Initial Approval Date: January 8, 2020
Revised Dates: January 20, 2021, September 10, 2020;
July 8, 2020

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.[1-22]

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). Treatment of seizures associated with Tuberous Sclerosis Complex (TSC).	≥ 1 years	LGS/DS: 10mg/kg orally twice daily. TSC: 12.5mg/kg orally twice daily.	N/A
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 *F508del* mutation or a mutation that is responsive based on *in vitro* data.	≥ 12 years	2 combination tablets (100mg/50mg/75mg/tablet) orally in the morning and 1 ivacaftor 150mg tablet in the evening.	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
Ivacaftor (Kalydeco®)	Cystic fibrosis with ≥1 CFTR gene mutation that is responsive to ivacaftor based on clinical and/or in vitro assay.	≥ 4 months	4 months to < 6 months, ≥ 5 kg: 25mg packet orally every 12 hours. 6 months to < 6 years, 5kg to < 7kg: 25mg packet orally every 12 hours	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
			6 months to < 6 years, 7kg to < 14kg: 50mg packet orally every 12 hours. 6 months to < 6 years, ≥ 14kg: 75mg packet orally every 12 hours. 6 years and older: 150mg tablet orally every 12 hours.	
Lumacaftor/ivacaftor (Orkambi®)	Cystic fibrosis with homozygous *F508del* mutation.	≥ 2 years	2-5 years, <14kg: 100mg/125mg packet orally every 12 hours. 2-5 years, ≥14kg: 150mg/188mg packet orally every 12 hours. 6-11 years: 2 tablets (100mg/125mg/tablet) orally every 12 hours. ≥12 years: 2 tablets (200mg/125mg) orally every 12 hours.	N/A
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	≥ 18 years	1 capsule (150mg) orally twice daily.	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
	systemic sclerosis-associated interstitial lung disease.			
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
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. 44-55kg: 5mg SQ daily. 35-45kg: 4mg SQ daily. <35kg: 0.1mg/kg SQ daily.	N/A
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 mg orally per day >60 kg: 10 mg orally per day	N/A

APPROVED PA Criteria

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
Stiripentol (Diacomit®)	Treatment of seizures associated with Dravet syndrome taking clobazam.	≥ 2 years	3,000mg 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 *F508del* 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) 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.	N/A

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.
2. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences, Inc.; October 2020.
3. Onfi (clobazam) [prescribing information]. Deerfield, IL: Lundbeck; Jun 2018.
4. Sympazan (clobazam) [prescribing information]. Warren, NJ: Aquestive Therapeutics; Nov 2018.
5. Nuedexta (dextromethorphan/quinidine) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc. June 2019.
6. Trikafta (elexacaftor/tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; December 2020.
7. Viberzi (eluxadoline) [package insert]. Madison, NJ: Allergan USA, Inc.; June 2020.
8. Fintepla (fenfluramine) [package insert]. Emeryville, CA: Zogenix, Inc; June 2020.
9. Kalydeco (ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; December 2020.

10. Orkambi (lumacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; July 2019.
11. Increlex (mecasermin) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; Dec 2019.
12. Ofev (nintedanib) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2020.
13. Osphena (ospemifene) [package insert]. Florham Park, NJ: Shionogi Inc.; Jan 2019.
14. Esbriet (pirfenidone) [package insert]. South San Francisco, CA: Genentech USA, Inc.; July 2019.
15. Evenity (romosozumab) [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2020.
16. Banzel (rufinamide) [package insert]. Woodcliff Lake, NJ: Eisai, Inc.; April 2020.
17. Vesicare LS (solifenacin succinate) [prescribing information]. Northbrook, IL: Astellas Pharma US; May 2020.
18. Diacomit (stiripentol) [package insert]. Beauvais, France: Biocodex; Aug 2018.
19. Xermelo (telotristat ethyl) [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; Feb 2017.
20. Symdeko (tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; December 2020.
21. Serostim (somatropin) [package insert]. Rockland, MA: EMD Serono, Inc.; June 2019.
22. Zorbtive (somatropin [package insert]. Rockland, MA: EMD Serono, Inc.; September 2019.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE