

CRITERIA FOR PRIOR AUTHORIZATION

Minimum Requirements Prior Authorization

BILLING CODE TYPE For drug coverage and provider type information, see the [KMAP Reference Codes webpage](#).

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Non-covered FDA-approved indications, if any, are also listed in Table 1. Per Section 1927 of the Social Security Act [42 USC § 1396r-8(d)(2)], as amended by P.L. 111-148 § 2502, certain drugs, or their medical use, may be excluded from coverage or otherwise restricted.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed age and dosing limits listed in Table 1.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months, unless otherwise specified

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months, unless otherwise specified

Table 1. FDA-approved indication, age, and dosing limits.¹⁻²⁶

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
Amikacin (Arikayce®)	As part of combination therapy for refractory Mycobacterium avium complex (MAC) lung disease in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen.	≥ 18 years	590mg nebulized inhalation once per day.	N/A
Cannabidiol (Epidiolex®)	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS). Treatment of seizures associated with Dravet syndrome (DS).	≥ 1 years	LGS/DS: 10mg/kg orally twice daily. TSC: 12.5mg/kg orally twice daily.	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
	Treatment of seizures associated with Tuberous Sclerosis Complex (TSC).			
Clobazam (Onfi®, Sympazan™)	Adjunctive treatment of seizures associated with LGS.	≥ 2 years	≤30kg: 20mg orally daily. >30kg: 40mg orally daily.	N/A
Dextromethorphan/quinidine (Nuedexta®)	Treatment of pseudobulbar affect (PBA).	≥ 18 years	20mg/10mg orally every 12 hours.	N/A
Elexacaftor/tezacaftor/ivacaftor (Trikafta®)	Cystic fibrosis with ≥1 <i>F508del</i> mutation or a mutation that is responsive based on <i>in vitro</i> data.	≥ 6 years	2 combination tablets (up to 100mg/50mg/75mg/tablet) orally in the morning and 1 ivacaftor tablet (up to 150mg) in the evening.	N/A
Eltrombopag (Promacta®)	<p>Treatment of thrombocytopenia in:</p> <ul style="list-style-type: none"> • Patients age ≥ 1 year with persistent or chronic immune thrombocytopenia (ITP) with insufficient response to corticosteroids, immunoglobulins, or splenectomy; • Adult patients ≥ 18 years of age with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. <p>In combination with standard immunosuppressive therapy for first-line treatment of severe aplastic anemia in patients age ≥ 2 years.</p> <p>Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.</p>	≥ 2 years	150mg orally per day, depending on indication, patient factors, and test results.	N/A
Eluxadoline (Viberzi®)	Irritable bowel syndrome with diarrhea (IBS-D).	≥ 18 years	100mg orally twice daily.	N/A
Fenfluramine (Fintepla®)	Treatment of seizures associated with Dravet Syndrome (DS)	≥ 2 years	0.35mg/kg orally twice daily or 26mg total daily dose.	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
Fosdenopterin (Nulibry™)	Reduce risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A	All ages	9mg/kg IV once daily	N/A
Ivacaftor (Kalydeco®)	Cystic fibrosis with ≥1 CFTR gene mutation that is responsive to ivacaftor based on clinical and/or in vitro assay.	≥ 4 months	<p>4 months to < 6 months, ≥ 5 kg: 25mg packet orally every 12 hours.</p> <p>6 months to < 6 years, 5kg to < 7kg: 25mg packet orally every 12 hours</p> <p>6 months to < 6 years, 7kg to < 14kg: 50mg packet orally every 12 hours.</p> <p>6 months to < 6 years, ≥ 14kg: 75mg packet orally every 12 hours.</p> <p>6 years and older: 150mg tablet orally every 12 hours.</p>	N/A
