Sajazir

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

Last Updated: 10/01/2024

# HUMAN GROWTH HORMONES

## Products Affected

- Omnitrope

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

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| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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 |

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| PA Criteria | Criteria Details |
|---|---|
| | 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). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, an endocrinologist. |
| **Coverage Duration** | AIDS wasting: 12 months. All other uses: initial/reauth for 12 months. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | 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 |

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

Last Updated: 10/01/2024

# INCRELEX

## Products Affected

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | 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 |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year. |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# ISTURISA/SIGNIFOR

## Products Affected

- Isturisa oral tablet 1 mg, 5 mg
- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# KERENDIA

## Products Affected

- Kerendia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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). |
| **Age Restrictions** | Approved for patients 18 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be approved until no longer eligible with the plan. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# LIBERVANT

## Products Affected

- Libervant

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **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: 10/01/2024

# LIDOCAINE PATCH

## Products Affected

- DermacinRx Lidocan
- lidocaine topical adhesive patch, medicated 5 %
- Lidocan III
- Lidocan IV
- Lidocan V
- Tridacaine
- Tridacaine II
- Tridacaine III

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

Last Updated: 10/01/2024

# LIVTENCITY

## Products Affected

- Livtencity

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use in combination with ganciclovir or valganciclovir |
| **Required Medical Information** | For initial authorization, all of the following must be met: 1. Documentation of history of hematopoietic stem cell or solid organ transplant, and 2. Documentation of post-transplant cytomegalovirus (CMV) infection/disease with CMV DNA of 2730 IU/mL or greater in whole blood or 910 IU/mL or greater in plasma, and 3. Documentation that patient is refractory (with or without genotypic resistance), or has an intolerance or contraindication to, treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet. Reauthorization requires documentation that continued therapy is medically necessary (such as incomplete resolution of clinical symptoms, incomplete virologic clearance, or relapse in CMV infection). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a transplant surgeon, infectious disease specialist, oncologist, hematologist |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for eight weeks |
| **Other Criteria** | |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# LODOCO

## Products Affected

- Lodoco

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of strong CYP3A4 or P-glycoprotein inhibitors  Renal failure (CrCl less than 15 mL/min)  Severe hepatic impairment  Pre-existing blood dyscrasias |
| **Required Medical Information** | For initial authorization, patient must meet all of the following criteria: 1. Diagnosis of clinical Atherosclerotic Cardiovascular Disease (ASCVD) or previous cardiovascular (CV) event  2. Documentation that patient is receiving maximally tolerated statin therapy or, if statin intolerant, other lipid-lowering therapy unless contraindicated or not tolerated 3. Documentation of blood pressure less than 130/80 or that patient is optimized on standard of care medications for high blood pressure unless contraindicated or not tolerated |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a cardiologist |
| **Coverage Duration** | Authorization will be approved until no longer eligible with the plan |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# LONG-ACTING OPIOIDS

## Products Affected

- buprenorphine
- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr
- methadone oral solution
- methadone oral tablet

Last Updated: 10/01/2024

- Xtampza ER

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | 1. As needed (prn) use, 2. For treatment of acute pain such as recent injury, sprain, strain, surgery, migraines, or headaches, 3. Concurrent use with another long-acting opioid |
| **Required Medical Information** | 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, pertinent physical examination findings and prescriber attestation that a prescription for opioid rescue medication (e.g. naloxone, nalmefene) has been given to the patient. In addition, patient must meet all the criteria under one of the patient-specific conditions listed below: 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. 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. |

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| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | 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 |

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

Last Updated: 10/01/2024

# 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 |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Approved until no longer elig with the plan. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# MIFEPRISTONE

## Products Affected

- mifepristone oral tablet 300 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Current pregnancy |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, an endocrinologist. |
| **Coverage Duration** | Initial authorization will be approved for 6 months. Reauthorization will be approved for one year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# NEXLETOL/NEXLIZET

