Clinical Policy: clobazam (Onfi®)
Reference Number: NE.PMN.54
Effective Date: 01/01/2017

**IMPORTANT REMINDER**
This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough 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 the policy; and other indicia of medical necessity. Centene Corporation makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this policy.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based 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 policy is current at the time of approval, may be updated and therefore is subject to change. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or 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.

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**Description**
The intent of the criteria is to ensure that patients follow selection elements established by Centene medical policy for clobazam (Onfi®).

**Policy/Criteria**
It is the policy of health plans affiliated with Centene Corporation® that clobazam (Onfi®) is **medically necessary** for members meeting the following criteria:

**Initial Approval Criteria (must meet all):**

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 formulary anticonvulsants at adequate dosing for at least ≥ 4 weeks within the past 180 days: valproic acid (divalproex), lamotrigine, topiramate or felbamate unless contraindicated or patient demonstrates intolerance;
E. Must be used as adjunctive therapy with any of the following formulary anticonvulsants: valproic acid (divalproex), lamotrigine, topiramate, or felbamate;
F. 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 weighs > 30kg, dose should not exceed 40mg/day.

Approval duration: 3 months

Continued Approval (must meet all as applicable):
A. Member is currently receiving this medication via Centene benefit;
B. 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.

Approval duration: 12 months

Background
Clobazam is a benzodiazepine derivative anticonvulsant medication. The exact mechanism of action for clobazam, a 1, 5-benzodiazepine, is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABAA receptor. It is approved by the FDA for the treatment seizures associated with Lennox-Gastaut syndrome in children 2 years of age and older to adults.

References (or Bibliography):
   [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4710331/].