Effective Date: 2/2019
Reviewed: 4/2020, 1/2021, 6/2021, 5/2022, 1/2023, 1/2024, 1/2025 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

EPIDIOLEX (cannabidiol)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome, or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Seizures associated with Lennox-Gastaut syndrome or Dravet syndrome
Authorization of 6 months may be granted for treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome when all of the following criteria are met:

A. Member is one year of age or older
B. Medication must be prescribed by or in consultation with a neurologist.
C. Member has a documented inadequate response to prior therapy with at least one anti-epileptic drug. Examples of antiepileptic drugs[4-6]:
   For Lennox-Gastaut syndrome: clobazam, felbamate, lamotrigine, levetiracetam, topiramate, rufinamide, valproate
   For Dravet syndrome: clobazam, levetiracetam, stiripentol, topiramate, valproate
D. Epidiolex will be used in combination with one or more anti-epileptic drugs.
E. Documentation that member has received clinical assessments that include all of the following:
   1. EEG, MRI, or SCN1A gene mutation confirmed by genetic testing
   2. Age at seizure onset, seizure types, and frequency of episodes
   3. Review of risk factors, other causes of seizures (e.g., other medical conditions and medications), family history, and developmental history

Tuberous sclerosis complex (TSC)
Authorization of 6 months may be granted for treatment of TSC when all of the following criteria are met:

A. Member has documented diagnosis of Tuberous sclerosis complex
B. The member is one year of age or older

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who meets both of the following:

A. Documentation of EEG, MRI, or SCN1A gene mutation confirmed by genetic testing has been submitted for members with Lennox-Gastaut syndrome or Dravet syndrome; OR
B. Documentation that members with TSC continue to meet initial criteria; AND
C. Documentation that member has achieved and maintained positive clinical response with Epidiolex therapy as evidenced by reduction in frequency or duration of seizures.

IV. QUANTITY LIMIT

Epidiolex 100 mg/mL: 600 mL per 30 days

V. REFERENCES

1. Epidiolex [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; March 2024.
2. National Institute for Health and Care Excellence (2012). Epilepsies: diagnosis and management. NICE Guideline [CG137]. Updated April 2018. Available at: https://www.nice.org.uk/guidance/cg137. Accessed December 7, 2018.
3. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. Pediatric Neurology 68 (2017) 18-34.
4. Devinsky O, Cross H, Laux L, et al. Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. N Engl J Med 2017;376:2011-20.
5. Thiele EA, Marsh ED, French JA, et al. Cannabidiol in patients with seizures associated with Lennox-Gastaut syndrome (GWPCARE4): a randomised,double-blind, placebo-controlled phase 3 trial. Lancet;391:1085-96, Published online January 24, 2018. Available at: http://dx.doi.org/10.1016/S0140-6736(18)30136-3
6. Epilepsy Foundation. LGS: Seizure Medications. Available at: https://www.epilepsy.com/learn/types-epilepsy-syndromes/lennox-gastaut-syndrome-lgs/treatment/lgs-seizure-medications. Accessed January 22, 2019.