Medical Policy

BlueCross BlueShield of Kansas
An independent licensee of the Blue Cross Blue Shield Association

Title: New to Market Drugs: Including Epidiolex (cannabidiol)

- **Prime Therapeutics will review Prior Authorization requests**
  Prior Authorization Form:
  http://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth-6360KS-FP.pdf

  Link to Drug List (Formulary):
  https://www.bcbsks.com/drugs/

Professional

Original Effective Date: October 20, 2014
Revision Date(s): October 20, 2014; January 23, 2015, May 1, 2015; June 16, 2015; July 8, 2015; July 12, 2015; August 2, 2015; January 1, 2016; February 3, 2016; March 21, 2016; June 5, 2016; October 1, 2016; February 9, 2017; April 5, 2017; May 2, 2017; August 15, 2017; September 25, 2017; November 15 2017; November 21, 2017, April 1, 2018; July 1, 2018; October 23, 2018
Current Effective Date: October 23, 2018

Institutional

Original Effective Date: October 20, 2014
Revision Date(s): October 20, 2014; January 23, 2015; May 1, 2015; June 16, 2015; July 8, 2015; July 12, 2015; August 2, 2015; January 1, 2016; February 3, 2016; March 21, 2016; June 5, 2016; October 1, 2016; February 9, 2017; April 5, 2017; May 2, 2017; August 15, 2017; September 25, 2017; November 15, 2017; November 21, 2017, April 1, 2018; July 1, 2018; October 23, 2018
Current Effective Date: October 23, 2018

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

DESCRIPTION

The intent of the prior authorization (PA) criteria is to ensure appropriate selection of patients for treatment according to FDA approved product labeling. The PA defines appropriate use as use in patients who have a Food and Drug Administration (FDA) approved indication, who are receiving the FDA labeled dose, and who do not have any FDA labeled contraindications. Requests will be reviewed when patient-specific documentation has been provided.

Target Agent(s)	Effective Date
Epidiolex (cannabidiol)	October 23, 2018

POLICY

Prior Authorization and Quantity Limit Criteria for Approval

The targeted agent will be approved when **ALL** of the following are met:

1. The patient has an FDA approved indication for the requested agent
   AND
2. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
3. ONE of the following
   a. The requested quantity (dose) is less than or equal to the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is less than the maximum FDA labeled dose OR there is no maximum FDA labeled dose for the requested indication
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval: see table below

FDA Approved Indications and Dosage

Drug	FDA Labeled Indications	FDA Labeled Contra-indications	FDA Labeled Dose	Quantity Limit (if applicable)	Duration of Approval
Epidiolex (cannabidiol)	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older	Hypersensitivity to cannabidiol or any of the ingredients in Epidiolex	Recommended starting dosage is 2.5 mg/kg taken twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day) Based on individual clinical response and tolerability, Epidiolex can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day)	Reviewer must calculate appropriate dosing based on patient's weight	12 months

RATIONALE[1]

Drug	FDA Labeled Indications	FDA Labeled Contraindications	FDA Labeled Dose
Epidiolex (cannabidiol)	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older	Hypersensitivity to cannabidiol or any of the ingredients in Epidiolex	Recommended starting dosage is 2.5 mg/kg taken twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day) Based on individual clinical response and tolerability, Epidiolex can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day)

