SmartPA Criteria

Drug/Drug Class:	Epidiolex® (cannabidiol) Clinical Edit
First Implementation Date:	August 22, 2019
Proposed Date:	March 21, 2019
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization of Epidiolex® (cannabidiol) oral solution.

Why was this 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. Epidiolex is the first ever approved drug for Dravet syndrome. Due to the high cost and specific approved indications, MO HealthNet will edit Epidiolex claims to ensure proper utilization.

Program-specific information:

Drug	Cost (WAC)
Epidiolex®	*$12.35/unit* *$1235.00/package*

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Clinical Edit** ☒ **Appropriate Indications**

Data Sources: ☐ **Only administrative databases** ☒ **Databases + Prescriber-supplied**

Setting & Population

- Drug/Drug class for review: Epidiolex® (cannabidiol)
- Age range: all appropriate MO HealthNet participants 2 years of age and older

Approval Criteria

- Documented diagnosis of Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in the past year
- Participant aged 2 years or older
- Prescribed by a neurologist or in consultation with a neurologist
- Documented trial of 2 or more anti-epileptic agents for LGS (no trial required for DS):
    - Trial agents include Banzel, Felbatol, Depakene, Depakote, Klonopin, Onfi, or Sympazan
- Baseline serum transaminases (ALT and AST) and total bilirubin levels obtained prior to treatment
- Documentation of baseline seizure frequency and duration
- Documentation of participant's weight for dose determination
- Quantity limits:
    - 200mL per fill
    - Max daily dose of 20mg/kg/day
- Approval by Clinical Consultant Review
- Required for prior authorization renewal:
    - Documentation of current lab monitoring in regard to participants serum transaminases and total bilirubin levels
    - Documentation of a decrease in the frequency and duration of seizures

Denial Criteria

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

References

1. Epidiolex (cannabidiol) [package insert]. Carlsbad, CA: Greenwich Biosciences; December 2018
2. https://www.epidiolex.com/
3. https://www.greenwichbiosciences.com/