

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Epidiolex (cannabidiol)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

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. It is supplied as a 100 mg/mL oral solution. Cannabidiol, the active ingredient, is a cannabinoid that naturally occurs in the *Cannabis sativa* plant (marijuana). It is not a controlled substance.

Dravet syndrome is an epilepsy that usually presents in the first year of life with recurrent seizures which are often prolonged and triggered by fever. With time, other types of seizures may occur, as well as intellectual disability, neurological abnormalities, behavioral issues, and other comorbidities. Complete seizure control is rarely achievable. In 80-85% of cases, variants in the SCN1A gene are present.

Lennox-Gastaut syndrome is a severe developmental epileptic encephalopathy characterized by several seizure types, including drop seizures, as well as cognitive impairment. Seizures usually begin before 8 years of age and

For **reauthorization**:

1. Chart notes have been provided that show the member has decrease in frequency of seizures.

Lennox-Gastaut Syndrome (LGS)

For **initial** authorization:

1. Member is 1 year of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Medication must be used for the treatment of seizures associated with a documented diagnosis of Lennox-Gastaut syndrome; AND
4. Liver function tests (ALT, AST, total bilirubin) have been or will be obtained before starting; AND
5. Member's weight must be documented in chart notes for dosing; AND
6. Chart notes must document the member's seizure frequency on current treatment; AND
7. Chart notes must show trial and failure of at least 2 of the following: valproate, lamotrigine, topiramate, rufinamide, clobazam, felbamate.
8. **Dosage allowed/Quantity limit:** See package insert for titration schedule. The maximum recommended maintenance dosage is 10 mg/kg twice daily (20 mg/kg/day).

For **reauthorization**:

1. Chart notes have been provided that show the member has decrease in frequency of seizures.

Tuberous Sclerosis Complex (TSC)

For **initial** authorization:

1. Member is 1 year of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Medication is being used for the treatment of seizures associated with a documented diagnosis of TSC; AND
4. Liver function tests (ALT, AST, total bilirubin) have been or will be obtained before starting; AND
5. Member's weight must be documented in chart notes for dosing; AND
6. Chart notes must document the member's seizure frequency on current treatment; AND
7. Chart notes must show trial and failure of at least one first-line antiepileptic drug for TSC-related seizure (variable depending on seizure type).
8. **Dosage allowed/Quantity limit:** See package insert for titration schedule. The recommended maintenance dosage is 12.5 mg/kg twice daily (25 mg/kg/day).

For **reauthorization**:

1. Chart notes have been provided that show the member has decrease in frequency of seizures.

17. Cross JH, Auvin S, Falip M, Striano P, Arzimanoglou A. Expert Opinion on the Management of Lennox-Gastaut Syndrome: Treatment Algorithms and Practical Considerations. *Front Neurol.* 2017;8:505. Published 2017 Sep 29. doi:10.3389/fneur.2017.00505

Effective date: 10/01/2022

Revised date: 04/13/2022