Reference number(s)
2609-A

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, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older.

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For new starts only:
   1. Prior and current antiepileptic therapy
   2. Medical record documentation (i.e., chart notes or laboratory report) indicating the clinical assessments outlined in section IV have been performed.

B. For new starts and continuation requests:
   1. For Lennox Gastaut syndrome or Dravet syndrome: medical record documentation (i.e., chart notes, imaging report, or laboratory report) of electroencephalography (EEG), magnetic resonance imaging (MRI), or SCN1A gene mutation.
   2. For tuberous sclerosis complex: medical record documentation (i.e., chart notes, imaging report, or laboratory report) of electroencephalography (EEG), magnetic resonance imaging (MRI), or TSC1 or TSC2 gene mutation.

C. For continuation requests: chart notes demonstrating a reduction in frequency or duration of seizures.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

A. 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:

1. Member has a documented inadequate response to prior therapy with at least one antiepileptic drug. Examples of antiepileptic drugs:
   i. For Lennox-Gastaut syndrome: clobazam, felbamate, lamotrigine, levetiracetam, topiramate, rufinamide, valproate

ii. For Dravet syndrome: clobazam, levetiracetam, stiripentol, topiramate, valproate

2. Epidiolex will be used in combination with one or more antiepileptic drugs.
3. Member has received documented clinical assessments that include all of the following:
   i. EEG, MRI, or SCN1A gene mutation confirmed by genetic testing
   ii. Age at seizure onset, seizure types, frequency of episodes, and duration of seizures
   iii. Review of risk factors, other causes of seizures (e.g., other medical conditions and medications), family history, and developmental history

B. Seizures associated with Tuberous Sclerosis Complex

Authorization of 6 months may be granted for treatment of seizures associated with tuberous sclerosis complex when all of the following criteria are met:

1. Member has a documented inadequate response to prior therapy with at least one antiepileptic drug. Examples of antiepileptic drugs: clobazam, vigabatrin, levetiracetam, topiramate, valproate
2. Epidiolex will be used in combination with one or more antiepileptic drugs.
3. Member has received documented clinical assessments that include all of the following:
   i. EEG, MRI, or gene mutation of TSC1 or TSC2 confirmed by genetic testing
   ii. Age at seizure onset, seizure types, frequency of episodes, and duration of seizures
   iii. 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 meet all of the following:

A. Either of the following:
   1. For Lennox-Gastaut syndrome or Dravet syndrome: documentation of EEG, MRI, or SCN1A gene mutation confirmed by genetic testing has been submitted
   2. For tuberous sclerosis complex: documentation of EEG, MRI, or gene mutation of TSC1 or TSC2 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.; October 2020.
2. National Institute for Health and Care Excellence (2012). Epilepsies: diagnosis and management. NICE Guideline [CG137]. Updated February 2020. Available at: https://www.nice.org.uk/guidance/cg137. Accessed May 07, 2021.
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 May 12, 2021.
7. Epilepsy Foundation. Tuberous Sclerosis Complex (TSC). Available at: https://www.epilepsy.com/learn/epilepsy-due-specific-causes/specific-structural-epilepsies/tuberous-

sclerosis-complex-tsc#:~:text=Sclerosis%20Complex%20(TSC)-,Tuberous%20Sclerosis%20Complex%20(TSC),to%20become%20intractable%20to%20medication. Accessed May 12, 2021.

8. American Society of Clinical Oncology (ASCO). Tuberous Sclerosis Complex. Available at: cancer.net/cancer-types/tuberous-sclerosis-complex. Accessed May 12, 2021.