



PROVIDENCE MEDICARE ADVANTAGE PLANS

2026 PART D PRIOR AUTHORIZATION CRITERIA:

ALIGN GROUP PLAN + RX (HMO)

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

ALPHA1-PROTEINASE INHIBITOR

Products Affected

- Prolastin-C intravenous solution

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

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

Last Updated: 09/02/2025

ANTI-CANCER AGENTS

Products Affected

- abiraterone oral tablet 250 mg
- Abirtega
- Actimmune
- Akeega
- Alecensa
- Alunbrig
- Augtyro
- Avmapki-Fakzynja
- Ayvakit
- Balversa
- Besremi
- bexarotene
- Bosulif
- Braftovi
- Brukinsa oral capsule
- Cabometyx
- Calquence (acalabrutinib mal)
- Caprelsa
- Cometriq
- Copiktra
- Cotellic
- Danziten
- dasatinib
- Daurismo
- Erivedge
- Erleada
- erlotinib
- Eulexin
- everolimus (antineoplastic)
- Fotivda
- Fruzaqla
- Gavreto
- gefitinib
- Gilotrif
- Gleostine
- Gomekli
- Ibrance
- Iclusig
- Idhifa
- imatinib
- Imbruvica oral capsule
- Imbruvica oral suspension
- Imbruvica oral tablet 140 mg, 280 mg, 420 mg
- Imkeldi
- Inlyta
- Inqovi
- Inrebic
- Itovebi
- Iwilfin
- Jakafi
- Jaypirca
- Kisqali
- Kisqali Femara Co-Pack oral tablet 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg
- Koselugo
- Krazati
- lapatinib
- Lazcluze
- lenalidomide
- Lenvima
- Leukeran
- Lonsurf
- Lorbrena
- Lumakras
- Lynparza
- Lytobi oral tablet 12 mg/day (4

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- mg x 3), 16 mg/day (4 mg x 4), 20 mg/day (4 mg x 5)
- Mekinist
 - Mektovi
 - metyrosine
 - Nerlynx
 - nilotinib HCl
 - nilutamide
 - Ninlaro
 - Nubeqa
 - Odomzo
 - Ogsiveo
 - Ojemda
 - Ojjaara
 - Onureg
 - Orgovyx
 - Orserdu
 - Panretin
 - pazopanib
 - Pemazyre
 - Piqray
 - Pomalyst
 - Qinlock
 - Retevmo
 - Revuforj
 - Rezlidhia
 - Romvimza
 - Rozlytrek
 - Rubraca
 - Rydapt
 - Scemblix
 - sorafenib
 - Stivarga
 - sunitinib malate
 - Tabloid
 - Tabrecta
 - Tafenlar
 - Tagrisso
 - Talzenna
 - Tazverik
 - Tepmetko
 - Tibsovo
 - toremifene
 - Torpenz
 - tretinoin (antineoplastic)
 - Truqap
 - Tukysa
 - Turalio oral capsule 125 mg
 - Vanflyta
 - Venclexta
 - Venclexta Starting Pack
 - Verzenio
 - Vitrakvi
 - Vizimpro
 - Vonjo
 - Voranigo
 - Welireg
 - Xalkori
 - Xospata
 - Xpovio
 - Xtandi
 - Zejula oral tablet
 - Zelboraf
 - Zolinza
 - Zydelig
 - Zykadia

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PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	One of the following for initiation of the requested agent: 1. For Bosulif or Tassigna or Danziten or dasatinib (Sprycel): Documentation of use of imatinib for the requested indication, unless one of the following: a. The patient has an intolerance or hypersensitivity to imatinib, b. The patient has an FDA labeled contraindication to imatinib, c. CMS-approved compendia do not support the use of imatinib for the requested indication, or d. The prescriber has provided information in support of use of Bosulif or Tassigna or Danziten or dasatinib (Sprycel) over imatinib for the requested indication. 2. For Ibrance: Documentation of use of Kisqali or Verzenio for the requested indication (if applicable), unless one of the following: a. The patient has an intolerance or hypersensitivity to Kisqali or Verzenio, b. The patient has an FDA labeled contraindication to Kisqali or Verzenio, c. CMS-approved compendia do not support the use of Kisqali or Verzenio for the requested indication, or d. The prescriber has provided information in support of use of Ibrance over Kisqali or Verzenio 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 all other agents: Indication is supported by CMS-approved compendia.
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	For cancer diagnoses, must be prescribed by or in consultation with an oncologist, hematologist, 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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

ANTIFUNGAL AGENTS

Products Affected

- Cresemba oral
- posaconazole oral
- voriconazole
- voriconazole-HPBCD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. For oropharyngeal or esophageal candidiasis (posaconazole oral suspension and voriconazole only): Documented failure, intolerance, or contraindication to fluconazole. 2. For the treatment of invasive aspergillosis or invasive candidiasis: a. Confirmed diagnosis (fungal culture and other relevant laboratory studies, including histopathology, must be documented), b. voriconazole will be covered, c. for posaconazole or isavuconazonium: Documented failure, intolerance, or contraindication to voriconazole. 3. For the treatment of blastomycosis or histoplasmosis: Documented failure, intolerance, or contraindication to itraconazole 4. For prophylaxis of invasive aspergillosis or invasive candidiasis: posaconazole or voriconazole will be covered in severely immunocompromised patients.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, an infectious disease specialist, hematologist, oncologist, transplant specialist, or pulmonologist
Coverage Duration	Aspergillus/Candida infection prophylaxis: initial/reauth 1 yr. Other uses: initial 3 mo/reauth 1 yr

