Clinical Policy: Clobazam (Onfi)
Reference Number: CP.PMN.54
Effective Date: 11/12
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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. 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;
4. Dose does not exceed 40 mg/day.

Approval duration: 6 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. Failure of ≥ 4 anti-seizure drugs, unless all are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 40 mg/day.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to 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 Centene benefit, or documentation supports that member is currently receiving Onfi for Lennox-Gastaut syndrome or intractable/refractory epilepsy and has received this medication for at least 30 days;
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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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 – 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 Patients > 30 kg body weight: initiate at 10 mg daily and titrate as tolerated up to 40 mg daily * 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 > 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. Workflow Document

CP.PMN.54.clobazam (Onfi) Q2 2017.do

VIII. References

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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.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added Onfi suspension under available brands. Updated References to reflect current literature search.	11/13	11/13
Updated references. Revised concomitant use drug list.	12/14	12/14
Removed rufinamide from trial and failure drugs. Updated references.	05/15	05/15

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new policy template Updated references to reflect current literature search. Removed removal criteria: If documentation shows improvement in symptoms over prior treatments as this cannot be measured. Updated initial criteria bullet point# D to include duration for t/f of pdl for at least 4 weeks within the past 180 days. Added to renewal criteria: bullet point (a) patient previously on medication through health plan, and (b) dose does not exceed FDA limit per patient's weight. Updated background information including description, mechanism of action.	02/16	05/16
-Lennox-Gastaut: modified requirement related to treatment failure with clonazepam in conjunction with a PDL anticonvulsant to allow trial and failure of any 2 PDL anti-epileptics for Lennox-Gastaut since a neurologist is involved in the patient's care; removed requirement that Onfi "must be used as adjunctive therapy with any of the following PDL anticonvulsants: valproic acid (divalproex), lamotrigine, topiramate, or felbamate" since specialist is involved in patient's care and is better able to select appropriate therapy -Created criteria for treatment of intractable/refractory epilepsy (off-label) -Converted to new template- -Removed age restriction per new template update -Modified weight-based dose criteria to max dose of drug per new template update -Added criteria for continuity of care and documentation of positive response to therapy for re-auth. -Updated references	03/17	05/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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