## Products Affected

- Nexletol
- Nexlizet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For Initial Authorization, all of the following must be met: 1. Diagnosis of clinical atherosclerotic cardiovascular disease, high risk of developing atherosclerotic cardiovascular disease, or primary hyperlipidemia (defined as elevated lipid levels due to hereditary condition, such as familial hypercholesterolemia), 2. Fasting LDL-C greater than or equal to 70 mg/dL despite at least three months of treatment with the following, unless all are contraindicated/not tolerated: a. High-intensity statin therapy (defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily) AND b. Ezetimibe. Reauthorization requires documented response to therapy, defined as a reduction in fasting LDL-C from pre-treatment levels. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial auth approved for one year. Reauth will be approved until no longer eligible with the plan. |
| **Other Criteria** | |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# NUEDEXTA

## Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | 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. |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# NUPLAZID

## Products Affected

- Nuplazid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a neurologist, psychiatrist, or geriatrician. |
| **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: 10/01/2024

# OPZELURA

## Products Affected

- Opzelura

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

Last Updated: 10/01/2024

# ORENCIA

## Products Affected

- Orencia
- Orencia ClickJect

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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: For patients 18 years of age or over, use of TWO preferred agents , (secukinumab, etanercept, adalimumab, apremilast, upadacitinib, risankizumab, ustekinumab, guselkumab) is required for diagnosis of psoriatic arthritis. For patients between 6 and less than 18 years of age, use of TWO preferred agents (secukinumab, upadacitinib) is required for diagnosis of psoriatic arthritis. For patients between 2 and less than 6 years of age, use of ONE preferred agent (upadacitinib) is required for diagnosis of psoriatic arthritis. Use of TWO preferred agents (etanercept, adalimumab, upadacitinib,) is required for diagnosis of |
| | rheumatoid arthritis. Use of TWO preferred agents (etanercept, adalimumab, upadacitinib) is required for diagnosis of juvenile idiopathic arthritis. NO preferred agent is required for diagnosis of prophylaxis of acute graft vs host disease. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# OSTEOANABOLIC AGENTS

## Products Affected

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

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

Last Updated: 10/01/2024

# PCSK-9 INHIBITORS

## Products Affected

- Repatha Pushtronex
- Repatha SureClick
- Repatha Syringe

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with another PCSK9 inhibitor. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | For initial authorization, both criteria 1 and 2 must be met: 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 |
| | 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. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | 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 |
| **Coverage Duration** | Initial authorization for one year. Reauth will be approved until no longer eligible with plan. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# PREVYMIS

## Products Affected

- Prevymis oral

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

Last Updated: 10/01/2024

# PROMACTA

## Products Affected

- Promacta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with an oncologist, hematologist, infectious disease specialist, gastroenterologist, or hepatologist. |
| **Coverage Duration** | Initial authorization will be approved for 6 months. Reauthorization will be approved for 12 months. |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myelodysplastic syndromes. |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# PULMONARY ANTIHYPERTENSIVES

## Products Affected

- Adempas
- Alyq
- ambrisentan
- bosentan
- sildenafil (pulm.hypertension) oral tablet
- tadalafil (pulm. hypertension)
- Winrevair subcutaneous kit 45 mg, 60 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pulmonary hypertension associated with idiopathic interstitial pneumonia for riociguat (Adempas®) only, Idiopathic pulmonary fibrosis for ambrisentan only |
| **Required Medical Information** | For initial authorization the following criteria must be documented: 1. Diagnosis of Pulmonary Hypertension (PH) confirmed by right heart catheterization, as defined by the following: a. Mean pulmonary artery pressure (mPAP) greater than or equal to 20 mmHg at rest, b. Pulmonary vascular resistance (PVR) greater than 3 Wood units (WU), 2. Patient has documentation of World Health Organization (WHO) Group 1 classification PH (defined by a pulmonary capillary wedge pressure [PCWP] or left ventricular end diastolic pressure [LVEDP] less than or equal to 15 mmHg), or WHO Group 4 classification CTEPH (for Adempas only), with WHO/New York Heart Association (NYHA) functional class II, III, or IV, 3. For Tracleer tablets: 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. |
| **Age Restrictions** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a pulmonologist or cardiologist |
| **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: 10/01/2024

