SmartPA Criteria Proposal

Drug/Drug Class:	Clobazam Agents Clinical Edit
First Implementation Date:	May 23, 2013
Proposed Date:	March 19, 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 clobazam.

Why 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.

Although it does not have an FDA approved indication, clobazam is considered a first line agent for the treatment of Dravet syndrome. Dravet syndrome is a rare form of epilepsy typically appearing during the first year of life with frequent or prolonged seizures. Previously known as Severe Myoclonic Epilepsy of Infancy (SMEI), Dravet Syndrome affects 1:15,700 children, 80% of whom have a mutation in their SCN1A gene. Children with Dravet syndrome typically experience poor development of language and motor skills, hyperactivity and difficulty relating to others. Although an off-label indication, MO HealthNet will approve clobazam for use in Dravet syndrome.

Program-Specific Information:

Date Range FFS 1-1-2019 to 12-31-2019			
Drug	**Claims**	**Spend**	**Cost per unit**
ONFI® 2.5 MG/ML SUSP	2,616	$690,921.83	$0.69 per ml (NADAC)
ONFI® 10 MG TAB	2,922	$199,475.66	$0.49 per tab (NADAC)
ONFI® 20 MG TAB	986	$101,133.99	$0.95 per tab (NADAC)
SYMPAZAN™ 5 MG FILM	0	-	$13.65 per film (WAC)
SYMPAZAN™ 10 MG FILM	1	$1,574.37	$27.30 per film (WAC)
SYMPAZAN™ 20 MG FILM	0	-	$54.60 per film (WAC)

Type of Criteria:

☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

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

Setting & Population

- Drug class for review: Clobazam agents
- Age range: All appropriate MO HealthNet participants aged 2 years or older

Approval Criteria

- Participant aged 2 years or older **AND**
- Documented diagnosis of Lennox-Gastaut syndrome (LGS) in the past 2 years **OR**
- **Documented diagnosis of Dravet Syndrome in the past 2 years OR**
- Documented compliance on current therapy (defined as 90/120 days)
- For Sympazan: Documented therapeutic trial of generic clobazam tablets or solution in the past year
- Approval by Clinical Consultant Review

Denial Criteria

- Therapy will be denied if no approval crieria are met

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

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

Default Approval Period

1 year

References

- SYMPAZAN™ (clobazam) oral film [package insert]. Warren, NJ: Aquestive Therapeutics: November 2018
- Facts & Comparisons. Clobazam Oral. Accessed February 10, 2020.
- IPD Analytics. CNS: Epilepsy/Seizure Disorder. Accessed February 10, 2020.
- Dravet Syndrome Foundation. What is Dravet Syndrome? https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed February 10, 2020.