Pharmacy Medical Necessity Guidelines: Sodium Oxybate (Xyrem)

Effective: July 12, 2016

Prior Authorization Required ✓ Type of Review – Care Management
Not Covered
Type of Review – Clinical Review ✓
Pharmacy (RX) or Medical (MED) Benefit RX Department to Review RXUM

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

OVERVIEW

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Xyrem (sodium oxybate) is a central nervous system depressant indicated for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Xyrem (sodium oxybate) for Members when all of the following criteria are met:

1. Documented diagnosis of narcolepsy

2. Documentation the Member is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, a sedative hypnotic, or carisoprodol

3. One of the following:
   a) The Member is new to Tufts Health Plan and has been stable on sodium oxybate for at least 3 months prior to enrollment
   b) The Member failed a course of therapy with either modafinil or armodafinil

**LIMITATIONS**

1. Initial length of approval will be for 6 months. Subsequent of 12 months will require documentation 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 central nervous system depressant.

2. The following quantity limitation applies:

   Xyrem (sodium oxybate) oral solution 540 mL per 30 days (9 gm/day)

**CODES**

None

**REFERENCES**

1. Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; Apr 2015.


**APPROVAL HISTORY**

July 15, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- June 4, 2014: No changes
- July 14, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- July 12, 2016: Removed limitation #3 "Quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria."

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity 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 service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.