

Generic Name: Sodium Oxybate

Therapeutic Class or Brand Name: Xyrem®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/8/2014

Date Last Reviewed / Revised: 7/15/2021

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. Cataplexy associated with narcolepsy.
 - B. Excessive daytime sleepiness (EDS) associated with narcolepsy and criterion 1 is met:
 1. Documented failure, intolerance, or contraindication to Provigil® (modafinil) or Nuvigil® (armodafinil).
- II. Minimum age requirement: 7 years old.
- III. Patient and physician must enroll in Xywav™ and Xyrem® REMS Program.
- IV. Prescribing physician must be a neurologist or a sleep disorder specialist.

EXCLUSION CRITERIA

- Patient has succinic semialdehyde dehydrogenase deficiency.
- Patient is being treated with sedative hypnotic agents or using alcohol.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Adults: Quantities of up to 540mL per 30 days.
- Children:
 - Weight 20 kg to < 30 kg: Quantities up to 360mL per 30 days.
 - Weight 30 kg to < 45 kg: Quantities up to 450mL per 30 days.
 - Weight ≥ 45 kg: Quantities up to 540 mL per 30 days.

APPROVAL LENGTH

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

APPENDIX

N/A

REFERENCES

1. <http://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf> .
2. http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021196s005lbl.pdf .
3. Medi-Span®.

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.