CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Epidiolex (cannabidiol)
BENEFIT TYPE	Pharmacy
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 a developmental epileptic encephalopathy 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 persist into adulthood.

Tuberous sclerosis complex is a neurocutaneous disorder most often caused by mutations of the *TSC1* or *TSC2* genes resulting in upregulation of the mechanistic target of rapamycin (mTOR) pathway with subsequent excessive cell growth and proliferation presenting as benign tumors in multiple organs. Epilepsy is the most common neurologic manifestation of the disease, often with onset during infancy as infantile spasms and focal seizures. Neuropsychiatric manifestations are also common.

Epidiolex (cannabidiol) will be considered for coverage when the following criteria are met:

Dravet Syndrome

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. Member has a documented diagnosis of seizures associated with Dravet 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. The member has tried and failed, or has contraindication to, valproic acid and clobazam.
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).

If all the above requirements are met, the medication will be approved for 3 months.

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

If all the above requirements are met, the medication will be approved for an additional 12 months.

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. Member has a documented diagnosis of seizures associated with 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).

If all the above requirements are met, the medication will be approved for 3 months.

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

If all the above requirements are met, the medication will be approved for an additional 12 months.

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. Member has a documented diagnosis of seizures associated with 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).

If all the above requirements are met, the medication will be approved for 3 months.

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

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Epidiolex (cannabidiol) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/31/2018	New policy for Epidiolex created.
08/11/2020	Simplified dosing information. Fixed grammatical errors. Added specialist requirement. Added that they must include weight and baseline/current seizure frequency in chart notes. Removed minimum number of seizures. Changed DS and LGS drug trial criteria to align with clinical literature. Added criteria for new TSC indication. Expanded age approved for DS and LGS.
04/13/2022	Transferred to new template. Added/updated references (all dx). Revised wording of LFT requirement. DS: Removed trial of Diacomit or topiramate. LGS and TSC: Added weight and baseline seizure frequency.
02/10/2025	Updated references.

References:

1. Epidiolex [package insert]. Jazz Pharmaceuticals, Inc.; 2024.
2. Devinsky O, Patel AD, Cross JH, et al. Effect of Cannabidiol on Drop Seizures in the Lennox–Gastaut Syndrome. *N Engl J Med* 2018;378:1888-97.
3. 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. *The Lancet*. Published online January 24, 2018 http://dx.doi.org/10.1016/S0140-6736(18)30136-3.
4. Devinsky O, Cross JH, et al. Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. *N Engl J Med* 2017;376:2011-20
5. Thiele EA, Bebin EM, Bhathal H, et al. Add-on Cannabidiol Treatment for Drug-Resistant Seizures in Tuberous Sclerosis Complex: A Placebo-Controlled Randomized Clinical Trial. *JAMA Neurol*. 2021;78(3):285-292. doi:10.1001/jamaneurol.2020.4607
6. Brigo F, Jones K, Eltze C, Matricardi S. Anti-seizure medications for Lennox-Gastaut syndrome. *Cochrane Database Syst Rev*. 2021;4(4):CD003277. Published 2021 Apr 7. doi:10.1002/14651858.CD003277.pub4
7. 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
8. Strzelczyk A, Schubert-Bast S. Expanding the Treatment Landscape for Lennox-Gastaut Syndrome: Current and Future Strategies. *CNS Drugs*. 2021;35(1):61-83. doi:10.1007/s40263-020-00784-8
9. Wirrell EC, Hood V, Knupp KG, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63(7):1761-1777. doi:10.1111/epi.17274
10. Devi N, Madaan P, Asrar MM, Sahu JK, Bansal D. Comparative short-term efficacy and safety of add-on anti-seizure medications in Dravet syndrome: An indirect treatment comparison. *Seizure*. 2021;91:316-324. doi:10.1016/j.seizure.2021.06.020
11. Epilepsies in children, young people and adults: Treating childhood-onset epilepsies. NICE guideline [NG217]. Published: 27 April 2022. Last updated: 30 January 2025. Available from https://www.nice.org.uk/guidance/ng217/chapter/6-Treating-childhood-onset-epilepsies
12. Northrup H, Aronow ME, Bebin EM, et al. Updated International Tuberous Sclerosis Complex Diagnostic Criteria and Surveillance and Management Recommendations. *Pediatr Neurol*. 2021;123:50-66. doi:10.1016/j.pediatrneurol.2021.07.011

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