Drug/Drug Class: Epidiolex Clinical Edit
First Implementation Date: August 22, 2019
Revised Date: October 23, 2020
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 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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date Range FFS 1-1-2019 to 12-31-2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidiolex® 100 mg/ml soln</td>
<td>1,510 Claims $1,873,076.55 Spend $1,310.00 (WAC)</td>
</tr>
</tbody>
</table>

Type of Criteria: □ Increased risk of ADE  ☒ Preferred Drug List  ☐ Appropriate Indications  ☒ Clinical Edit  ☐ Only Administrative Databases  ☒ Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Epidiolex® (cannabidiol)
- Age range: All appropriate MO HealthNet participants
Approval Criteria

- 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-OR
- Documented diagnosis of tuberous sclerosis complex in the past year AND documented trial of vigabatrin in the past 2 years 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 25 mg/kg/day for diagnosis of tuberous sclerosis complex, all other indications max daily dose of 20 mg/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 therapy meeting the goals of therapy AND
  - Documentation of reduced seizure burden or improvement in quality of life using a validated scale for the disease state 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 25 mg/kg/day for diagnosis of tuberous sclerosis complex, all other indications max daily dose of 20 mg/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

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progress Notes:</td>
<td>X</td>
</tr>
<tr>
<td>MedWatch Form:</td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td>X</td>
</tr>
</tbody>
</table>

Disposition of Edit

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

Default Approval Period

- 6 months for FDA approved indications (LGS, DS, and tuberous sclerosis complex)
- 3 months for off-label indications
References

- Epidiolex (cannabidiol) [package insert]. Carlsbad, CA: Greenwich Biosciences; December 2018