Updated: 11/2021
PARP Approved: 11/2021

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 <u>diagnosis</u> 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

- 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.

Gateway Health℠ It's Wholecare.

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XYWAV (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES) AND 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:	
Health Options ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

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

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

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

Place of Service Information

Name:	NPI:
Address:	Phone:

Diagnosis: ☐ Excessive daytime sleepiness with narcolepsy ☐ Cataplexy associated with narcolepsy ☐ Idiopathic hypersomnia ☐ 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: _____

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

CURRENT or PREVIOUS THERAPY

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

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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 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

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