# PULMONARY FIBROSIS AGENTS

## Products Affected

- Ofev
- pirfenidone oral capsule
- pirfenidone oral tablet 801 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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. Reauthorization: Documentation of positive clinical |
| | 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). |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | 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 |
| **Coverage Duration** | Initial authorization will be approved for 6 months. Reauthorization will be approved for one year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# QUININE

## Products Affected

- quinine sulfate

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

Last Updated: 10/01/2024

# RESPIRATORY AGENTS-FASENRA

## Products Affected

- Fasenra
- Fasenra Pen

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another therapeutic immunomodulator agent utilized for the same indication |
| **Required Medical Information** | 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: 10/01/2024

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

Last Updated: 10/01/2024

# RESPIRATORY AGENTS-NUCALA

## Products Affected

- Nucala

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another therapeutic immunomodulator agent utilized for the same indication |
| **Required Medical Information** | 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: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | |
| **Prescriber Restrictions** | 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. |
| **Coverage Duration** | EGPA/HES/CRSwNP:Initial 6 mo/reauth 1 yr. Asthma: Initial 1 yr/reauth until no longer elig with plan |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | 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, |
| | FDA labeled contraindication, or hypersensitivity to an intranasal corticosteroid. Reauthorization for CRSwNP requires documentation of positive clinical response to therapy. |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# RESPIRATORY AGENTS-XOLAIR

## Products Affected

- Xolair

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

Last Updated: 10/01/2024

# SOMAVERT

## Products Affected

- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# SPRAVATO

## Products Affected

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

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

Last Updated: 10/01/2024

# TADALAFIL

## Products Affected

- tadalafil oral tablet 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Use for sexual dysfunction without comorbid diagnosis of benign prostatic hypertrophy (BPH) |
| **Required Medical Information** | Documentation of confirmed diagnosis of benign prostatic hyperplasia (BPH). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **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: 10/01/2024

# 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 subcutaneous syringe kit 40 mg/0.8 mL
- Humira(CF)
- 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 (51), 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 subcutaneous auto-injector
- Tremfya subcutaneous syringe 100 mg/mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | 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 the following criteria must be met: 1. Patient must have an FDA labeled indication for the requested agent, AND 2. For Rinvoq (except in atopic dermatitis): 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial auth approved for 1 year. Reauth will be approved until no longer eligible with the plan |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Notes: Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, juvenile 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 severe juvenile psoriatic arthritis, 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, juvenile idiopathic arthritis or adult psoriatic arthritis. Only preferred TNF adalimumab is required for diagnosis of ulcerative colitis or Crohn's disease. NO preferred TNF agents are required for diagnoses of pediatric psoriatic arthritis or non-radiographic axial spondyloarthritis. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# TOPICAL RETINOID PRODUCTS

## Products Affected

- adapalene topical cream
- tazarotene topical cream
- tazarotene topical gel
- Tazorac topical cream 0.05 %
- tretinoin

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

Last Updated: 10/01/2024

# VERQUVO

## Products Affected

- Verquvo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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%, and 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, and 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. |
| **Age Restrictions** | Approved for adults 18 years of age and older |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a cardiologist |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **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: 10/01/2024

