Pharmacy Medical Necessity Guidelines: Xyrem® (sodium oxybate)

Effective: January 1, 2018

Prior Authorization Required: √
Type of Review – Care Management

Not Covered
Type of Review – Clinical Review: √

Pharmacy (RX) or Medical (MED) Benefit
Department to Review: RX

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 RITogether – A Rite Care + Rhody Health Partners 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. 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 AND

2. For a documented diagnosis of narcolepsy with cataplexy:
   • The Member is new to Tufts Health Plan and has been stable on sodium oxybate for at least 2 months prior to enrollment
   OR
   • Member has had an inadequate response, intolerance, or contraindication to a tricyclic antidepressant (TCA), a selective serotonin receptor inhibitor (SSRI), or venlafaxine.
   OR

3. For a documented diagnosis of narcolepsy without cataplexy:
   • The Member is new to Tufts Health Plan and has been stable on sodium oxybate for at least 2 months prior to enrollment
   OR
   • The Member has had an inadequate response, intolerance, or contraindication to either modafinil or armodafinil

LIMITATIONS

1. Initial length of approval will be for 6 months. Subsequent approval 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. A quantity limitation of 540 mL per 30 days (9 gm/day) applies.

CODES

None

REFERENCES


**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.”
- May 9, 2017: Administrative update, adding Tufts Health RITogether to the template.
- August 8, 2017: Updated criteria to differentiate between narcolepsy with cataplexy versus narcolepsy without cataplexy. Added previous trial requirements for members with narcolepsy with cataplexy.

**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.