Pharmacy Medical Necessity Guidelines: Sodium Oxybate (Xyrem)

Effective: October 1, 2019

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These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**
- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
- Tufts Health Freedom Plan products – small group plans
- CareLinkSM - Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Xyrem (sodium oxybate) is a central nervous system depressant indicated for cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

Xyrem is contraindicated in patients being treated with sedative hypnotics.

**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

2. For a documented diagnosis of **narcolepsy with cataplexy**:
   - Documentation the member has a diagnosis of narcolepsy with cataplexy
   - The prescriber is a neurologist or sleep specialist, or a specialist consult is provided
   - Member has had an inadequate response or intolerance to two, or contraindication to all of the following: tricyclic antidepressant (TCA), atomoxetine, a selective serotonin receptor inhibitor (SSRI), venlafaxine.
   - The Member is new to Tufts Health Plan and has been stable on sodium oxybate for at least 2 months prior to enrollment

3. For a document diagnosis of **excessive daytime sleepiness in narcolepsy**:
   - Documentation the member has a diagnosis of excessive daytime sleepiness due to narcolepsy
   - The prescriber is a neurologist or sleep specialist, or a specialist consult is provided
   - Inadequate response, adverse reaction, or contraindication to one generic cerebral stimulant agent from each class (methylphenidate and amphetamine) AND either modafinil or armodafinil
   - The Member is new to Tufts Health Plan and has been stable on sodium oxybate for at least 2 months prior to enrollment
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; October 2018.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:
1. June 4, 2014: No changes
2. July 14, 2015: No changes
3. January 1, 2016: Administrative change to rebranded template.
4. July 12, 2016: Removed limitation #3 “Quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria.”
6. August 8, 2017: For diagnosis of narcolepsy without cataplexy, changed the length of time of Xyrem use for new members to 2 months. Added venlafaxine as a trial option for the treatment of narcolepsy with cataplexy.
7. August 7, 2018: Effective 1/1/19, Xyrem must be prescribed by or in consultation with a specialist. Updated the diagnosis of “narcolepsy without cataplexy” to “excessive daytime sleepiness”. For a diagnosis of narcolepsy with cataplexy, Members must try and fail two of the following: TCA, selective serotonin reuptake inhibitor, venlafaxine. For the diagnosis of narcolepsy without cataplexy, added that Members must try and fail two stimulants: one methylphenidate product, and one amphetamine product.

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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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.