CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Epidiolex (cannabidiol)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— See "dosage allowed"
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Epidiolex (cannabidiol) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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. Medication must be used for the treatment of seizures associated with Dravet syndrome; AND
4. Member has serum transaminases (ALT and AST) and total bilirubin baseline levels submitted with prior authorization request prior to starting treatment; 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) ALL of the following first and second line drugs[8,11] for at least 30 days (alone or in combination):
   a) First line: valproic acid AND clobazam;
   b) Second line: Diacomit (requires prior authorization) OR topiramate.
8. **Dosage allowed:** See package insert for titration schedule.[1] The maximum recommended maintenance dosage is 10 mg/kg twice daily (20 mg/kg/day).

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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. Medication must be used for the treatment of seizures associated with Lennox-Gastaut syndrome; AND
4. Member has serum transaminases (ALT and AST) and total bilirubin baseline levels submitted with prior authorization request prior to starting treatment; AND

5. Chart notes must show trial and failure of at least 2 of the following: valproate, lamotrigine, topiramate, clobazam, felbamate, rufinamide (Banzel).[9,10]
6. **Dosage allowed:** See package insert for titration schedule.[1] The maximum recommended maintenance dosage is 10 mg/kg twice daily (20 mg/kg/day).

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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. Medication is being used for the treatment of seizures associated with TSC; AND
4. Member has serum transaminases (ALT and AST) and total bilirubin baseline levels submitted with prior authorization request prior to starting treatment; AND
5. Chart notes must show trial and failure of at least one first-line antiepileptic drug for TSC-related seizure (variable depending on seizure type).
6. **Dosage allowed:** See package insert for titration schedule.[1] The recommended maintenance dosage is 12.5 mg/kg twice daily (25 mg/kg/day).

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Epidiolex (cannabidiol) not medically necessary for the treatment of the diseases that are not listed in this document.

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.
09/16/2021	Annual Review, no changes

References:

1. Epidiolex [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; July 2020.
2. ClinicalTrials.gov Identifier: NCT02091375. Antiepileptic Efficacy Study of GWP42003-P in Children and Young Adults With Dravet Syndrome (GWPCARE1). Available at: https://clinicaltrials.gov/ct2/show/NCT02091375. Accessed on July 26, 2018.
3. ClinicalTrials.gov Identifier: NCT02224560. A Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P; CBD) as Adjunctive Treatment for Seizures Associated With Lennox-Gastaut Syndrome in

Children and Adults (GWPCARE3). Available at: https://clinicaltrials.gov/ct2/show/NCT02224560?term=NCT02224560&rank=1. Accessed on July 26, 2018.
4. ClinicalTrials.gov Identifier: NCT02224690. A Study to Investigate the Efficacy and Safety of Cannabidiol (GWP42003-P; CBD) as Adjunctive Treatment for Seizures Associated With Lennox-Gastaut Syndrome in Children and Adults (GWPCARE4). Available at: https://clinicaltrials.gov/ct2/show/NCT02224690?term=GWPCARE4&cond=Lennox+Gastaut+Syndrome&rank=1. Accessed on July 26, 2018.
5. 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.
6. 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.
7. 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.
8. 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*. 2017;68:18-34. doi:10.1016/j.pediatrneurol.2017.01.025
9. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database Syst Rev. 2013;2013(2):CD003277. Published 2013 Feb 28. doi:10.1002/14651858.CD003277.pub3
10. Arzimanoglou A, French J, Blume WT, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. Lancet Neurol. 2009;8(1):82-93. doi:10.1016/S1474-4422(08)70292-8
11. Knupp KG, Wirrell EC. Treatment Strategies for Dravet Syndrome [published correction appears in CNS Drugs. 2018 Aug;32(8):783. Abstract corrected]. *CNS Drugs*. 2018;32(4):335-350. doi:10.1007/s40263-018-0511-y
12. ClinicalTrials.gov. NCT02544763 [Internet]. Bethesda, MD: U.S. National Library of Medicine; [Accessed on: August 11. 2020]. Available from: https://clinicaltrials.gov/show/NCT02544763.
13. Hess EJ, Moody KA, Geffrey AL, et al. Cannabidiol as a new treatment for drug-resistant epilepsy in tuberous sclerosis complex. *Epilepsia*. 2016;57(10):1617-1624. doi:10.1111/epi.13499
14. Curatolo P, Nabbout R, Lagae L, et al. Management of epilepsy associated with tuberous sclerosis complex: Updated clinical recommendations. *Eur J Paediatr Neurol*. 2018;22(5):738-748. doi:10.1016/j.ejpn.2018.05.006

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