Pharmacy Medical Necessity Guidelines: Sodium Oxybate Products: Lumryz, Xyrem, and Xywav

Effective: October 1, 2023

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
These pharmacy medical necessity guidelines apply to the following: ☒ 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) and Xywav (calcium, magnesium, potassium, and sodium oxybates) are central nervous system depressants indicated for cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. Xywav is also approved for the treatment of idiopathic hypersomnia in adults. Xyrem is administered twice nightly, while Xywav is administered once or twice nightly depending on the patient's indication, dose, and age.

Lumryz (sodium oxybate) is an extended-release oral suspension approved for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy. Lumryz is administered once nightly.

Xyrem has a high salt content. Patients who are sensitive to salt intake (for example, patients with heart failure, hypertension, or renal impairment) should consider the amount of daily sodium intake in each dose of Xyrem.

Lumryz, Xyrem and Xywav are contraindicated in patients being treated with sedative hypnotics or alcohol. They are also contraindicated in patients with succinic semialdehyde dehydrogenase deficiency.

COVERAGE GUIDELINES

The plan may authorize coverage of Lumryz (sodium oxybate), Xyrem (sodium oxybate) or Xywav (calcium, magnesium, potassium, and sodium oxybates) 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**:

- Documentation the member has a diagnosis of narcolepsy with cataplexy

AND

- The prescriber is a neurologist or sleep specialist, or a specialist consult is provided

AND

- **Lumryz:** Member has had an inadequate response or intolerance to Xyrem or Xywav

AND

- 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.

OR

The Member is new to Tufts Health Plan and has been stable on sodium oxybate for at least 2 months prior to enrollment

OR

3. For a document diagnosis of **excessive daytime sleepiness in narcolepsy**:

- Documentation the member has a diagnosis of excessive daytime sleepiness due to narcolepsy

AND

- The prescriber is a neurologist or sleep specialist, or a specialist consult is provided

AND

- **Lumryz:** Member has had an inadequate response or intolerance to Xyrem or Xywav

AND

- Inadequate response, adverse reaction, or contraindication to all three of the following: modafinil, armodafinil, and Sunosi (solriamfetol)

OR

The Member is new to Tufts Health Plan and has been stable on sodium oxybate for at least 2 months prior to enrollment

4. For a documented diagnosis of **idiopathic hypersomnia:**

- Request is for Xywav

AND

- Documentation that the member has a diagnosis of idiopathic hypersomnia

AND

- The prescriber is a neurologist or sleep specialist, or a specialist consult is provided

AND

- Inadequate response, adverse reaction, or contraindication to both of the following: modafinil and armodafinil

OR

The Member is new to Tufts Health Plan and has been stable on the requested medication for at least 2 months prior to enrollment.

Reauthorization

1. Documentation that the Member had an office visit and was reassessed for the condition within the past year, continued therapy continues to be considered medically necessary, and the Member is not concurrently using a central nervous system depressant.

LIMITATIONS

1. Initial length of approval will be for 6 months. Subsequent approvals will be for 12 months.

CODES

None

REFERENCES

1. Black J, Houghton WC. Sodium oxybate improves excessive daytime sleepiness in narcolepsy. *Sleep*. 2006;29:939-46.
2. Lumryz (sodium oxybate for oral suspension, extended-release) [prescribing information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.
3. Mamelak M. Narcolepsy and Depression and the Neurobiology of Gammahydroxybutyrate. *Progress in Neurobiology*. 2009; 89:193-219.
4. Morgenthaler TI, Kapur VK, Brown TM, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. An American Academy of Sleep Medicine Report. *Sleep*. 2007;30:1705-11.
5. Scammell TE. Treatment of narcolepsy in adults. UpToDate. Accessed May 24, 2019.
6. The U.S. Xyrem® Multicenter Study Group. A Randomized, Double Blind, Placebo-Controlled Multicenter Trial Comparing the Effects of Three Doses of Orally Administered Sodium Oxybate with Placebo for the Treatment of Narcolepsy. *Sleep*. 2002;25: 42-9.
7. U.S. Xyrem® Multicenter Study Group. Sodium Oxybate Demonstrated Long-Term Efficacy for the Treatment of Cataplexy in Patients with Narcolepsy. *Sleep Medicine*. 2004;5:119-23.
8. Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; September 2020.
9. Xyrem® International Study Group. Further Evidence Supporting the Use of Sodium Oxybate for the Treatment of Cataplexy: A Double-Blind, Placebo-Controlled Study in 228 Patients. Sleep Medicine. 2005; 6: 415-421.
10. Xywav (calcium, magnesium, potassium, and sodium oxybates) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; August 2021.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: Effective August 1, 2023, added Lumryz to the MNG, requiring an inadequate response, intolerance, or contraindication to Xyrem or Xywav for its FDA-approved indications. Also updated title of MNG to include Lumryz. Effective October 1, 2023, updated criteria for idiopathic hypersomnia to require that the request is for Xywav.

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.

Provider Services