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, levetiracetam, 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, levetiracetam, 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.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/31/2018</td>
<td>New policy for Epidiolex created.</td>
</tr>
</tbody>
</table>

References:


Effective date: 09/14/2018
Revised date: 08/31/2018