

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

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— up to 20 mg/kg/day
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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 2 years of age or older; AND
2. Medication must be used for the treatment of seizures associated with Dravet syndrome; AND
3. Member has serum transaminases (ALT and AST) and total bilirubin baseline levels submitted with prior authorization request prior to starting treatment; AND
4. Member has been taking one or more antiepileptic drugs (e.g., clobazam, valproate, stiripentol, levatiracetam, topiramate, etc.) and has chart notes confirming presents of at least 4 convulsive seizures (all countable atonic, tonic, clonic, and tonic-clonic seizures) per month.
5. **Dosage allowed:** The recommended starting dosage is 2.5 mg/kg taken twice daily (5mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). Based on individual clinical response and tolerability, Epidiolex can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day). See drug package insert for titration.

***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; AND
2. Member does not have elevations of transaminase levels greater than 3 times the upper limit of normal and bilirubin levels greater than 2 times the upper limit of normal.

***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 2 years of age or older; AND
2. Medication must be used for the treatment of seizures associated with Lennox-Gastaut syndrome; AND
3. Member has serum transaminases (ALT and AST) and total bilirubin baseline levels submitted with prior authorization request prior to starting treatment; AND

4. Member has been taking one or more antiepileptic drugs (e.g., clobazam, valproate, lamotrigine, levatiracetam, rufinamide, etc.) and has chart notes confirming presents of at least of 8 drop seizures per month.
5. **Dosage allowed:** The recommended starting dosage is 2.5 mg/kg taken twice daily (5mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). Based on individual clinical response and tolerability, Epidiolex can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day). See drug package insert for titration.

***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; AND
2. Member does not have elevations of transaminase levels greater than 3 times the upper limit of normal and bilirubin levels greater than 2 times the upper limit of normal.

***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.

References:

1. Epidiolex [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; June, 2018.
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](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.

Effective date: 09/14/2018

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