CareSource

| PHARMACY POLICY STATEMENT<br>**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)<br>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:


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Children and Adults (GWPCARE3). Available at: https://clinicaltrials.gov/ct2/show/NCT02224560?term=NCT02224560&rank=1. Accessed on July 26, 2018.
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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.
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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
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