

**Epidiolex (cannabidiol)**  
**Effective 11/01/2025**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>		Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A			

### Overview

Epidiolex (cannabidiol) indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age or older.

### Coverage Guidelines

Authorization may be granted for members who are new to the plan within the past 90 days currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

### OR

Authorization may be granted when all of the following diagnosis-specific criteria are met:

#### Dravet Syndrome

1. Diagnosis of Dravet Syndrome
2. Member is 1 year of age or older
3. Requested medication is prescribed by or in consultation with a neurologist
4. Member has had an inadequate response or adverse reaction to at least 2 of the following anticonvulsant agents OR a contraindication to all 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. Diagnosis of Lennox-Gastaut Syndrome
2. Member is 1 year of age or older

3. Requested medication is prescribed by or in consultation with a neurologist
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. Member is 1 year of age or older
2. Member has a diagnosis of tuberous sclerosis complex (TSC)
3. Requested medication is prescribed by or in consultation with a neurologist

### **Continuation of Therapy**

Requests for reauthorization will be approved when all of the following criteria are met:

1. Documentation member has had a positive response to therapy (e.g., decrease in number or frequency of seizures member is experiencing)

### **Limitations**

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

Drug Name and Dosage Form	Quantity Limit
Epidiolex 100mg/mL oral solution	26.67 mL per day

### **References**

1. Devinsky O, Cross JH, Laux L, et al. Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. N Engl J Med 2017; 376:2011
2. Devinsky O, Marsh E, Friedman D, et al. Cannabidiol in patients with treatment-resistant epilepsy: an open-label interventional trial. Lancet Neurol 2016; 15:270
3. Epidiolex (cannabidiol) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; July 2025.
4. Gupta A, de Bruyn G, Toussey S, et al. Epilepsy and Neurodevelopmental Comorbidities in Tuberous Sclerosis Complex: A Natural History Study. Pediatr Neurol 2020; 106:10

### **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

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

11/15/2023 – Reviewed and Updated for Nov P&T; updated age requirement for all indications to > 1 year of age per FDA approved indications. Effective 1/1/2024

08/13/2025 – Reviewed and updated at August P&T. Updated specialist prescriber verbiage for all diagnoses. Removed requirement that Epidiolex is prescribed as adjunctive therapy. Removed carbamazepine/oxcarbazepine trial requirement for TSC. Updated reauthorization criteria to require documentation of improvement (e.g., decreased number or frequency of seizures). Effective 11/01/2025.