# VIJOICE

## Products Affected

- Vijoice

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | For PIK3CA-related overgrowth spectrum (PROS), all the following criteria must be met: 1. Confirmed diagnosis, defined by all the following: a. Presence of somatic PIK3CA mutation, b. Congenital or early childhood onset, c. Overgrowth is sporadic and mosaic (other terms: patchy, irregular), AND d. Clinical features as described by one of the following: i. Spectrum features, defined as overgrowth (adipose, muscle, nerve, skeletal) and vascular malformations (capillary, venous, arteriovenous malformations, lymphatic OR ii. Isolated features, defined as one of the following: large isolated lymphatic malformation, isolated macrodactyly or overgrown splayed feet/hands, overgrown limbs, truncal adipose overgrowth, hemimegalencephaly (bilateral)/dysplastic megalencephaly/focal cortical dysplasia, epidermal nevus (localized lesions of epidermal thickening with hyperpigmentation that are present at birth or develop early during childhood), seborrheic keratoses, benign lichenoid keratoses, 2. Patient has at least one target lesion identified on imaging (this may be waived for patients established on therapy), AND 3. Patient's condition is severe/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. |
| **Age Restrictions** | Approved for patients 2 years of age and older |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, a specialist in treating PROS. |
| **Coverage Duration** | Initial authorization will be approved for six months. Reauthorization will be approved for one year |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# VMAT-2 INHIBITORS

## Products Affected

- tetrabenazine

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

Last Updated: 10/01/2024

# VOWST

## Products Affected

- Vowst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment of CDI |
| **Required Medical Information** | Authorization for the prevention of recurrence of Clostridioides difficile infection (CDI) requires all the following criteria be met: 1. Confirmed diagnosis of recurrent CDI, defined as two or more recurrences after a primary episode (greater than or equal to three total CDI episodes) within 12months, and 2. Positive stool test for C. difficile within 30 days before prior authorization request, and 3. Member has completed, or will have completed, an appropriate antibiotic treatment regimen for recurrent CDI prior to administration (either oral vancomycin or oral fidaxomicin for 10-21 days), and 4. Current episode of CDI must be controlled (less than three unformed/loose stools/day for two consecutive days) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by or in consultation with an infectious disease specialist or gastroenterology specialist |
| **Coverage Duration** | Authorization will be approved for one treatment course (30 days) |
| **Other Criteria** | |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# WAKEFULNESS PROMOTING AGENT - WAKIX

## Products Affected

- Wakix

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

Last Updated: 10/01/2024

# WAKEFULNESS PROMOTING AGENT-SUNOSI

## Products Affected

- Sunosi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Idiopathic central nervous system hypersomnia |
| **Required Medical Information** | For excessive daytime sleepiness in narcolepsy, 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. |
| **Age Restrictions** | |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024

# XDEMVY

## Products Affected

- Xdemvy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initial authorization: Documentation of acquired Demodex blepharitis (defined as presence of Demodex mites). For reauthorization: Documentation of positive response to therapy (such as improvement of collarette, and reduction of mites) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, an optometrist or ophthalmologist |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for three months. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# XERMELO

## Products Affected

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | 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), and 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. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial authorization and reauthorization will be approved for one year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

Last Updated: 10/01/2024

| PA Criteria | Criteria Details |
| --- | --- |
| **Part B Prerequisite** | No |

Last Updated: 10/01/2024

# XIAFLEX

## Products Affected

- Xiaflex

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

Last Updated: 10/01/2024

# XIFAXAN

## Products Affected

- Xifaxan

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

Last Updated: 10/01/2024

# ZTALMY

## Products Affected

- Ztalmy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For initiation of therapy, all the following criteria must be met:1. Diagnosis of CDKL5 deficiency disorder (CDD) as confirmed with genetic testing AND 2. Documented trial and failure of at least two antiepileptic drugs |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Must be prescribed by, or in consultation with, an epilepsy specialist or 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: 10/01/2024

# ZURZUVAE

## Products Affected

- Zurzuvae

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | • Past medical history of bipolar disorder, schizophrenia, or schizoaffective disorder • Current pregnancy |
| **Required Medical Information** | Initial Authorization: 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 2. Patient is within the first twelve months postpartum 3. Submission of validated screening tool results (for example, HAM-D, PHQ-9, MADRS) confirming diagnosis 4. Member has not received prior treatment with Zurzuvae for the current pregnancy 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 requirement may be waived in cases of severe postpartum depression |
| **Age Restrictions** | Ages 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | One month (one 14-day fill) per pregnancy |

Last Updated: 10/01/2024

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

Last Updated: 10/01/2024