Updated: 01/2019
PARP Approved: 01/2019

Prior Authorization Criteria

Xyrem (sodium oxybate)

All requests for Xyrem (sodium oxybate) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Xyrem (sodium oxybate) all of the following criteria must be met:

- The member must be 7 years of age or older
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be prescribed by or in consultation with a neurologist or sleep specialist
- Documentation within any time frame that the member has had daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following:
    - Cerebrospinal fluid (CSF) hypocretin-1 deficiency one-third less than normal or <110 pg/mL
    - Polysomnogram sleep study test with REM sleep latency ≤ 15 minutes
    - Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes with ≥ 2 sleep onset REM sleep periods (SOREMP)

Coverage may be provided with a diagnosis of excessive daytime sleepiness associated with narcolepsy the following criteria is met:

- Documentation of a baseline Epworth Sleepiness Scale score or Epworth Sleepiness Scale (Child and Adolescent) Score
- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to one of the following: (please note all require a prior authorization for members 21 years of age and older)
    - Amphetamines
    - Methamphetamine
    - Dextroamphetamine
    - Methylphenidate

- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to one of the following: (please note all require a prior authorization)
    - Modafinil
    - Armodafinil

Coverage may be provided with a diagnosis of cataplexy with narcolepsy the following criteria is met:

- Documentation of weekly cataplexy attacks at baseline prior to treatment with Xyrem

- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to two of the following:
    - a tricyclic antidepressant
    - a SSRI
    - venlafaxine

- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
    - For Excessive daytime sleepiness associated with narcolepsy
        - Documentation of an improvement in Epworth Sleepiness Scale score from baseline
    - For cataplexy with narcolepsy
        - Documentation of a decrease in the number of cataplexy attacks from baseline

- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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XYREM (SODIUM OXYBATE) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Frequency:	Duration:	
Is the member currently receiving requested medication? ☐ Yes ☐ No		Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ☐ Excessive daytime sleepiness with narcolepsy ☐ Cataplexy associated with narcolepsy
☐ Other: _____

(Please provide chart documentation to support the above diagnosis please include sleep study results)

If member has excessive daytime sleepiness associated with narcolepsy please provide a baseline Epworth Sleepiness Scale score or Epworth Sleepiness Scale Child and Adolescent Score: _____ Date taken:_____

If the member has cataplexy please provide baseline number of weekly cataplexy attacks _____ Date: _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

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REAUTHORIZATION
Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No If member has excessive daytime sleepiness associated with narcolepsy please provide an Epworth Sleepiness Scale score taken after initiating therapy: _____ Date taken:_____ If the member has cataplexy please provide the number of weekly cataplexy attacks since initiating therapy _____ Date: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date