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PA Criteria	Criteria Details
Other Criteria	5. For treatment of mucormycosis: isavuconazonium or posaconazole will be covered. 6. For empiric antifungal therapy in patients with febrile neutropenia: voriconazole or posaconazole will be covered. For reauthorization: Documentation supporting continued use of the requested agent for the intended diagnosis (such as continued active disease, length of therapy is supported by literature or guidelines, for prophylaxis patient continues to be severely immunocompromised)
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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ANTIPSYCHOTICS

Products Affected

- asenapine maleate
- Caplyta
- Cobenfy
- Cobenfy Starter Pack
- Fanapt
- Fanapt Titration Pack A
- Lybalvi
- Rexulti oral tablet
- Secuado
- Vraylar oral capsule

PA Criteria	Criteria Details
Exclusion Criteria	

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PA Criteria	Criteria Details
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), d. For agitation with Alzheimer's dementia (brexpiprazole), all the following criteria must be met: i. Diagnosis of Alzheimer's dementia with signs and symptoms of agitation (such as excessive motor activity, verbal and/or physical aggression) and ii. Documentation of medical rationale for antipsychotic therapy given risk of significant adverse effects. Rationale may include significant safety concern for patient or caregiver, or significant distress for patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be approved until no longer eligible with the plan.

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

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ARCALYST

Products Affected

- Arcalyst

PA Criteria	Criteria Details
Exclusion Criteria	The requested agent will not be given concurrently with another therapeutic immunomodulator agent

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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/glucocorticoids, in combination with colchicine. 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

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PA Criteria	Criteria Details
Prescriber Restrictions	For Cryopyrin-Associated Periodic Syndrome (CAPS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Must be prescribed by, or in consultation with, a rheumatologist or immunologist. For Recurrent Pericarditis (RP): Must be prescribed by, or in consultation with, a cardiologist, rheumatologist, or immunologist
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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

BENLYSTA

Products Affected

- Benlysta subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	For patients initiating therapy for Systemic Lupus Erythematosus (SLE) and active lupus nephritis, all the following must be met: 1. Confirmed diagnosis of Systemic Lupus Erythematosus (SLE) or active lupus nephritis, 2. Documented failure (such as inadequate control with ongoing disease activity and/or frequent flares) to at least one of the following, unless all are contraindicated/not tolerated: a. For Non-Renal SLE: i. Hydroxychloroquine, ii. Glucocorticoids, iii. Immunosuppressive drugs (methotrexate, mycophenolate, azathioprine, cyclophosphamide, cyclosporine, tacrolimus), b. For SLE with Active Lupus Nephritis: i. Low-dose IV cyclophosphamide or ii. Mycophenolate and glucocorticoids, 3. Documentation that patient will continue to receive standard therapy (e.g., hydroxychloroquine, glucocorticoids or immunosuppressants) as this therapy has not been studied as monotherapy in patients with SLE. For patients established on therapy: Documentation of positive clinical response to belimumab (such as improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications, decrease in the number of exacerbations since prior to start of belimumab, reduction of renal related events).

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a rheumatologist or nephrologist.
Coverage Duration	Initial authorization will be approved for six months. Reauthorization will be approved for one year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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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 18 years and older
Prescriber Restrictions	
Coverage Duration	Initial authorization and reauthorization will be approved for 8 weeks.

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

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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
Prerequisite Therapy Required	No

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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	UNDER CMS REVIEW
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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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	UNDER CMS REVIEW
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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CGRP-NURTEC ODT

Products Affected

- Nurtec ODT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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CONTINUOUS GLUCOSE MONITORS FOR PERSONAL USE

Products Affected

- Dexcom G6 Receiver
- Dexcom G6 Sensor
- Dexcom G6 Transmitter
- Dexcom G7 Receiver
- Dexcom G7 Sensor
- FreeStyle Libre 14 Day Reader
- FreeStyle Libre 14 Day Sensor
- FreeStyle Libre 2 Plus Sensor
- FreeStyle Libre 2 Reader
- FreeStyle Libre 2 Sensor
- FreeStyle Libre 3 Plus Sensor
- FreeStyle Libre 3 Reader
- FreeStyle Libre 3 Sensor

PA Criteria	Criteria Details
Exclusion Criteria	I-CGM devices will not be considered reasonable and necessary for short-term (72 hours to 1 week) diagnostic use.

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PA Criteria	Criteria Details
Required Medical Information	I. Continuous glucose monitors may be considered medically necessary and covered for the treatment of diabetes when all the following criteria are met: A. The requested device is FDA-approved and is being used in accordance with the approved indications of use, and B. One of the following: 1. The patient is using insulin. This may automatically adjudicate with history of pharmacy claim for insulin within the previous 120 days. 2. The patient has experienced hypoglycemia, defined as documentation of at least one of the following a. Recurrent hypoglycemic events, [defined as glucose less than 54mg/dL (3.0mmol/L)] that persist despite multiple attempts to adjust medication(s) and/or modify the diabetes treatment plan b. History of one hypoglycemic event [defined as glucose less than 54mg/dL (3.0mmol/L)] characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia c. Within six months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria above are met. II. Upgrade or replacement of continuous glucose monitor systems may be considered medically necessary and covered when there is documentation that one or more of the device components meet all of the following criteria (A.-C.): A. Are no longer functional, and B. Are not under warranty, and C. Cannot be repaired. III. Upgrade or replacement of continuous glucose monitor systems is considered not

