SmartPA Criteria

Drug/Drug Class: Clobazam Agents Clinical Edit (previously Onfi® Clinical Edit)
First Implementation Date: May 23, 2013
Revised Date: October 24, 2019
Prepared for: MO HealthNet
Prepared by: MO HealthNet/Conduent
Criteria Status: ☒ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of clobazam.

Why was this Issue Selected: Clobazam is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS). LGS is a severe form of epilepsy usually beginning before four years of age. Seizure types include tonic, atonic, atypical absence, and myoclonic. As children with LGS grow older, the seizure types change. Some children have developed normally when LGS begins, but then lose skills, sometimes dramatically, due to uncontrolled seizures. By age six, most children with this syndrome have some degree of mental retardation. Behavioral problems are also common, ranging from hyperactivity to autistic behaviors. Treatment of LGS includes a variety of anti-epileptic medications. Clobazam products provide additional treatment options for LGS and are now available in tablet, liquid, and film formulations.

Program-specific information:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cost (WAC) per unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONFI® 2.5MG/ML SUSP</td>
<td>6.92</td>
</tr>
<tr>
<td>ONFI® 10MG TAB</td>
<td>2.49</td>
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<tr>
<td>ONFI® 20MG TAB</td>
<td>1.29</td>
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<tr>
<td>SYMPAZAN™ 5MG FILM</td>
<td>13</td>
</tr>
<tr>
<td>SYMPAZAN™ 10MG FILM</td>
<td>26</td>
</tr>
<tr>
<td>SYMPAZAN™ 20MG FILM</td>
<td>52</td>
</tr>
</tbody>
</table>

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

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

Setting & Population

- Drug class for review: Clobazam agents
- Age range: all appropriate MO HealthNet participants 2 years of age or older
**Approval Criteria**

- Participant aged 2 years or older AND
- Documented diagnosis of Lennox-Gastaut syndrome (LGS) or Dravet Syndrome in the past 2 years OR
- Documented compliance on current therapy regimen defined as 90/120 days
- If claim for Sympazan:
  - All of the above criteria AND
  - History of generic clobazam oral tablets or solution in the past year
- Approval by Clinical Consultant Review

**Denial Criteria**

- Therapy will be denied if no approval criteria are met

**Approval Period**

Default Approval Period: 1 year

**Disposition of Edit**

Denial: Exception Code “682” (Clinical Edit)

**References**

1. “Aquestive Therapeutics Announces U.S. Food and Drug Administration (FDA) Approval for SYMPAZAN™ (clobazam) Oral Film”. Citizens United for Research in Epilepsy. November 2, 2018
3. Epilepsy Foundation of America, March 2019
4. National Institute of Neurological Disorders and Stroke, March 2019