MEDICATION POLICY:

Epidiolex®

Generic Name: Cannabidiol

Therapeutic Class or Brand Name: Epidiolex

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 7260001700

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/10/2018

Date Last Reviewed / Revised: 12/10/2018

Prior Authorization Criteria

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

I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:

   A. Seizures associated with Lennox-Gestaut Syndrome (LGS).

      1. Inadequate treatment response, intolerance to, or contraindication to at least two antiepileptic drugs (i.e. valproic acid, topiramate, lamotrigine, rufinamide, felbamate).

   B. Seizures associated with Dravet Syndrome (DS).

      1. Inadequate treatment response, intolerance to, or contraindication to at least two antiepileptic drugs (i.e. valproic acid, clobazam, topiramate, levetiracetam, rufinamide).

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

III. Must be prescribed by or in consultation with a neurologist.

IV. Minimum age requirement: 2 years old.

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Dose does not exceed 20 mg/kg daily.

Approval Length

- **Authorization:** 12 months.

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

APPENDIX

Dose Table

Hepatic Impairment	Starting Dosage	Maximum Recommended Dosage
Mild (Child-Pugh A)	2.5 mg/kg twice daily (5 mg/kg daily)	10 mg/kg twice daily (20 mg/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)
Severe (Child-Pugh C)	0.5 mg/kg twice daily (1 mg/kg daily)	2 mg/kg twice daily (4 mg/kg daily)

REFERENCES

1. Hancock EC, Cross, JH, et. al. Treatment of Lennox-Gastaut syndrome. Cochrane Database Syst Rev. 2013 Feb 28;(2):CD003277. doi: 10.1002/14651858.CD003277.pub3. Available at: https://www.ncbi.nlm.nih.gov/pubmed?term=28284397.
2. Wirrell EC, et. al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. Pediatr Neurol. 2017 Mar;68:18-34.e3. doi: 10.1016/j.pediatrneurol.2017.01.025. Epub 2017 Feb 4. Available at: https://www.ncbi.nlm.nih.gov/pubmed?term=28284397.
3. Medi-Span®
4. https://www.epidiolex.com/sites/default/files/EPIDIOLEX_Full_Prescribing_Information.pdf.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
12/10/2018	1. New Policy.