

Pharmacy Policy Bulletin

Title: Epidiolex ® (cannabidiol)

Policy #: Rx.01.209

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▸ Intent:

The intent of this policy is to communicate the medical necessity criteria for **Epidiolex ® (cannabidiol)** as provided under the member's prescription drug benefit.

▸ Description:

Lennox-Gastaut syndrome: A form of severe epilepsy that begins in childhood. It is characterized by multiple types of seizures and intellectual disability. People with Lennox-Gastaut syndrome begin having frequent seizures in early childhood, usually between ages 3 and 5 years.

Dravet syndrome (DS): A severe form of epilepsy which appears during the first year of life characterized by frequent, prolonged seizures often triggered by high body temperature (hyperthermia), developmental delay, speech impairment, loss of full control of bodily movements, low muscle tone, sleep disturbances, and other health problems.

Epidiolex ® (cannabidiol (CBD)); the exact mechanism by which CBD produces its anticonvulsant effects is unknown. CBD may exert a cumulative anticonvulsant effect, modulating a number of endogenous systems including, but not limited to, neuronal inhibition (synaptic and extrasynaptic GABA channels), modulation of intracellular calcium (TRPV, VDAC, GPR55), and possible anti-inflammatory effects (adenosine).

Epidiolex ® is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.

▸ Policy:

Initial criteria

Epidiolex ® (cannabidiol) is approved when ALL of the following are met:

1. Member is 2 years of age or older; AND
2. Baseline CBC, serum transaminases and total bilirubin obtained prior to initiating therapy; AND

3. ONE of the following
 - a. Diagnosis of Dravet syndrome and inadequate response or inability to tolerate ONE of the following
 - i. Clobazam; OR
 - ii. Valproic acid; OR
 - iii. Levetiracetam; OR
 - iv. Topiramate
 - OR
 - b. Diagnosis of Lennox-Gastaut syndrome and inadequate response or inability to tolerate ONE of the following
 - i. Valproic acid; OR
 - ii. Lamotrigine; OR
 - iii. Topiramate; OR
 - iv. Felbamate; OR
 - v. Rufinamide; OR
 - vi. Clobazam

AND

4. Documentation of concurrent use with additional anti-epileptic(s); AND
5. Prescribed by a neurologist

Authorization length: 6 months

Continuation criteria: Documentation of reduction in seizure activity or intensity
 Authorization length: Indefinite

▶ Black Box Warning:

NONE

▶ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ References:

"Dravet Syndrome." Genetic and Rare Diseases Information Center, U.S. Department of Health and Human Services, 7 Aug. 18AD, rarediseases.info.nih.gov/diseases/10430/dravet-syndrome.

"Epidiolex (Cannabidiol) Dosing, Indications, Interactions, Adverse Effects, and More." Medscape Drugs & Diseases - Comprehensive Peer-Reviewed Medical Condition, Surgery, and Clinical Procedure Articles with Symptoms, Diagnosis, Staging, Treatment, Drugs and Medications, Prognosis, Follow-up, and Pictures, 26 June 2018, reference.medscape.com/drug/epidiolex-cannabidiol-1000225#10.

Epidiolex® (cannabidiol) [package insert]. Cambridge, United Kingdom. GW Pharmaceuticals Co. Ltd. June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf

"Lennox-Gastaut Syndrome - Genetics Home Reference - NIH." U.S. National Library of Medicine, National Institutes of Health, 21 Aug. 2018, ghr.nlm.nih.gov/condition/lennox-gastaut-syndrome.

Applicable Drugs:

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Epidiolex®	Cannabidiol

Cross References:

N/A

Policy Version Number:	1.00
P&T Approval Date:	October 11, 2018
Policy Effective Date:	October 12, 2018
Next Required Review Date:	July 12, 2018

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.