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PA Criteria	Criteria Details
	medically necessary and not covered when criterion II above is not met. Upon approval, concurrent use of test strips will be limited to: Dexcom/Freestyle Libre: 150 strips per 30-day supply. Requests above this quantity are not considered medically necessary. Coverage may be allowed with discontinuation of continuous glucose monitoring system and is subject to test strip quantity criteria (See Diabetic DME policy)
Age Restrictions	Age must be appropriate based on FDA-approved indication
Prescriber Restrictions	
Coverage Duration	Gestational diabetes: 1 year. Others: approved for life, subject to formulary or benefit change
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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CORLANOR

Products Affected

- Corlanor oral solution
- ivabradine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
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.
Other Criteria	For inappropriate sinus tachycardia, all of the following must be met: 1. Documentation of sinus rhythm and resting HR greater than 100 bpm (with a mean HR greater than 90 bpm over 24 hours), 2. Documentation that other causes of sinus tachycardia have been ruled out (such as thyroid disease, drug-induced, postural orthostatic tachycardia syndrome), 3. Documentation that inappropriate sinus tachycardia is causing significant functional impairment or distress (such as presyncope, headache, dyspnea, weakness)
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

DIACOMIT

Products Affected

- Diacomit

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initiation of therapy (new starts), 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, 4. Baseline absolute neutrophil count (ANC) above 1,900 cells per microliter and platelet count above 150,000 cells per microliter.
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	

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

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DISPOSABLE INSULIN PUMPS

Products Affected

- Omnipod 5 (G6/Libre 2 Plus)
- Omnipod 5 G6-G7 Intro Kt(Gen5)
- Omnipod 5 G6-G7 Pods (Gen 5)
- Omnipod 5 Intro(G6/Libre2Plus)
- Omnipod Dash Intro Kit (Gen 4)
- Omnipod Dash Pods (Gen 4)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Disposable insulin pumps may be considered medically necessary and covered for the treatment of insulin-dependent diabetes, defined as use of rapid- or short-acting insulin. Omnipods are limited to 15 pods per 30 days. Requests for additional pods may be covered when the patients total daily dose of insulin is more than 65 units per day. The quantity will be limited to the appropriate number of pods per month based on insulin utilization (each pod can hold 200 units of insulin and must be changed every 72 hours).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be approved until no longer eligible with the plan
Other Criteria	
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

DUPIXENT

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication.
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: Asthma/COPD: respiratory specialist (such as a pulmonologist, immunologist, or allergist), AD: dermatologist, allergist, or immunologist, EOE: allergist or gastroenterologist, CRSwNP: otolaryngologist, allergist, or pulmonologist, PN: dermatologist.
Coverage Duration	Asthma/COPD: Init 1 yr/reauth life. AD: Init 6 mos/reauth life. Other: init 6 mos/reauth 1 yr
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	

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

Last Updated: 09/02/2025

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	

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

Last Updated: 09/02/2025

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: 09/02/2025

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) and 2e (perioperative use in anemic patients scheduled for cardiac surgery) must have one of the following: a. hemoglobin (HGB) levels of less than or equal to 10 g/dl for adult patients, b. HGB levels of less than or equal to 11 g/dl for patients less than 18 years old, or c. 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), one of the following: i. Adequate iron stores as indicated 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% or ii. Current use of oral or intravenous (IV) iron therapy, b. For anemia due to chemotherapy in cancer and related neoplastic conditions (see exclusion criteria for non-covered indications): i. Anemia is secondary to myelosuppressive chemotherapy in solid tumors, multiple myeloma, lymphoma, or lymphocytic leukemia and ii. One of the following: 1) 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% or 2) Current use of oral or intravenous (IV) iron therapy, c. Anemia associated with zidovudine-treated HIV-infection patients: 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	

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PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	Initial authorization and reauthorization will be approved for one year.
Other Criteria	d. Preoperative use in anemic patients scheduled for elective hip or knee surgery: i. 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. Attestation that the patient will be undergoing cardiac surgery and anemia is due to chronic disease, AND ii. 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, or 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. Current (within last three months) endogenous serum erythropoietin levels less than or equal to 500 mU/mL and ii. One of the following: 1) 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% or 2) Current use of oral or intravenous (IV) iron therapy. Reauthorization requires: 1. Continued medical necessity AND 2. HGB levels of less than or equal to 12 g/dl within previous 45 days.
Indications	All Medically-accepted Indications.

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

EUCRISA

Products Affected

- Eucrisa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial authorization, both of the following criteria must be met: 1. Patient has a diagnosis of atopic dermatitis and 2. One of the following: a. Patient has tried and had an inadequate response to a topical calcineurin inhibitor (tacrolimus or pimecrolimus) or b. Patient has an intolerance, hypersensitivity, or contraindication to a topical calcineurin inhibitor. Reauthorization requires positive response to therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial approval and reauthorization will be approved for one year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

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 FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

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	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, an appropriate specialist (e.g., a neurologist for multiple sclerosis or a hematologist for autoimmune hemolytic anemia)
Coverage Duration	Initial authorization for 6 months. Reauthorization for 12 months.

