Clinical Policy: sodium oxybate (Xyrem®)

Reference Number: NE.PMN.42
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 sodium oxybate (Xyrem®).

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

Initial Approval Criteria:

A. Narcolepsy associated with cataplexy or Excessive daytime sleepiness (EDS) (must meet all)
   1. Member must be ≥ 16 years of age;
   2. Member has confirmed diagnosis of narcolepsy with cataplexy;
3. Trial and failure of all of the following (a, b, and c), one of which used within the past 6 months:
   a) Stimulant from each class, namely amphetamines and methylphenidates, at maximized tolerated doses up to 60mg/day for at least ≥ 4 weeks, unless contraindicated;
   b) Armodafinil or Modafinil at maximized tolerated doses for at least ≥ 4 weeks, unless contraindicated to both armodafinil and modafinil (NOTE: both medications require prior authorization);
   c) Venlafaxine for ≥ 2 months, unless intolerant to venlafaxine.
      (i) If intolerant to venlafaxine, trial and failure of generic formulary from one of the following drug classes for ≥ 4 weeks: SSRI (fluoxetine) or TCA (clomipramine, protriptyline), unless contraindicated;
4. No concurrent use of sedative hypnotics as evidenced by review of pharmacy claim history;
5. Dose within FDA approved limit with starting doses of no more than 4.5 grams/day and titration not more often than every two weeks up to a maximum of 9 grams/day.

Approval duration: 3 months

Continued Approval (must meet all as applicable):

A. Member is currently receiving this medication through Centene benefit per provider’s documentation or pharmacy record;
B. Dose must not exceed FDA approved limit of 9 grams per day.

Approval duration: 12 months

Background
Sodium oxybate is the sodium salt of gamma hydroxybutyric acid (GHB), a naturally-occurring central nervous system transmitter with sedative and anesthetic properties. The precise mechanism by which sodium oxybate produces anti-cataplectic activity in patients with narcolepsy is unknown. However, its actions are thought to be mediated through brain receptors specific for GHB as well as through binding to GABA-B receptors. At low doses, the drug inhibits presynaptic dopamine release, while at high doses, dopamine release may be stimulated. It is FDA approved for management of Cataplexy and excessive daytime sleepiness in patients with narcolepsy.

References (or Bibliography):
   http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2276123/
   http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4686331/

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