Generic Name: Sodium oxybate (authorized generic), calcium, magnesium, potassium and sodium oxybates

Applicable Drugs: sodium oxybate (authorized generic), Lumryz®, Xyrem®, Xywav®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/6/2022

Date Last Reviewed / Revised: 7/1/2024

VSI Excluded Drugs: Lumryz®

Formulary Shield Drugs: Xyrem®

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Documented diagnosis of one of the following conditions A through C and must meet criteria listed under applicable diagnosis:

A. Cataplexy associated with narcolepsy

1. Documentation of polysomnogram (PSG) and multiple sleep latency test (MSLT) confirming the diagnosis of narcolepsy (see Appendix Table 1 for diagnostic criteria).
2. Documented treatment failure with or contraindication to dextroamphetamine.
3. For patients 18 years or older, documented treatment failure or contraindication to pitolisant (Wakix®).
4. Minimum age requirement:
   a) Sodium oxybate, Xywav®, Xyrem®: 7 years old
   b) Lumryz®: 18 years old

B. Excessive daytime sleepiness (EDS) associated with narcolepsy

1. Documentation of polysomnogram (PSG) and multiple sleep latency test (MSLT) confirming the diagnosis of narcolepsy (see Appendix Table 1 for diagnostic criteria).
2. Documented treatment failure with or contraindication to both of the following a and b:
   a) Amphetamine, amphetamine-dextroamphetamine, or dextroamphetamine
   b) Modafinil or armodafinil
3. For patients 6 years or older, documented treatment failure with or contraindication to Pitolisant (Wakix®)
4. For patients 18 years or older, documented treatment failure with or contraindication to Pitolisant (Wakix®) AND solriamfetol (Sunosi®)
5. Minimum age requirement:
   a) Sodium oxybate (authorized generic), Xywav®, Xyrem®: 7 years old
   b) Lumryz®: 18 years old

C. Idiopathic hypersomnia (IH)

1. Documentation of all the following a through c:
   a) Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months
   b) MSLT with one of the following:
      (1) Fewer than two SOREMPs
      (2) No SOREMPs and the REM sleep latency on the preceding PSG was ≤ 15 minutes
   c) Presence of at least one of the following:
      (1) MSLT with a mean sleep latency of ≤ 8 minutes
      (2) Total 24-hour sleep time is ≥ 660 minutes on 24-hour PSG or by wrist actigraphy in association with a sleep log
2. Documented treatment failure or contraindication to all the following:
   a) Methylphenidate
   b) Modafinil or armodafinil
   c) Pitolisant (Wakix®)
3. Minimum age requirement: 18 years old.
4. Request is for Xywav.

II. For requests for Lumryz®, there must be documented treatment failure or contraindication to both sodium oxybate (authorized generic) and Xywav®.

III. Documentation of PSG (with at least 6 hours of sleep time) that shows the absence of other pathology which would cause chronic daytime sleepiness or documentation that known contributing pathology is adequately treated.

IV. Treatment is prescribed by or in consultation with a neurologist or sleep disorder specialist.

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Documented succinic semialdehyde dehydrogenase deficiency.
- Concurrent use of sedative hypnotic agents
- Concurrent use of alcohol or opioid narcotics.

- Uncontrolled depressive or neuropsychiatric disorders

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adults:
  - Xywav®, Xyrem®, sodium oxybate: 540 mL per 30 days.
  - Lumryz®: 30 packets per 30 days.
- Children (Xywav®, Xyrem®, or sodium oxybate):
  - Weight 20 kg to < 30 kg: 360 mL per 30 days.
  - Weight 30 kg to < 45 kg: 450 mL per 30 days.
  - Weight ≥ 45 kg: 540 mL per 30 days.

APPROVAL LENGTH

- **Authorization:** 4 months
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

Table 1. Diagnostic criteria for narcolepsy

Narcolepsy type 1 (with cataplexy)
Criteria a and b must be met: a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. b) At least one episode of cataplexy defined as generally brief [≤ 2 min], usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness c) The presence of one or both of the following: o Mean sleep latency of ≤8 minutes and ≥1 SOREMPs on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT. o CSF hypocretin-1 deficiency defined as orexin concentration is < 110 pg/nl or < 1/3 of the normative values with the same standardized assay)
Narcolepsy type 2

Criteria a through e must be met:

a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

b) A mean sleep latency of ≤8 minutes and ≥2 SOREMPs are found on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.

c) Cataplexy is absent.

d) Either CSF orexin concentration has not been measured or CSF orexin concentration is either >110 pg/mL or >1/3 of mean values obtained in normal subjects with the same standardized assay.

e) The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal.

REFERENCES

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2. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(9):1881-1893. https://jcsm.aasm.org/doi/10.5664/jcsm.9328
3. Bassetti CLA, Kallweit U, Vignatelli L, et al. European guideline and expert statements on the management of narcolepsy in adults and children. *Eur J Neurol*. 2021;28(9):2815-2830. doi:10.1111/ene.14888
4. Lumryz® [Package Insert], Chesterfield, MO; Avadel CNS Pharmaceuticals, LLC; May 2023. https://www.avadel.com/lumryz-prescribing-information.pdf
5. Wakix® [Package Insert], Plymouth Meeting, PA; Harmony Biosciences, LLC; December 2022. https://wakix.com/pdf/wakix-tablets-pi.pdf
6. Xyrem® [Package Insert], Palo Alto, CA; Jazz Pharmaceuticals, Inc.; April 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021196s042lbl.pdf
7. Xywav® [Package Insert], Palo Alto, CA; Jazz Pharmaceuticals, Inc.; April 2023. https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf
8. Xywav® and Xyrem® REMS. Risk Evaluation Mitigation Strategies. https://www.xywavxyremrems.com/. Accessed August 21, 2023.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.