Mass General Brigham
Health Plan

Epidiolex (cannabidiol)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
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 programs
OR
Authorization may be granted for members who meet all of the following criteria and documentation has been submitted:

Dravet Syndrome

1. Member is at least 1 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 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 1 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
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;
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.
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