

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Epidiolex® (cannabidiol) Clinical Edit
<b>First Implementation Date:</b>	August 22, 2019
<b>Revised Date:</b>	August 17, 2020
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Epidiolex® (cannabidiol) oral solution

**Why Issue Selected:** Epidiolex® is indicated for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome (LGS) and Dravet syndrome, in patients two years of age and older. LGS is characterized by multiple seizures beginning in childhood. Most of the affected patients have tonic seizures which causes the muscles to contract uncontrollably. Dravet syndrome is a rare genetic condition that appears during the first year of life with frequent fever-related seizures and later on, includes myoclonic seizures (involuntary muscle spasms) and status epilepticus, a potentially life-threatening state of continuous seizure activity. Between the two indications, there are 36,000 patients diagnosed in the US. LGS syndrome represents 1-4% of childhood epilepsies and Dravet syndrome represents less than 1% of all epilepsies. FDA approved in June 2018, Epidiolex is the first ever approved drug for Dravet syndrome. In addition to LGS and DS, Epidiolex is currently in trials for use in Infantile spasms, Rett syndrome, and Tuberous sclerosis complex. Due to the high cost and specific approved indications, MO HealthNet will edit Epidiolex claims to ensure proper utilization.

### Program-Specific Information:

Epidiolex® 100 mg/ml soln	1,510	\$1,873,076.55	\$1,310.00 (WAC)
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**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Epidiolex® (cannabidiol)
- Age range: All appropriate MO HealthNet participants **aged 2 years or older**

## Approval Criteria

### Participant aged 2 years or older AND

- Prescribed by a neurologist or in consultation with a neurologist **AND**
- Documented diagnosis of Lennox-Gastaut syndrome (LGS) in the past year **AND** documented trial of 2 or more anti-epileptic agents for LGS in the past year (includes Banzel, Felbatol, Depakene, Depakote, Klonopin, Onfi, or Sympazan) **OR**
- Documented diagnosis of Dravet syndrome (DS) in the past year **AND**
  - Documented trial of valproate (defined as 30 days in the past year) **AND**
  - Documented trial of clobazam (defined as 30 days in the past 60 days) **AND**
- Documentation of all of the following:
  - Baseline seizure frequency and duration **AND**
  - Baseline serum transaminases (ALT and AST) and total bilirubin levels (obtained prior to treatment) **AND**
  - Documentation of participant's weight for dose determination (max daily dose of 20mg/kg/day) **AND**
- Quantity limit of 200ml per fill
- Approval by Clinical Consultant Review
- Documentation of all of the following required for prior authorization renewal:
  - Documentation of decrease in the frequency and duration of seizures **AND**
  - Documentation of current lab monitoring in regard to serum transaminases and total bilirubin levels **AND**
  - Documentation of participant's current weight for dose determination (max daily dose of 20mg/kg/day)

## Denial Criteria

- Therapy will be denied if no approval criteria are met
- Documentation of hepatic impairment in the past two years

## Required Documentation

Laboratory Results:  
MedWatch Form:

X

Progress Notes:  
Other:

X
X

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

6 months for FDA approved indications (LGS and DS)  
3 months for off-label indications

## References

- Epidiolex (cannabidiol) [package insert]. Carlsbad, CA: Greenwich Biosciences; December 2018
- IPD Analytics. New Drug Approval: Epidiolex (cannabidiol/CBD). July 2018.
- IPD Analytics. Rx Insights: Central Nervous System: Epilepsy Update. May 2019.
- IPD Analytics. CNS: Epilepsy/Seizure Disorder. Accessed February 12, 2020.

*SmartPA Clinical Proposal Form*

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