Lumacaftor/ivacaftor (Orkambi®)	Cystic fibrosis with homozygous <i>F508del</i> mutation.	≥ 2 years	<p>2-5 years, <14kg: 100mg/125mg packet orally every 12 hours.</p> <p>2-5 years, ≥14kg: 150mg/188mg packet orally every 12 hours.</p> <p>6-11 years: 2 tablets (100mg/125mg/tablet) orally every 12 hours.</p> <p>≥12 years: 2 tablets (200mg/125mg) orally every 12 hours.</p>	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
Mecasermin (Increlex®)	Growth failure in severe primary insulin-like growth factor-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.	≥ 2 years	0.12mg/kg SQ twice daily.	N/A
Nintedanib (Ofev®)	Treatment of idiopathic pulmonary fibrosis. Treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype. Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease.	≥ 18 years	1 capsule (150mg) orally twice daily.	N/A
Ospemifene (Osphena®)	Treatment of moderate to severe dyspareunia or moderate to severe vaginal dryness due to menopause.	≥ 18 years and unable to become pregnant	60mg orally once daily.	N/A
Pirfenidone (Esbriet®)	Treatment of idiopathic pulmonary fibrosis	≥ 18 years	1 tablet (801mg) orally three times daily.	N/A
Romiplostim (Nplate®)	Treatment of thrombocytopenia in ITP with insufficient response to corticosteroids, immunoglobulins, or splenectomy in: <ul style="list-style-type: none"> • adults or • pediatric patients ≥ 1 year of age with ITP for at least 6 months. 	≥ 1 year	Up to 10 mcg/kg SQ, depending upon platelet count.	N/A
Romosozumab (Evenity®)	Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or for patients who have failed or are intolerant to other available osteoporosis therapy.	≥ 18 years	Limit 12 monthly doses, with each dose limited to 210mg SQ each month	N/A
Rufinamide (Banzel®)	Adjunctive treatment of seizures associated with LGS.	≥ 1 year	45mg/kg/day up to 3,200mg orally per day.	N/A
Somatropin (Serostim®)	Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.	≥ 18 years	>55kg: 6mg SQ daily. 4445-55kg: 5mg SQ daily.	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
			35-45kg: 4mg SQ daily. <35kg: 0.1mg/kg SQ daily.	
Somatropin (Zorbtive®)	Treatment of short bowel syndrome in adult patients receiving specialized nutritional support.	≥ 18 years	Lesser of 0.1mg/kg or 8mg SQ daily for 4 weeks.	N/A
Solifenacin (Vesicare LS™)	Pediatric neurogenic detrusor overactivity	2-17 years	9-15 kg: 4 mg orally per day >15 to 30 kg: 5 mg orally per day >30 to 45 kg: 6 mg orally per day >45 to 60 kg: 7 8 mg orally per day >60 kg: 10 mg orally per day	N/A
Stiripentol (Diacomit®)	Treatment of seizures associated with Dravet syndrome taking clobazam.	≥ 2 years	3,000mg orally per day.	N/A
Tasimelteon (Hetlioz®)	Non-24-Hour Sleep-Wake Disorder (Non-24) in adults age ≥ 18 years. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients age ≥ 16 years.	≥ 16 years	20mg orally per day.	N/A
Tasimelteon (Hetlioz LQ™)	Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients age 3 to 15 years.	3 to 15 years	≤ 28kg: 0.7mg/kg orally per day. >28kg: 20mg orally per day.	N/A
Telotristat ethyl (Xermelo™)	Carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in those inadequately controlled by SSA therapy.	≥ 18 years	250mg orally three times daily.	N/A
Tezacaftor/ivacaftor (Symdeko®)	Cystic fibrosis with homozygous <i>F508del</i> mutation or ≥1 CFTR gene mutation that is responsive to tezacaftor/ivacaftor based on clinical and/or in vitro assay.	≥ 6 years	6 to <12 years, <30kg: 1 tablet (50mg/75mg) every morning and 1 ivacaftor tablet (75mg) orally every evening. 6 to <12 years, ≥30kg: 1 tablet (100mg/150mg)	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
			every morning and 1 ivacaftor 150mg tablet orally every evening. ≥12 years: 1 tablet (100mg/150mg) every morning and 1 ivacaftor 150mg tablet orally every evening.	

