



MEDICATION POLICY

Generic Name: Sodium Oxybate

Therapeutic Class or Brand Name: Xyrem®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 4/8/14

Date Last Reviewed/Revised: 9/29/16

GPI Code: 6245006020

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: 16 years old.
- III. Patient and physician must enroll in 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:

- Quantities of up to 540mLs per 30 days.

Approval Length:

- **Authorization:** 1 year.

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 judgment in providing the most appropriate care for their patients.



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- **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/2005/021196s0051bl.pdf.
3. [Medi-Span](#).
4. <http://blue.regence.com/trgmedpol/drugs/dru093.pdf>.

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<i>Historical Tracking Of Changes Made To Policy</i>	
9/29/2016	<ol style="list-style-type: none">1. Changed “III. Patient and physician must enroll in Xyrem Success Program®” to “III. Patient and physician must enroll in Xyrem® REMS Program” under Prior Authorization Criteria.2. Updated “http://www.xyrem.com/images/XYREM_PI.pdf” to “http://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf” under References.
5/5/2015	<ol style="list-style-type: none">1. Policy reviewed: no changes made.

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