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PA Criteria	Criteria Details
Other Criteria	For Guillain-Barre Syndrome: 1. Documentation of symptom onset within 2 weeks or severe symptoms (such as being unable to ambulate independently) and 2. Documented inadequate response or contraindication to plasma exchange. For prevention of infections in patients with chronic B-cell CLL: 1. Hypogammaglobulinemia (as defined above) OR 2. History of recurrent, severe infections (e.g., need for antibiotics, hospitalization). For dermatomyositis and polymyositis: 1. Documented trial and failure, intolerance, or contraindication to one systemic corticosteroid and one immunosuppressant agent, 2. Documentation of severe symptoms despite therapy with above agents. For multifocal motor neuropathy: 1. Motor involvement of at least two nerves (for more than one month) without symptoms of sensory abnormalities AND 2. Documentation of severe disease/disability. For MS: 1. Documentation of relapsing/remitting disease AND 2. Documented trial and failure, intolerance, or contraindication to at least 2 disease modifying therapies (e.g. dimethyl fumarate, glatiramer). For Allogenic Bone Marrow Transplantation or Hematopoietic Stem Cell Transplant (HSCT) Recipients: 1. Therapy is requested for use within 100 days of transplantation (transplantation date must be documented) OR 2. Hypogammaglobulinemia (as defined above). For chronic inflammatory demyelinating polyneuropathy (CIDP): 1. Documentation of severe disability and 2. One of the following: a. Documented trial and failure, intolerance or contraindication to systemic

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PA Criteria	Criteria Details
	corticosteroids or b. Documentation of pure motor CIDP. For autoimmune hemolytic anemia: 1. Documented trial and failure, intolerance or contraindication to one systemic corticosteroid AND one other conventional therapy (e.g., cyclophosphamide, azathioprine, cyclosporine). For myasthenia gravis: One of the following: a. Evidence of myasthenic exacerbation, defined by at least one of the following symptoms in the last month: difficulty swallowing, acute respiratory failure, major functional disability responsible for the discontinuation of physical activity or b. Evidence of refractory disease defined as the following: 1. Documentation of severely impaired function AND 2. Documented trial and failure, intolerance, or contraindication to at least 2 of the following conventional therapies: acetylcholinesterase inhibitors, corticosteroids, immunosuppressive agents, or plasma exchange. For autoimmune mucocutaneous blistering disease [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]: 1. Biopsy proven disease AND 2. Documented trial and failure, intolerance, or contraindication to one systemic corticosteroid and one immunosuppressive agent. For reauthorization for all indications: Documentation of response to therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Hematopoietic stem cell transplant recipients, acute Guillain-Barre syndrome, relapsing-remitting type multiple sclerosis, myasthenia gravis, autoimmune hemolytic anemia, autoimmune mucocutaneous blistering disease, and polymyositis.

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

GLP-1 AGONISTS

Products Affected

- Mounjaro mg/dose (8 mg/3 mL)
- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg (2 mg/3 mL), 1 mg/dose (4 mg/3 mL), 2
- Rybelsus oral tablet 14 mg, 3 mg, 7 mg
- Trulicity

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	The patient has documentation of confirmed type 2 diabetes mellitus (e.g., medical records, chart notes, A1C or other lab results)
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
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

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: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

HEREDITARY ANGIOEDEMA THERAPY

Products Affected

- icatibant
- Orladeyo
- Sajazir

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of more than one agent used for prophylaxis
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, an immunologist or allergist.
Coverage Duration	Initial authorization and reauthorization will be approved for 1 yr.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

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	HIV wasting: Must be prescribed by, or in consultation with a specialist in the management of HIV. All other uses: must be prescribed by, or in consultation with, an endocrinologist.
Coverage Duration	HIV wasting: 12 months. All other uses: initial/reauth for 12 months.

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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
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

IMPAVIDO

Products Affected

- Impavido

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. Current body weight AND 3. Dosing regimens are within FDA labeled dosing or supported by compendia
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with an infectious disease specialist
Coverage Duration	Authorization will be approved for one month
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

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: 09/02/2025

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

Last Updated: 09/02/2025

KERENDIA

Products Affected

- Kerendia oral tablet 10 mg, 20 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	Approved for 18 years and older
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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

LIDOCAINE PATCH

Products Affected

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

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: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

LIVTENCITY

Products Affected

- Livtency

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: 09/02/2025

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

Last Updated: 09/02/2025

LONG-ACTING OPIOIDS

Products Affected

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

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

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PA Criteria	Criteria Details
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, and pertinent physical examination findings documented in chart notes from the past six months. Documentation must show that education and access for an opioid rescue medication (e.g., naloxone, nalmeferene) has been discussed with 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. (This criterion is waived for stage IV and/or metastatic cancer.) 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.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	Initial authorization and reauthorization will be approved for one year.
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 year, 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 cancer

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

Last Updated: 09/02/2025

LUPRON DEPOT

Products Affected

- 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	
Part B Prerequisite	No

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

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: 09/02/2025

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

Last Updated: 09/02/2025

NEXLETOL/NEXLIZET

Products Affected

- Nexletol
- Nexlizet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial authorization, all 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 high-intensity statin therapy (defined as atorvastatin 80 mg daily or rosuvastatin 40 mg daily), unless contraindicated/not tolerated. 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	

