Epidiolex (cannabidiol)  
Effective 02/01/2021

<table>
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<tr>
<th>Plan</th>
<th>MassHealth</th>
<th>☒ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
<th>☒ Quantity Limit</th>
<th>☐ Step Therapy</th>
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<td>Benefit</td>
<td>☒ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
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<td>Specialty Limitations</td>
<td>This medication has been designated specialty and must be filled at a contracted specialty pharmacy.</td>
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<td>Specialty Medications</td>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
<td>Fax: 866-249-6155</td>
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<tr>
<td>Non-Specialty Medications</td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
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<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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<tr>
<td>Medical Specialty Medications (NLX)</td>
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<td>Phone: 844-345-2803</td>
<td>Fax: 844-851-0882</td>
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<td>Exceptions</td>
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**Overview**

Epidiolex is a chemical component of the Cannabis sativa plant indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients at least 2 years of age. It is also indicated for seizures associated with tuberous sclerosis complex (TSC) for patients 1 year and older.

**Coverage Guidelines**

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Epidiolex, excluding when the product is obtained as samples or via manufacturer’s patient assistance program

**OR**

Authorization may be granted when all the following diagnosis specific criteria are met, and documentation has been provided.

**Dravet Syndrome:**
1. Member is at least 2 years old
2. Prescriber is a neurologist or documentation provided of recent neurology consultation
3. Member will be using requested medication as adjunctive therapy
4. Member has had an inadequate response or adverse reaction to at least 2 of the following anticonvulsant agents OR a contraindication to all of the following agents:
a. clobazam  
 b. clonazepam  
 c. ethosuximide  
 d. levetiracetam  
 e. phenobarbital  
 f. stiripentol  
 g. topiramate  
 h. valproic acid  
 i. zonisamide

**Lennox-Gastaut syndrome:**
1. Member is at least 2 years old
2. Prescriber is a neurologist or documentation provided of recent neurology consultation
3. Member will be using requested medication as adjunctive therapy
4. Member has had an inadequate response or adverse reaction to at least 2 of the following anticonvulsant agents OR a contraindication to all of the following agents:
   a. clobazam
   b. felbamate
   c. lamotrigine
   d. topiramate
   e. valproic acid

**Tuberous Sclerosis Complex (TSC)**
1. The member is at least 1 year old
2. The member has been diagnosed with seizures associated with TSC confirmed by genetic testing showing a mutation in either the TSC1 or TS2 gene.
3. The prescriber is a neurologist or documentation provided of recent neurology consultation
4. The member has had an inadequate response, intolerance or has a contraindication with carbamazepine or oxcarbazepine.

**Continuation of Therapy**
Reauthorization may be approved when physician assessment has been provided documenting a decrease in the number of seizures.

**Limitations**
1. Initial approvals will be approved for 3 months
2. Reauthorizations will be approved for 12 months
3. The following quantity limits apply:

   Epidiolex 100mg/mL | 600mL per 30 days

**References**
1. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences, Inc;

**Review History**
04/17/2019 – Reviewed
07/22/2020 – Reviewed and updated July P&T Mtg; references updated; updated Program Type to PA and QL; added QL to criteria; added started and stabilized statement. Effective 10/01/2020.
11/18/2020- Updated and added new indication and criteria for Tuberous Sclerosis Complex. Effective 2/1/21

Disclaimer
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