CENTENE Corporation

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** clobazam (Onfi)
PAGE: 1 of 4	**REFERENCE NUMBER:** NH.PMN.54
EFFECTIVE DATE: 11/12	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 11/12, 12/14, 3/17
PRODUCT TYPE: All	**REVISED:** 11/13, 12/14, 6/16

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Description: Clobazam is a benzodiazepine derivative anticonvulsant that acts primarily through positive allosteric modulation of $GABA_A$ receptors, similar to other clinically useful benzodiazepines. It has the potential for psychological and physical dependence and is classified as a schedule IV controlled substance.

Brand: clobazam (Onfi): 5mg, 10mg, 20mg, 2.5mg/ml suspension

FDA Labeled Indications: Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome

Criteria for Approval:

A. Must be prescribed by a neurologist.
B. Age ≥ 2 years old.
C. Diagnosis of seizures or epilepsy associated with Lennox-Gastaut syndrome.
D. Documented treatment failure with adherent use of clonazepam in conjunction with one of the following preferred drug list (PDL) anticonvulsants at adequate dosing

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for at least ≥ 4 weeks within the past 180 days: valproic acid (divalproex), lamotrigine, topiramate, felbamate or rufinamide at maximum recommended doses, unless contraindicated or patient demonstrates intolerance.

E. Must be used as an adjunctive therapy to any of the following PDL medications: valproic acid (divalproex), lamotrigine, topiramate, felbamate or rufinamide

Approval: Initial Approval: 6 months.
Continued Approval: 12 months **IF;**

A. Dose does not exceed FDA approved limit based on patient's weight:
(a) If patient weighs ≤ 30kg, dose should not exceed 20mg/day;
(b) If patient weight > 30kg, dose should not exceed 40mg/day.

Special Instructions

- Clobazam is classified as a schedule IV controlled substance and should be used cautiously in patients with a history of substance abuse and only if the benefit justifies the potential risk of dependence.
- Ethanol ingestion should be avoided while on clobazam as alcohol increases the bioavailability of clobazam by 50% and thus increase the risk of side effects such as sedation.
- Dosage adjustments are recommended on clobazam in patients with mild to moderate hepatic impairment and in geriatric patients.
- Like other antiepileptic drugs, clobazam may increase the risk of suicidal thoughts or behavior in patients
- Clobazam is excreted into human breast milk and the effects of this infant exposure are unknown, therefore caution should be used in breastfeeding patients.
- Abrupt discontinuation of clobazam should be avoided. Clobazam should be withdrawn gradually to minimize the risk of precipitating seizures, seizure exacerbation, or status epilepticus.

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References:

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5. Cherian KA et al. Lennox-Gastaut Syndrome. Medscape: http://emedicine.medscape.com/article/1176735-overview. Accessed February 2016.
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8. Montouris GD. Rational approach to treatment options for Lennox-Gastaut syndrome. Epilepsia. 2011 July: 52:10-20. [PubMed]. Accessed February 2016. http://onlinelibrary.wiley.com/doi/10.1111/j.1528-1167.2011.03178.x/full.
9. Wilfong A. Epilepsy Syndrome in Children. In: UpToDate, Nordli DR (Ed), UpToDate, Waltham, MA. Accessed February 2016.

Revision Log	
Revision	**Date**
Added Onfi suspension under available brands.	11/13
Updated References to reflect current literature search.	11/13
Updated references. Revised concomitant use drug list.	12/14
Changed initial approval from 3 months to 6 months	06/15

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Removed continued approval criteria if documentation shows improvement in symptoms over prior treatments as this can't be measured. Added to bullet D "at adequate dosing for at least ≥ 4 weeks within the past 180 days" Added continued approval criteria of: Dose does not exceed FDA approved limit based on patient's weight: (a) If patient weighs ≤ 30kg, dose should not exceed 20mg/day; (b) If patient weight > 30kg, dose should not exceed 40mg/day. Updated references to reflect current literature search.	6/16
Annual Review, No changes	03/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file