Sodium Oxybate (Xyrem)
Effective: 7/14/15

Clinical documentation and prior authorization required  ✓  Type of review – case management

Not covered  Type of review – clinical review
Fax: 617-673-0988  ✓

Pharmacy (RX) or medical (MED) benefit  RX  Department to review  RxUM

OVERVIEW

FDA-APPROVED INDICATIONS
Xyrem (sodium oxybate) oral solution is indicated for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of Xyrem (sodium oxybate) for members when all the following criteria for a particular regimen are met and limitations do not apply:

- The request is for a member with the diagnosis of narcolepsy AND
- The member is not concurrently taking a CNS depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, a sedative hypnotic, or the skeletal muscle relaxant carisoprodol AND
- One of the following:
  - The member is new to Tufts Health Plan – Network Health and has been stable on sodium oxybate for at least 3 months prior to enrollment.
  - The member failed a course of therapy with one of the CNS stimulants, modafinil or armodafinil.

LIMITATIONS
- Initial length of approval will be for 6 months. Subsequent lengths of approval will be for 1 year; subsequent approval will require the member had an office visit and was re-assessed for this condition within the past year, and continued therapy with this medication is considered medically necessary, and the member is not concurrently using a CNS depressant.
- Coverage is limited to 9 gm per day.
- Quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria.

CODES
None

REFERENCES
1. Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; April 2014.

APPROVAL HISTORY
- 07/15/10: Reviewed by the Pharmacy and Therapeutics Committee
- 06/04/14: Reviewed by the Pharmacy and Therapeutics Committee
- 07/14/15: Reviewed by the Pharmacy and Therapeutics Committee

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.