# Clinical Policy: Clobazam (Onfi)

Reference Number: PA.CP.PMN.54
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

**Description**
Clobazam (Onfi®) is a benzodiazepine.

**FDA approved indication**
Onfi is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.

**Policy/Criteria**
*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of Pennsylvania Health and Wellness ® that Onfi is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Lennox-Gastaut Syndrome** (must meet all)**:**

1. Diagnosis of Lennox-Gastaut syndrome;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 2 years;
4. Failure of 2 of the following PDL agents: clonazepam, valproic acid (divalproex), lamotrigine, topiramate, felbamate, each trialed for ≥ 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 40 mg/day (2 tablets/day, or 16 mL/day).

**Approval duration: 12 months**

**B. Intractable/Refractory Epilepsy (off-label)** (must meet all)**:**

1. Diagnosis of intractable/refractory epilepsy;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 2 years;
4. Failure of ≥ 4 anti-seizure drugs, unless all are contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 40 mg/day (2 tablets/day, or 16 mL/day).

**Approval duration: 12 months**

**C. Other diagnoses/indications**

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. All Indications** (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit, or documentation supports that member is currently receiving Onfi for Lennox-Gastaut syndrome or intractable/refractory epilepsy;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 40 mg/day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**Approval duration: 12 months**

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
LGS: Lennox-Gastaut syndrome
PDL: preferred drug list

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Lennox-Gastaut syndrome | Patients ≤ 30 kg body weight: initiate at 5 mg daily and titrate as tolerated up to 20 mg daily<br>Patients > 30 kg body weight: initiate at 10 mg daily and titrate as tolerated up to 40 mg daily<br>* A daily dose of Onfi greater than 5 mg should be administered in divided doses twice daily; a 5 mg daily dose can be administered as a single dose. | ≤ 30 kg body weight: 20 mg/day<br>> 30 kg body weight: 40 mg/day |
| Intractable/refractory epilepsy (off-label) | See Lennox-Gastaut syndrome | See Lennox-Gastaut syndrome |

## VI. Product Availability

Tablet: 10 mg and 20 mg with a functional score
Oral suspension: 2.5 mg/mL in 120 mL bottles

## VII. References

1. Onfi Prescribing Information. Deerfield, IL: Lundbeck; December 2016. Available at: https://www.onfihcp.com/. Accessed December 18, 2017.
2. National Guideline Clearinghouse (NGC). Guideline summary: The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2012 Jan 01. Available at: https://www.guideline.gov. Accessed December 18, 2017.
3. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database Syst Rev. 2013 Feb 28;(2).
4. Arzimanoglou A, French J, Blume WT, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. Lancet Neurol. 2009 Jan;8(1):82-93.
5. French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: treatment of refractory epilepsy: report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2004 Apr 27;62(8):1261-73.
6. Mills JK, Lewis TG, Mughal K, et al. Retention rate of clobazam, topiramate and lamotrigine in children with intractable epilepsies at 1 year. Seizure. 2011 June;20(5): 402-405.
7. Gauthier AC, Mattson RH. Clobazam: a safe, efficacious, and newly rediscovered therapeutic for epilepsy. CNS Neurosci Ther. 2015 Jul;21(7):543-8.
8. Montenegro MA, Arif H, Nahm EA, et al. Efficacy of clobazam as add-on therapy for refractory epilepsy: experience at a US epilepsy center. Clin Neuropharmacol. 2008 Nov-Dec;31(6):333-8.
9. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed December 15, 2017.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2018 annual review: added age; added QL of 2 tablets/day, or 16 mL/day to max dose; increased initial approval duration from 6 to 12 months; references reviewed and updated. | 12.18.17 | |