Commercial/Healthcare Exchange PA Criteria

Effective: November 7, 2018

Prior Authorization: Epidiolex

Products Affected: Epidiolex (cannabidiol) oral solution

Medication Description:
Epidiolex is indicated to treat seizures associated with Lennox-Gastaut syndrome in patients 1 year or older. In 2 randomized trials of patients 2 to 55 years old with Lennox-Gastaut syndrome and seizures inadequately controlled with at least 1 antiepileptic drug, the addition of cannabidiol compared with the addition of placebo significantly reduced the percentage of drop seizures from baseline after 14 weeks or treatment. Epidiolex is also indicated to treat seizures associated with Dravet syndrome in patients 1 year or older [1]. In addition to standard epileptic treatment, cannabidiol compared with placebo significantly reduced the convulsive-seizure frequency after 14 weeks of treatment but was associated with a higher rate of adverse events, in a randomized trial. Epidiolex is also indicated to treat patients who are at least one year old for seizures caused by tuberous sclerosis complex (TSC).

Covered Uses: Treatment of seizures associated with Lennox‑Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

Exclusion Criteria: N/A

Required Medical Information:
1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 1 year of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist, specializing in seizure therapy.

Coverage Duration: 12 months

Other Criteria:
Dravet Syndrome and Lennox-Gastaut
A. Patient has a diagnosis of Dravet syndrome; OR
B. Patient has a diagnosis of Lennox-Gastaut syndrome; AND
C. Patient had a at least an eight-week trial and failure, contraindication, or intolerance of at least TWO of the following drugs: divalproex, lamotrigine, topiramate, valproic acid, felbamate.

Tuberous sclerosis complex
A. Patient has a diagnosis of tuberous sclerosis complex

References:

1. Epidiolex [package insert]. Carlsbad, CA; Greenwich Biosciences; June 2018.
2. Devinsky O, Patel AD, Cross JH, et al for the GWPCARE3 Study Group. Effect of cannabidiol on drop seizures in the Lennox-Gastaut syndrome. N Engl J Med. 2018 May 17. 378 (20):1888-1897. DOI: 10.1056/NEJMoa1714631.
3. Thiele EA, Marsh ED, French JA, et al for the GWPCARE4 Study Group. Cannabidiol in patients with seizures associated with Lennox-Gastaut syndrome (GWPCARE4): a randomized, double-blind, placebo-controlled phase 3 trial. Lancet. 2018; 391(10125): 1085-1096. DOI: 10.1016/S0140-6736(18)30136-3
4. Devinsky O, Cross JH, Laux L, et al. Trial of cannabidiol for drug-resistant seizures in the Dravet syndrome. N Engl J Med. 2017 May 25;376(21):2011-2020. DOI: 10.1056/NEJMoa1611618.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	11/7/2018
2	Update	Removal of Exclusion: Epidiolex is now schedule V in NY, CT, NJ, and MA	All	11/26/2018
3	Update	Included examples of acceptable drugs for approval	Other Criteria	1/23/2020
4	Update	Criteria updated to capture newly approved FDA indication and expanded indications: Treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.	Age restrictions Covered Uses Medication description Other criteria	8/12/2020