MEDICATION POLICY:
Xyrem®

Generic Name: Sodium Oxybate

Therapeutic Class or Brand Name: Xyrem®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 6245006020

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/8/2014

Date Last Reviewed / Revised: 2/6/2019

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 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 < 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®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
2/6/2019	1. **Changed** age criteria **from** 16 years **to** 7 years **under Prior Authorization Criteria** for **new pediatric indication**. • **Changed** quantity limits **under Quantities/Days Supply Restrictions from** "Quantities of up to 540mL per 30 days" **to** • Adults: Quantities of up to 540mL per 30 days. • Children: o Weight < 30 kg: Quantities up to 360mL per 30 days. o Weight 30 kg to < 45 kg: Quantities up to 450mL per 30 days. o Weight ≥ 45 kg: Quantities up to 540 mL per 30 days. 2. **Deleted** obsolete URL **under References** item #4 http://blue.regence.com/trgmedpol/drugs/dru093.pdf.
12/7/2017	1. Policy reviewed: no changes made.
9/29/2016	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	1. Policy reviewed: no changes made.

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.