

SPECIALTY GUIDELINE MANAGEMENT

EPIDIOLEX (cannabidiol)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Seizures associated with Lennox-Gastaut syndrome or Dravet syndrome

Authorization of 12 months may be granted for treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in members 1 year of age and older.

B. Seizures associated with Tuberous Sclerosis Complex

Authorization of 12 months may be granted for treatment of seizures associated with tuberous sclerosis complex in members 1 year of age and older.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who meet all of the following:

1. The member meets one of the following
 - a. The member has a diagnosis of Lennox-Gastaut syndrome
 - b. The member has a diagnosis of Dravet syndrome
 - c. The member has a diagnosis of seizures associated with tuberous sclerosis complex
2. The member is at least 1 year of age
3. The member has achieved and maintained positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiating Epidiolex.

IV. REFERENCES

1. Epidiolex [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; February 2022.