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

Last Updated: 09/02/2025

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	Authorization requires diagnosis of pseudobulbar affect (PBA).
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

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

NUPLAZID

Products Affected

- Nuplazid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

OPIPZA

Products Affected

- Opienza

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.Documentation of clinical rationale explaining why aripiprazole orally disintegrating tablets AND aripiprazole oral solution are not indicated for the patient.
Age Restrictions	
Prescriber Restrictions	
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: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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ORENCIA

Products Affected

- Orenica
- Orenica ClickJect

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 09/02/2025

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 (Cosentyx, Enbrel, Hadlima/Simlandi, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya) is required for diagnosis of psoriatic arthritis. For patients between 6 and less than 18 years of age, use of TWO preferred agents (Cosentyx, Rinvoq) is required for diagnosis of psoriatic arthritis. For patients between 2 and less than 6 years of age, use of ONE preferred agent (Rinvoq) is required for diagnosis of psoriatic arthritis. Use of TWO preferred agents (Enbrel, Hadlima/Simlandi, Rinvoq) is required for diagnosis of rheumatoid arthritis. Use of TWO preferred agents
	(Enbrel, Hadlima/Simlandi, Rinvoq) 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: 09/02/2025

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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

OSTEOANABOLIC AGENTS

Products Affected

- teriparatide
- Tymlos

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For the treatment of osteoporosis, must meet ONE of the following criteria: a. High risk of fracture defined as one of the following: i. Spine or hip bone mineral density (BMD) T-score of less than -3.0, ii. Very high fracture probability as indicated by a FRAX (Fracture Risk Assessment) score for hip fracture of greater than 4.5% or other major osteoporotic fracture of greater than 30%, iii. Fracture History (defined as 1 fracture within the last 12 months, fracture while on approved osteoporosis therapy, multiple fractures, fracture while on drugs causing skeletal harm (such as long-term glucocorticoids), iv. High risk of falls or history of injurious falls, OR b. Patient has documented failure to anti-resorptive therapy (e.g., denosumab, bisphosphonates), defined as a new fracture or worsening BMD while on therapy, unless both denosumab and bisphosphonate are contraindicated or not tolerated.
Age Restrictions	
Prescriber Restrictions	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

PCSK-9 INHIBITORS

Products Affected

- Repatha Pushtrex
- Repatha SureClick
- Repatha Syringe

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with another PCSK9 inhibitor.

Last Updated: 09/02/2025

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: 09/02/2025

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

PREVYMIS

Products Affected

- Prevymis oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	One of the following criteria must be met: 1. Patient is using for prophylaxis of cytomegalovirus (CMV) infection after allogeneic hematopoietic stem cell transplant (HSCT) and all the following: a. Patient is CMV seropositive, b. Attestation that therapy will be started within 28 days post-transplantation, c. If requesting for prophylaxis beyond 100 days post-transplantation, documentation that the patient is at high risk for late CMV infection. 2. Patient is using for prophylaxis of CMV disease after kidney transplant and all the following: a. Patient is at high risk, defined as CMV seropositive donor in a recipient that is CMV seronegative (D+/R-) and b. Attestation that therapy will be started within seven (7) days post-transplantation.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a hematologist, nephrologist, oncologist, transplant specialist, or infectious disease specialist.
Coverage Duration	Authorization will be approved for 200 days post-transplantation.

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

PROMACTA

Products Affected

- eltrombopag olamine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
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.
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Myelodysplastic syndromes.
Part B Prerequisite	No

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

PULMONARY ANTIHYPERTENSIVES

Products Affected

- Adempas
- Alyq
- ambrisentan
- bosentan oral tablet
- sildenafil (pulm.hypertension) oral tablet

Last Updated: 09/02/2025

- tadalafil (pulm. hypertension)

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. Reauthorization requires one of the following: 1. documentation of improvement or stabilization of disease (such as lack of disease progression, improvement in walk distance, reduced hospitalizations, or improvement in WHO functional class), or 2. Documentation supporting continued use of the requested agent.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist
Coverage Duration	Approve until no longer eligible with the plan.
Other Criteria	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

PULMONARY ANTIHYPERTENSIVES - ORENITRAM

Products Affected

- Orenitram
- Orenitram Month 1 Titration Kt
- Orenitram Month 2 Titration Kt
- Orenitram Month 3 Titration Kt

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 09/02/2025

PA Criteria	Criteria Details
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) with WHO/New York Heart Association (NYHA) functional class II, III, or IV, 3. Patient is currently established on (for at least 90 days) at least one of the following, unless all are not tolerated or contraindicated: a. Endothelin receptor antagonist (such as bosentan, ambrisentan) or b. Phosphodiesterase-5 inhibitor (such as sildenafil or tadalafil). Reauthorization requires all the following criteria to be met: 1. Documentation of improvement or stabilization of disease (such as lack of disease progression, improvement in walk distance, reduced hospitalizations, or improvement in WHO functional class) and 2. Medication will continue to be used in combination with at least one other PH agents, unless not tolerated or contraindicated.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist.
Coverage Duration	Initial authorization will be approved for 6 months. Reauthorization will be approved for one year.
Other Criteria	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

