Effective Date: 2/2019
Revised: 4/2020
Reviewed: 4/2020
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 Indications
Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- For new starts only:
  - Prior and current antiepileptic therapy
  - Medical record documentation (i.e., chart notes or laboratory report) indicating the clinical assessments outlined in section IV have been performed.
- For new starts and continuation requests: Medical record documentation (i.e., chart notes, imaging report, or laboratory report) of electroencephalography (EEG), magnetic resonance imaging (MRI), or SCN1A gene mutation

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist.

IV. 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 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, falbamate, lamotrigine, levetiracetam, topiramate, rufinamide, valproate
   - For Dravet syndrome: clobazam, levetiracetam, stiripentol, topiramate, valproate

B. Epidiolex will be used in combination with one or more anti-epileptic drugs.
C. Member is greater or equal to 2 years
D. Member has received documented 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

V. 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
B. Member has achieved and maintained positive clinical response with Epidiolex therapy as evidenced by reduction in frequency or duration of seizures

VI. REFERENCES

1. Epidiolex [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; November 2018.
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.