REVISIONS	
10-20-2014	New policy (FastPAth) published to bcbsks.com on 12-02-2014; policy became effective on 10-20-2014.
	Drugs Added: Esbriet (pirfenidone), Ofev (nintedanib) (effective 10-20-2014)
01-23-2015	Policy published 03-17-2015.
	Revised Title to "New to Market Drugs Including:..." from "Esbriet (pirfenidone), Ofev (nintedanib)"
	Drug Added: Afrezza (effective 01-23-2015).
	Clarified 10-20-2014 Revision.
05-01-2015	Policy published 03-31-2015.
	Esbriet® (pirfenidone) and Ofev® (nintedanib) removed from policy as they are discussed in a new stand-alone policy titled, "Idiopathic Pulmonary Fibrosis (Esbriet® [pirfenidone], Ofev® [nintedanib])" (effective 05-01-2015)
06-16-2015	New to Market Drugs (Including: Afrezza [human insulin]) medical policy removed from bcbsks.com as a stand-alone policy titled, "Afrezza [human insulin]" became effective on 06-01-2015. No new to market drugs remained on the policy at that time.
07-08-2015	Policy published 07-16-2015; update became effective 07-08-2015.
	Drug Added: Orkambi (ivacaftor, lumacaftor).
07-12-2015	Policy published 07-20-2015; update became effective 07-12-2015.
	Drug Added Entresto (sacubitril / valsartan)
	In FDA Approved Indications and Dosage chart: ▪ Corrected Orkambi FDA labeled dose from "Recommended dosage: 801 mg (three capsules) three times daily taken with food." to "Two tablets taken orally every 12 hours with a fat-containing food." ▪ Corrected Orkambi Quantity Limits from "9 capsules/day" to "4 capsules/day".
08-02-2015	Policy published 09-09-2015; update became effective 08-02-2015.
	Drugs Added: Daklinza™ (daclatasvir), Technivie™ (ombitasvir / paritaprevir / ritonavir)
01-01-2016	New to Market Drugs (Including: Daklinza™ [daclatasvir], Entresto™ [sacubitril / valsartan], Orkambi™ [ivacaftor, lumacaftor], Technivie™ [ombitasvir / paritaprevir/ritonavir]) medical policy removed from bcbsks.com as each drug was placed in the following existing or stand-alone policy that became effective on 01-01-2016. No new to market drugs remained on the policy at that time. ▪ Daklinza [daclatasvir] - Hepatitis C Sovaldi and Daklinza ▪ Entresto [sacubitril / valsartan] - Neprilysin Inhibitor (Entresto) ▪ Orkambi [ivacaftor, lumacaftor] - Kalydeco (ivacaftor), Orkambi (lumacaftor/ivacaftor) ▪ Technivie [ombitasvir / paritaprevir/ritonavir]) - Hepatitis C Second Generation Antivirals (Harvoni, Viekira, Technivie)
02-03-2016	Policy published 02-19-2016; update became effective 02-03-2016.
	Drugs Added: ZepatierTM (elbasvir/grazoprevir)
03-21-2016	New to Market Drugs (Including: Zepatier™ (elbasvir/grazoprevir) medical policy removed from bcbsks.com as Zepatier was placed in the Hepatitis C Second Generation Antivirals – Through Preferred Oral Agent(s) medical policy that became effective on 03-21-2016. No new to market drugs remained on the policy at that time.
06-05-2016	Policy published 06-13-2016. Policy retro-effective to 06-05-2016.
	Drug Added: Ocaliva (obeticholic acid)
10-01-2016	New to Market Drugs (Including: Ocaliva (obeticholic acid) medical policy removed from bcbsks.com as Ocaliva was placed in a stand-alone medical policy titled Ocaliva (obeticholic acid) that became effective on 10-01-2016. No new to market drugs remained on the policy at that time.
02-09-2017	Policy published 03-10-2017. Policy retro-effective to 02-09-2017
	Drug Added: Emflaza (deflazacort)
04-05-2017	Policy published 04-19-2017. Policy retro-effective to 04-05-2017.
	Drug Added: Dupixent (dupilumab)
	In Revision section: ▪ Corrected 02-09-2017 Revision to added "Drug Added: Emflaza (deflazacort)"
05-02-2017	Policy published 05-10-2017. Policy retro-effective to 05-02-2017.
	Drug Added: Ingrezza (valbenazine)

REVISIONS	
08-15-2017	Drugs Removed: Dupixent (dupilumab) due to new stand-alone policy titled "Injectable Atopic Dermatitis Agent(s)" and Emflaza (deflazacort) due to new stand-alone policy titled "Emflaza (deflazacort)".
09-25-2017	Policy published 10-06-2017. Policy retro-effective to 09-25-2017.
	Drug Added: Endari (L-glutamine oral powder)
11-15-2017	Drug Removed: Ingrezza (valbenazine) due to new stand-alone policy titled "Ingrezza (valbenazine)".
11-21-2017	Policy published 01-05-2018. Policy retro-effective to 11-21-2017.
	Drug Added: Hemlibra® (emicizumab)
04-01-2018	Drug Removed: Endari (L-glutamine) due to new stand-alone policy titled "Endari (L-glutamine)"
07-01-2018	Drug Removed: Hemlibra (emicizumab-kxwh) due to new stand-alone policy titled "Hemlibra (emicizumab-kxwh)".
10-23-2018	Policy published 10-23-2018. Policy effective to 10-23-2018.
	Drug Added: Epidiolex (cannabidiol)
	In Policy Section: ▪ In Item 3 a removed "within the set" and added "less than or equal to the program" to read "The requested quantity (dose) is less than or equal to the program quantity limit" ▪ In Item 3 b removed "The quantity (dose) requested is within FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength" and added "ALL of the following: i. The requested quantity (dose) is greater than the program quantity limit AND ii. The requested quantity (dose) is less than the maximum FDA labeled dose OR there is no maximum FDA labeled dose for the requested indication AND iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit"

REFERENCES

1. Epidiolex prescribing information. GW Research Ltd. June 2018.