MEDICATION POLICY:
Epidiolex®

Generic Name: Cannabidiol

Therapeutic Class or Brand Name: Epidiolex

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/10/2018

Date Last Reviewed / Revised: 7/7/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

I. Documented diagnosis of one of the following conditions A through C:
   A. Seizures associated with Lennox-Gastaut syndrome (LGS).
   B. Seizures associated with Dravet syndrome (DS).
   C. Seizures associated with tuberous sclerosis complex (TSC).

II. Documented treatment failure with at least two or contraindication to all antiepileptic drugs used for the associated seizure (ie, clobazam, felbamate, lamotrigine, levetiracetam, rufinamide, topiramate, valproic acid).

III. Documentation of patient's baseline serum transaminases (ALT and AST) and total bilirubin levels, and dose is appropriate for liver function (see Appendix).

IV. Treatment is prescribed by or in consultation with a neurologist.

V. Minimum age requirement: 1 year of age or older.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Seizures associated with Lennox-Gestaut syndrome or Dravet syndrome:
  - Dose does not exceed 20 mg/kg daily.

- Seizures associated with tuberous sclerosis complex:
    - Dose does not exceed 25mg/kg daily.

APPROVAL LENGTH

- **Authorization:** 12 months.
- **Re-Authorization:** An updated letter of medical necessity showing maintenance or improvement on medication

APPENDIX

Dose Adjustments in Patients with Hepatic Impairment

Hepatic Impairment	Starting Dosage	Maximum Maintenance Dosage	
		Patients with LGS or DS	Patients with TSC
Mild (Child-Pugh A)	2.5 mg/kg twice daily (5 mg/kg daily)	10 mg/kg twice daily (20 mg/kg daily)	12.5 mg/kg twice daily (25mg/kg daily)
Moderate (Child-Pugh B)	1.25 mg/kg twice daily (2.5 mg/kg daily)	5 mg/kg twice daily (10 mg/kg daily)	6.25 mg/kg twice daily (12.5mg/kg daily)
Severe (Child-Pugh C)	0.5 mg/kg twice daily (1 mg/kg daily)	2 mg/kg twice daily (4 mg/kg daily)	2.5 mg/kg twice daily (5mg/kg daily)

REFERENCES

1. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. *Cochrane Database Syst Rev*. 2013;2013(2):CD003277. Published 2013 Feb 28. doi:10.1002/14651858.CD003277.pub3
2. Thiele EA, Bebin EM, Bhathal H, et al. Add-on cannabidiol treatment for drug-resistant seizures in tuberous sclerosis complex: a placebo-controlled randomized clinical trial. *JAMA Neurol*. 2021;78(3):285-292. doi:10.1001/jamaneurol.2020.4607
3. Krueger DA, Northrup H; International Tuberous Sclerosis Complex Consensus Group. Tuberous sclerosis complex surveillance and management: recommendations of the 2012 International Tuberous Sclerosis Complex Consensus Conference. *Pediatr Neurol*. 2013;49(4):255-265. doi:10.1016/j.pediatrneurol.2013.08.002
4. Wirrell EC, Laux L, Donner E, et al. Optimizing the diagnosis and management of Dravet syndrome: recommendations from a North American consensus panel. *Pediatr Neurol*. 2017;68:18-34.e3. doi:10.1016/j.pediatrneurol.2017.01.025
5. Epidiolex. Prescribing information. Greenwhich Biosciences, LLC; 2023. Accessed November 6, 2023. https://www.epidiolex.com/PI

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.