



## Clinical Edit Criteria Proposal

Drug/Drug Class: Onfi® (clobazam) Tablet / Benzodiazepine

Date: May 23, 2013

Prepared for:

Prepared by: MO HealthNet

**New Criteria**

**Revision of Existing Criteria**

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Onfi® (clobazam tablets).

**Why was this Issue Selected:**

Onfi® is a branded drug product containing clobazam 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. Onfi® provides an additional treatment option for LGS.

**Program-specific information:**

Drug	Claims	Expenses
• Onfi® Tablets	439	\$134955.53

**Setting & Population:**

Patients 2 years of age and older

**Type of Criteria:**

- Increased risk of ADE**       **Non-Preferred Agent**
- Appropriate Indications**

**Data Sources:**

- Only administrative databases**       **Databases + Prescriber-supplied**

## Setting & Population

- Drug for review: Onfi® (clobazam tablets)
- Age range: Patients 2 years of age and older
- Gender: Male and female

## Approval Criteria

- Appropriate diagnosis (Lennox-Gastaut Syndrome)
  - Generalized nonconvulsive epilepsy 345.0
  - Generalized convulsive epilepsy 345.1
- Appropriate age of patient
  - 2 years of age or older
- Documented compliance on current therapy regimen

## Denial Criteria

- Lack of appropriate diagnosis
- Patients younger than 2 years of age

## References

1. Clinical Pharmacology, 2013.
2. Daily Med, 2013.
3. Epilepsy Foundation of America, 2013.
4. National Institute of Neurological Disorders and Stroke, 2012.
5. USPDI, Micromedex, 2013.