Epidiolex (cannabidiol)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits 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.

POLICY

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 the Criteria for Initial Approval have been performed.
- For new starts and continuation requests:
  - 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
  - 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

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

Prescriber Specialties

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

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:

   a) For Lennox-Gastaut syndrome: clobazam, felbamate, lamotrigine, levetiracetam, topiramate, rufinamide, valproate
   b) 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:
   a) EEG, MRI, or SCN1A gene mutation confirmed by genetic testing
   b) Age at seizure onset, seizure types, frequency of episodes, and duration of seizures
   c) 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 anti-epileptic drugs
3. Member has received documented clinical assessments that include all of the following:
   a) EEG, MRI, or gene mutation of TSC1 or TSC2 confirmed by genetic testing
   b) Age at seizure onset, seizure types, frequency of episodes, and duration of seizures
   c) Review of risk factors, other causes of seizures (e.g., other medical conditions and medications), family history, and developmental history

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

Epidiolex is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

100 kg (220.5 lbs) or less Quantity Limit: up to 800 mL per 30 days
Greater than 100 kg (220.5 lbs) Quantity Limit: up to 1500 mL per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

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- 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.
- 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.

POLICY HISTORY

Policy #: 05.02.58
Original Effective Date: December 1, 2018
Reviewed: July 2022
Revised: October 2021
Current Effective Date: December 10, 2021