SQ = subcutaneously; LGS = Lennox-Gastaut Syndrome; DS = Dravet Syndrome; TSC = Tuberous sclerosis complex; IBS-D = Irritable bowel syndrome with diarrhea

References:

1. Arikayce (amikacin liposome inhalation suspension) [prescribing information]. Bridgewater, NJ: Insmed; ~~October 2020~~ May 2021.
2. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences, Inc.; ~~October 2020~~ Mar 2022.
- ~~3. Onfi (clobazam) [prescribing information]. Deerfield, IL: Lundbeck; Jun 2018.~~
- ~~4.3.~~ Sympazan (clobazam) [prescribing information]. Warren, NJ: Aquestive Therapeutics; ~~Nov-Mar 2021~~ 18.
- ~~5.4.~~ Nuedexta (dextromethorphan/quinidine) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc. June 2019.
- ~~6.5.~~ Trikafta (elexacaftor/tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; ~~June~~ October 2021.
- ~~7.6.~~ Viberzi (eluxadoline) [package insert]. Madison, NJ: Allergan USA, Inc.; June 2020.
- ~~8.7.~~ Fintepla (fenfluramine) [package insert]. Emeryville, CA: Zogenix, Inc.; ~~June 2020~~ August 2021.
- ~~9.8.~~ Kalydeco (ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; December 2020.
- ~~10.9.~~ Orkambi (lumacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; ~~July 2019~~ May 2020.
- ~~11.10.~~ Increlex (mecasermin) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; ~~Dec 2019~~ May 2020.
- ~~12.11.~~ Ofev (nintedanib) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; ~~October 2020~~ January 2022.
- ~~13.12.~~ Osphena (ospemifene) [package insert]. Florham Park, NJ: Shionogi Inc.; ~~Jan 2019~~ Feb 2022.
- ~~14.13.~~ Esbriet (pirfenidone) [package insert]. South San Francisco, CA: Genentech USA, Inc.; ~~July 2019~~ Feb 2022.
- ~~15.14.~~ Evenity (romosozumab) [package insert]. Thousand Oaks, CA: Amgen Inc.; ~~April 2020~~ October 2021.
- ~~16.15.~~ Banzel (rufinamide) [package insert]. Woodcliff Lake, NJ: Eisai, Inc.; ~~April 2020~~ December 2021.
- ~~17.16.~~ Vesicare LS (solifenacin succinate) [prescribing information]. Northbrook, IL: Astellas Pharma US; ~~May~~ June 2020.
- ~~18.17.~~ Diacomit (stiripentol) [package insert]. Beauvais, France: Biocodex; ~~Aug 2018~~ Nov 2021.
- ~~19.18.~~ Xermelo (telotristat ethyl) [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; ~~Feb 2017~~ Jan 2021.
- ~~20.19.~~ Symdeko (tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; ~~December 2020~~ Aug 2021.
- ~~21.20.~~ Serostim (somatropin) [package insert]. Rockland, MA: EMD Serono, Inc.; ~~June 2019~~ Feb 2022.
- ~~22.21.~~ Zorbtive (somatropin) [package insert]. Rockland, MA: EMD Serono, Inc.; ~~September 2019~~ Feb 2022.
- ~~23.22.~~ Nplate (romiplostim) [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
- ~~24.23.~~ Promacta (eltrombopag) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; ~~February~~ October 2021.

~~APPROVED-DRAFT~~ PA Criteria

~~25-24.~~ Hetlioz (tasimelteon) [package insert]. Washington, DC: Vanda Pharmaceuticals, Inc.; December 2020.

~~26-25.~~ Nulibry (fosdenopterin) [package insert]. Boston, MA: Origin Biosciences, Inc.; ~~February-March~~ 2021.