

Generic Name: Sodium oxybate and calcium, magnesium, potassium and sodium oxybates

Applicable Drugs: Xyrem®, Xywav®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/6/2022

Date Last Reviewed / Revised: 12/19/2022

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V 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).
 2. Documented treatment failure with one or contraindication to all the following: venlafaxine, duloxetine, fluoxetine, or tricyclic antidepressant (ie, clomipramine).
 3. Documented treatment failure or contraindication to pitolisant (Wakix).
 4. For requests for Xyrem, there must be documented treatment failure or contraindication to Xywav.
 5. Minimum age requirement: 7 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 for diagnostic criteria.
 2. Documented treatment failure or contraindication to both of the following a and b:
 - a) Amphetamine, amphetamine-dextroamphetamine, or dextroamphetamine
 - b) Methylphenidate
 3. For patients 18 years or older, documented treatment failure or contraindication to all the following a through c:
 - a) Armodafinil or modafinil
 - b) Solriamfetol (Sunosi)
 - c) Pitolisant (Wakix)
 4. For requests for Xyrem®, there must be documented treatment failure or contraindication to Xywav
 5. Minimum age requirement: 7 years old.

C. Idiopathic hypersomnia (IH)

1. Documentation of all the following a through d:
 - 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 \leq 15 minutes
 - c) Presence of at least one of the following:
 - (1) MSLT with a mean sleep latency of \leq 8 minutes
 - (2) Total 24-hour sleep time is \geq 660 minutes on 24-hour PSG or by wrist actigraphy in association with a sleep log
 - d) Baseline scoring on at least one of the following
 - (1) Score \geq 10 on Epworth Sleepiness Scale (ESS)
 - (2) Score \geq 22 on Idiopathic Hypersomnia Severity Scale (IHSS)
2. Documented treatment failure or contraindication to all the following:
 - a) Amphetamine, amphetamine-dextroamphetamine, or dextroamphetamine
 - b) Methylphenidate
 - c) Armodafinil or modafinil
 - d) Pitolisant (Wakix)
3. Minimum age requirement: 18 years old.
4. Request is for Xywav.

- II. 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.
- III. Treatment is prescribed by or in consultation with a neurologist or sleep disorder specialist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. 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.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adults: Quantities of up to 540 mL per 30 days.
- Children:
 - Weight 20 kg to < 30 kg: Quantities up to 360 mL per 30 days.
 - Weight 30 kg to < 45 kg: Quantities up to 450 mL per 30 days.
 - Weight \geq 45 kg: Quantities up to 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)
<p>Criteria a and b must be met:</p> <ul style="list-style-type: none"> a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. b) The presence of one or both of the following: <ul style="list-style-type: none"> ○ Cataplexy and a mean sleep latency of \leq8 minutes and \geq2 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. ○ CSF orexin-A concentration, measured by immunoreactivity, is either \leq110 pg/mL or $<$1/3 of mean values obtained in normal subjects
Narcolepsy type 2
<p>Criteria a through e must be met:</p> <ul style="list-style-type: none"> 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

1. Chervin RD. Idiopathic hypersomnia. In: Sammel TE, Eichler AF, ed. *UpToDate*. UpToDate; 2022. Accessed December 16, 2022. https://www.uptodate.com/contents/idiopathic-hypersomnia?search=idiopathic%20hypersomnia%20treatment&source=search_result&selectedTitle=1~17&usage_type=default&display_rank=1#H2247436
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. doi:10.5664/jcsm.9328
3. Scammell TE. Clinical features and diagnosis of narcolepsy in adults. In: Benca R, Eichler A, ed. *UpToDate*. UpToDate; 2022. Accessed December 16, 2022. https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-narcolepsy-in-adults?search=narcolepsy&source=search_result&selectedTitle=1~120&usage_type=default&display_rank=1#H23706075
4. Scammell TE. Treatment of narcolepsy in adults. In: Benca R, Eichler A, ed. *UpToDate*. UpToDate; 2022. Accessed December 1, 2022. <https://www.uptodate.com/contents/treatment-of-narcolepsy-in-adults#H2092033727>
5. Xyrem. Prescribing information. Jazz Pharmaceuticals, Inc; 2022. Accessed December 1, 2022. <https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf>
6. Xywav. Prescribing information. Jazz Pharmaceuticals, Inc; 2022. Accessed December 1, 2022. <https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf>

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.