

Epidiolex (cannabidiol)
Effective 02/01/2021

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

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 the plan 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

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 | d. levetiracetam | g. topiramate |
| b. clonazepam | e. phenobarbital | h. valproic acid |
| c. ethosuximide | f. stiripentol | i. Zonisamide |
| j. | | |

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 s 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
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
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References

1. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences, Inc;
2. 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
3. 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
4. Gupta A, de Bruyn G, Tousseyn 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.

