

Prior Authorization Criteria

Xywav (calcium, magnesium, potassium, and sodium oxybates) and Xyrem (sodium oxybate)

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

Xywav (calcium, magnesium, potassium, and sodium oxybates) and Xyrem (sodium oxybate)
Prior Authorization Criteria:

For all requests for Xywav (calcium, magnesium, potassium, and sodium oxybates) and Xyrem (sodium oxybate) all of the following criteria must be met:

- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- 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.

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
- Documentation of at least one of the following:
 - Cerebrospinal fluid hypocretin-1 deficiency one-third less than normal or <110 pg/mL
 - Polysomnography sleep study test with REM sleep latency ≤ 15 minutes.
 - Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes and ≥ 2 sleep onset REM sleep periods (SOREMP)
- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to one of the following: (please note may require prior authorization)
 - Modafinil
 - Armodafinil
- If requesting Xywav, must provide documentation showing the member has tried and failed or had an intolerance or contraindication to Xyrem (sodium oxybate)

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 Xywav OR Xyrem
- Documentation of at least one of the following:
 - Cerebrospinal fluid hypocretin-1 deficiency one-third less than normal or <110 pg/mL
 - Polysomnography sleep study test with REM sleep latency ≤ 15 minutes.
 - Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes and ≥ 2 sleep onset REM sleep periods (SOREMP)
- 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
- If requesting Xywav, must provide documentation showing the member has tried and failed or had an intolerance or contraindication to Xyrem (sodium oxybate)

Coverage may be provided with a diagnosis of idiopathic hypersomnia if the following criteria is met:

- Documentation of a baseline Epworth Sleepiness Scale score OR documentation of a baseline Idiopathic Hypersomnia Severity Score
- Insufficient sleep syndrome is confirmed absent via at least a week of wrist actigraphy or lack of improvement after an adequate trial of increased nocturnal time in bed
- Documentation of a MSLT showing fewer than 2 SOREMPs, OR, no SOREMPs, if the REM latency on the preceding sleep study was ≥ 15 minutes
- Cataplexy is confirmed to be absent
- Must provide documentation of at least one of the following:
 - MSLT shows a mean sleep latency of ≤ 8 minutes
 - Total 24-hour sleep time is ≥ 660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to one of the following: (please note may require prior authorization)
 - Modafinil
 - Armodafinil

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
- For idiopathic hypersomnia



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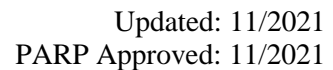
Updated: 11/2021
PARP Approved: 11/2021

- Documentation of an improvement in Epworth Sleepiness Scale score from baseline OR improvement in Idiopathic Hypersomnia Severity Score.

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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**XYWAV (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES) AND XYREM (SODIUM OXYBATE)
PRIOR AUTHORIZATION FORM (PAGE 2 of 2)**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway HealthSM 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

MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

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: _____

If the member has idiopathic hypersomnia, please provide a Epworth Sleepiness Scale score OR Idiopathic Hypersomnia Severity Score since initiating therapy. ☐ ESS: _____ ☐ IHSS: _____ Date: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date