PULMONARY ANTIHYPERTENSIVES - WINREVAIR

Products Affected

- Winrevair subcutaneous kit 45 mg,
60 mg

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 09/02/2025

PA Criteria	Criteria Details
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) with WHO/New York Heart Association (NYHA) functional class II or III, 3. Patient is currently established on (for at least 90 days) at least two of the following, unless all are not tolerated or contraindicated: a. Endothelin receptor antagonist (such as bosentan, ambrisentan), b. Phosphodiesterase-5 inhibitor (such as sildenafil or tadalafil) or soluble guanylate cyclase stimulator (such as Adempas®), c. Prostacyclin analogue or receptor agonist (such as treprostinil), 4. Medication will continue to be used as add-on therapy in combination with at least two other PH agents, unless not tolerated or contraindicated, and 5. Platelet count greater than or equal to 50,000. Reauthorization requires all the following criteria to be met: 1. Documentation of improvement or stabilization of disease (such as lack of disease progression, improvement in walk distance, reduced hospitalizations, or improvement in WHO functional class), 2. Medication will continue to be used as add-on therapy in combination
	with at least two other PH agents, unless not tolerated or contraindicated, and 3. Platelet count greater than or equal to 50,000

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a pulmonologist or cardiologist.
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
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

PULMONARY FIBROSIS AGENTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 09/02/2025

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: 09/02/2025

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
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

QUININE

Products Affected

- quinine sulfate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of confirmed diagnosis of malaria, babesiosis or an indication that is supported by CMS-approved compendia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

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	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	Medications must be prescribed by, or in consultation with the following specialists based on the diagnosis: Asthma: asthma specialist (such as a pulmonologist, immunologist, or allergist). EGPA: pulmonologist, neurologist, or rheumatologist
Coverage Duration	Asthma: Initial 1 yr/reauth until no longer elig with plan. EGPA: Initial 6 mo/reauth 1yr.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

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	UNDER CMS REVIEW
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	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

RESPIRATORY AGENTS-XOLAIR

Products Affected

- Xolair

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another therapeutic immunomodulator agent utilized for the same indication
Required Medical Information	UNDER CMS REVIEW
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. Urticaria: dermatologist, allergist, or immunologist, 3. nasal polyps: otolaryngologist, allergist, or pulmonologist, 4. IgE-mediated food allergy: allergist, immunologist.
Coverage Duration	Asthma: Init 1yr/reauth until no longer elig with plan. Others: Init 6mo/reauth 1yr
Other Criteria	UNDER CMS REVIEW
Indications	All FDA-approved Indications.
Off Label Uses	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

REVCovi

Products Affected

- Revcovi

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Required Medical Information	For initial authorization, all the following must be met: 1. Documented diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one of the following confirmatory tests: a. Mutation in the ADA gene by molecular genetic testing b. Deficient ADA catalytic activity (less than 1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (such as, blood mononuclear cells, fibroblasts). 2 . A marked increase in the metabolite deoxyadenosine triphosphate (dATP) or total dAdo nucleotides [the sum of deoxyadenosine monophosphate (dAMP), deoxyadenosine diphosphate (dADP), and dATP] in erythrocytes 3. Documentation showing that patient is not a candidate for or has failed a hematopoietic stem cell transplantation (HSCT). Can be approved as a "bridge" therapy before undergoing HSCT or an HSC-Gene Therapy clinical trial if a donor/ clinical trial has been identified (subject to policy coverage durations) 4. Documentation that patient does not have severe thrombocytopenia (platelet count less than 50,000 cells/microliter) 5. Dosing is within FDA-labeled guidelines. For patients currently established on the requested therapy, all the following criteria must be met: 1. Documentation of successful response to therapy (e.g., disease stability, improvement in symptoms or lack of decline compared to natural disease progression) 2. Documentation of plasma target trough ADA activity of at least 30 mmol/hr/L in the past two months 3. Documentation of a trough erythrocyte dAXP level
	maintained below 0.02 mmol/L in the past six months 4. Documentation of immune function improvement (such as decrease in number of infections) 5. Dosing is within FDA-labeled guidelines.

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with a hepatologist, endocrinologist, medical geneticist, cardiologist, pulmonologist, neurologist, hematologist, oncologist, immunologist, or bone and mineral specialist
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
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

REZDIFFRA

Products Affected

- Rezdiffra

PA Criteria	Criteria Details
Exclusion Criteria	Presence of cirrhosis
Required Medical Information	For initial authorization, all the following criteria must be met: 1. Diagnosis of nonalcoholic steatohepatitis (NASH), also known as metabolic dysfunction associated steatohepatitis (MASH), confirmed by liver biopsy or vibration-controlled transient elastography (such as FibroScan) within the previous six months, 2. Baseline nonalcoholic fatty liver disease activity score (NAS) taken within previous three months that is at least four, with a score of 1 or more for each component, 3. Fibrosis stage 2 or 3 (F2/F3) within the previous six months. For reauthorization: Documentation of response to therapy, such as no worsening of fibrosis score and no worsening of NAS.
Age Restrictions	Approved for 18 years and older
Prescriber Restrictions	Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist.
Coverage Duration	Initial authorization and reauthorization will be approved for one year
Other Criteria	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

SIGNIFOR

Products Affected

- 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: 09/02/2025

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

Last Updated: 09/02/2025

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: 09/02/2025

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

Last Updated: 09/02/2025

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	Concomitant use with ketamine, aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation, history of intracerebral hemorrhage

