

CLINICAL CRITERIA FOR APPROVING EPIDIOLEX™ (CANNABIDIOL)

Revision November 2018

Note to Prescribers: Cannabidiol (Epidiolex), a non-psychoactive cannabinoid receptor antagonist, is approved for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients ≥ 2 years of age. Please refer to the criteria below when completing a request for prior authorization for Epidiolex. Be sure to include all supporting documentation with the request.

A District of Columbia Fee for Service Medicaid beneficiary may qualify to receive Epidiolex (Cannabidiol) coverage if the following criteria are met:

CLINICAL CRITERIA FOR INITIAL APPROVAL

- Patient must be ≥ 2 years of age; **AND**
- Patient has been diagnosed with Lennox-Gastaut syndrome (LGS) OR Dravet syndrome (DS); and this is done by a neurologist or epileptologist; or a physician in consultation with a specialist in the treatment of Lennox-Gastaut Syndrome and Dravet Syndrome; **AND**
- Seizures have been inadequately controlled/ the patient is refractory to at least two antiepileptic drugs (i.e. clobazam, valproate, lamotrigine, levetiracetam); **AND**
- Prescriber to provide written attestation that Epidiolex will be used in adjunct to ≥ 1 antiepileptic drug; **AND**
- Prescriber to provide serum transaminases (ALT and AST) and total bilirubin levels in all patients prior to starting treatment; attestation to obtain serum transaminases and total bilirubin levels at 1 month, 3 months, and 6 months after initiation of treatment with EPIDIOLEX, and periodically thereafter or as clinically indicated.
- Written attestation that patient is not currently using recreational or medicinal cannabis along with this product.

CLINICAL CRITERIA FOR RENEWAL

Patient continues to meet above criteria; **AND**

- Prescriber to provide written attestation that annual serum transaminases (ALT and AST) and total bilirubin levels have been completed.
- Written attestation of patient improvement, defined by reduction in the frequency of drop or convulsive seizures.

CLINICAL CONSIDERATIONS

- The mechanism by which cannabidiol exerts its anticonvulsant effects is unknown.
- Cannabidiol (Epidiolex) is a Scheduled V controlled substance.

QUANTITY LIMITATIONS

- 20 mg/kg/day (Patient's dose of EPIDIOLEX should not exceed the maximum recommended dose of 20 mg/kg/day)

Package insert: https://www.epidiolex.com/sites/default/files/EPIDIOLEX_Full_Prescribing_Information.pdf