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Required Medical Information	For initiation of therapy, all the following criteria (1-4) must be met: 1. Confirmed diagnosis of one of the following (a or b): a. Treatment-resistant depression (TRD), defined as use of BOTH of the following regimens for the current depressive episode (clinical documentation must be provided that outlines the patient evaluation): i. Inadequate response to at least three oral antidepressants in two different therapeutic classes for at least eight weeks of treatment at a therapeutic dose for major depressive disorder (MDD) AND ii. Inadequate response to augmentation therapy (i.e., two antidepressants with different mechanisms of action used concomitantly or an antidepressant and a second-generation antipsychotic, lithium, thyroid hormone, or anticonvulsant used concomitantly), b. MDD with acute suicidal ideation or behavior, defined as BOTH of the following (clinical documentation must be provided that outlines the patient evaluation): i. Patient has thoughts about suicide, or thoughts of self-harm with at least some intent or awareness that they may die as a result and ii. Patient intends to act on thoughts of killing themselves, 2. Baseline score from one of the following standardized depression rating scales confirming severe depression: a. Patient Health Questionnaire-9 (PHQ-9) score of at least 20, b. Hamilton Depression Scale (HAM-D17) score of at least 24, c. Quick Inventory of Depressive Symptomatology, Clinician-Rated (QIDS-C16) score of at least 16, or d. Montgomery Asberg Depression Rating Scale (MADRS) total score of at least 28, 3. For MDD
	with acute suicidal ideation or behavior: Documentation that esketamine (Spravato) will be used in combination with oral antidepressant therapy, AND 4. Dosing is in accordance with the United States Food and Drug Administration approved labeling.

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Age Restrictions	Approved for 18 years and older
Prescriber Restrictions	Prescribed by, or in consultation with, a psychiatrist or a psychiatric nurse practitioner.
Coverage Duration	For MDD with suicidal ideation/behavior: 4 weeks. All others: until no longer eligible
Other Criteria	NOTE: For MDD with suicidal ideation or behavior, initial authorization will be approved for four weeks. Reauthorization requests for MDD with acute suicidal ideation or behavior will not be covered. Patient must meet criteria for initiation of therapy in TRD.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

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
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

TAFAMIDIS

Products Affected

- Vyndamax
- Vyndaqel

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

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
- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)- 20 mg (51), 10 mg (4)-20 mg (4)-30 mg (47)
- Rinvoq
- Rinvoq LQ
- Simlandi(CF)
- Simlandi(CF) Autoinjector
- Skyrizi subcutaneous
- Stelara
- Tremfya One-Press
- Tremfya Pen
- Tremfya Pen Induction Pk-Crohn
- Tremfya subcutaneous
- ustekinumab subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	

Last Updated: 09/02/2025

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, 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 prior to starting the requested drug, 3. Documentation of trial and failure, intolerance, or contraindication to conventional therapy prerequisite(s) for the following indications: a. For juvenile psoriatic arthritis, rheumatoid arthritis, and juvenile idiopathic arthritis: Use of ONE conventional prerequisite drug (such as methotrexate, leflunomide, sulfasalazine), b. For plaque psoriasis: Use of ONE conventional prerequisite drug (such as methotrexate, topical corticosteroids, tazarotene), c. For atopic dermatitis: Use of ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor, d. For all other FDA approved indications, no conventional therapies are required as a prerequisite.
Age Restrictions	
Prescriber Restrictions	

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Coverage Duration	Initial auth approved for 1 year. Reauth will be approved until no longer eligible with the plan
Other Criteria	4. For Rinvoq and Enbrel, must meet the following product specific requirements: a. For Rinvoq: i. For diagnoses of ankylosing spondylitis, rheumatoid arthritis, juvenile idiopathic arthritis or adult psoriatic arthritis, must try ONE preferred TNF (Enbrel or Hadlima/Simlandi), ii. For Crohn's disease, must try Hadlima or Simlandi, b. For Enbrel: i. For diagnoses of ankylosing spondylitis, rheumatoid arthritis, juvenile idiopathic arthritis, adult psoriatic arthritis, or adult plaque psoriasis, must try Hadlima or Simlandi, c. For all other FDA approved indications, no additional preferred drugs are required as a prerequisite.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

TOLVAPTAN (JYNARQUE)

Products Affected

- Jynarque oral tablet
- tolvaptan (polycys kidney dis)

PA Criteria	Criteria Details
Exclusion Criteria	1. Hepatic Impairment 2. Anuria 3. Hypovolemia 4. eGFR of less than 15 mL/min/1.73 m ²
Required Medical Information	For initial authorization, the prescriber must indicate that the patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and is at risk of rapid progression. Examples of rapidly declining renal function may include: a. eGFR decline of at least 3 mL/min/1.73 m ² per year over one year, b. Height-adjusted total kidney volume (htTKV) compatible with Mayo class 1C to 1E disease. Reauthorization for ADPKD requires a positive response to therapy (such as a slowing in patient's decline in kidney function).
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a nephrologist, cardiologist, or endocrinologist.
Coverage Duration	Initial approval and reauthorization will be approved for one year.
Other Criteria	
Indications	All FDA-approved Indications.

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

TOLVAPTAN (SAMSCA)

Products Affected

- tolvaptan

PA Criteria	Criteria Details
Exclusion Criteria	1. Hepatic Impairment 2. Anuria 3. Hypovolemia
Required Medical Information	For hypervolemic and euvolemic hyponatremia, all the following criteria must be met: 1. One of the following: a. Serum sodium of less than 125 mEq/L, b. Less marked hyponatremia (less than 135 mEq/L), but symptomatic, 2. Patient will be initiated or re-initiated on therapy in a hospital setting where serum sodium can be monitored closely, 3. Patient does not have an urgent need to raise serum sodium acutely (such as acute/transient hyponatremia associated with head trauma).
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a nephrologist, cardiologist, or endocrinologist.
Coverage Duration	Authorization will be approved for 30 days per treatment course.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

TOPICAL RETINOID PRODUCTS

Products Affected

- adapalene topical cream
- tazarotene topical cream
- tazarotene topical gel
- 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
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

TYENNE

Products Affected

- Tyenne Autoinjector
- Tyenne subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

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: 09/02/2025

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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

VMAT-2 INHIBITORS

Products Affected

- tetrabenazine

PA Criteria	Criteria Details
Exclusion Criteria	Use in combination with monoamine oxidase inhibitors or other VMAT2 inhibitors
Required Medical Information	For chorea associated with Huntington disease, all the following criteria must be met: 1. DNA testing showing CAG expansion of 36 or higher, 2. Family history (if known), 3. Classic presentation (choreiform movements, psychiatric problems, and dementia), and 4. Documentation that chorea is causing functional impairment. For tardive dyskinesia, all the following criteria must be met: 1. Diagnosis of tardive dyskinesia secondary to therapy with a dopamine receptor blocking agent (e.g. first or second-generation antipsychotics, metoclopramide) AND 2. Documentation that tardive dyskinesia is causing functional impairment. Reauthorization for all indications requires documentation of positive clinical response to therapy, such as improved function.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist or psychiatrist
Coverage Duration	UNDER CMS REVIEW

Last Updated: 09/02/2025

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

Last Updated: 09/02/2025

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 12 months, 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: 09/02/2025

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

Last Updated: 09/02/2025

WAKEFULNESS PROMOTING AGENT - WAKIX

Products Affected

- Wakix

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial authorization, both 1 and 2 must be met: 1. Diagnosis of narcolepsy must be confirmed by all the following: a. Sleep study testing 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), b. Documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months, c. Other causes of sleepiness have been ruled out or treated (such as obstructive sleep apnea, shift work, effects of substances or medications or their withdrawal, other sleep disorders), AND 2. One of the following: a. For treatment of excessive daytime sleepiness in narcolepsy, documentation of inadequate response (after three months of therapy), intolerance, or contraindication to (i) modafinil or armodafinil and (ii) For members 18 years and older, solriamfetol (Sunosi) OR b. Documentation of a diagnosis of cataplexy. Reauthorization requires documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks, if applicable.
Age Restrictions	

Last Updated: 09/02/2025

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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

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. 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. Documentation of a 30-day trial and failure, intolerance, or contraindication to modafinil or armodafinil. Reauthorization for all indications requires documentation of successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness.
Age Restrictions	

Last Updated: 09/02/2025

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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

XDEMVI

Products Affected

- Xdemvi

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: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

XERMELO

Products Affected

- Xermelo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

XIAFLEX

Products Affected

- Xiaflex

PA Criteria	Criteria Details
Exclusion Criteria	1. PD involving the urethra.2 More than three total injections per affected cord for DC.3 More than eight total injections per lifetime for PD.
Required Medical Information	For Dupuytren's contracture (DC): 1. Finger flexion contracture of at least 20 with a palpable cord in a metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint, 2. Documentation that affected joint has not had surgical intervention within the previous 90 days. For Peyronie's disease (PD): 1. Patient has stable disease, defined as unchanged degree of curvature for at least three months, 2. Patient has a curvature of the penis that is between 30 and 90 degrees with a palpable cord, or a cord that is documented through ultrasound, and 3. Patient has intact erectile function, with or without the use of medications. Reauthorization Criteria: For DC: Documentation of fewer than three total injections in affected cord. For PD: Documentation that the curvature of the penis remains greater than 15 degrees. Limited to eight total injections per lifetime.
Age Restrictions	Approved for 18 years and older
Prescriber Restrictions	

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Coverage Duration	DC: Init/reauth 3 mo (limit 3 inj, NTE 6 inj/cord), PD: Init/reauth 3/6 mo (limit 4 inj, NTE 8 inj)
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

XIFAXAN

Products Affected

- Xifaxan

PA Criteria	Criteria Details
Exclusion Criteria	More than 3 treatment courses in a rolling 6-month period for IBS-D
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	
Prescriber Restrictions	For irritable bowel syndrome with diarrhea (IBS-D): Must be prescribed by, or in consultation with, a gastroenterologist.
Coverage Duration	Traveler's diarrhea: 3 days, IBS-D: 14 days, HE: until no longer eligible with the plan
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

Last Updated: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

YONSA

Products Affected

- Yonsa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For initial authorization, all the following must be met: 1. Indication is supported by CMS-approved compendia 2. Documentation of medical rationale for the use of this formulation over the available generic abiraterone 250 mg tablets.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with an oncologist or urologist.
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: 09/02/2025

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

Last Updated: 09/02/2025

ZTALMY

Products Affected

- Ztalmy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	UNDER CMS REVIEW
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
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025

ZURZUVAE

Products Affected

- Zurzuvae

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	Approved for 18 years and older
Prescriber Restrictions	
Coverage Duration	One month (one 14-day fill) per pregnancy
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Last Updated: 09/02/2025