

Request for Prior Authorization for Xywav (calcium, magnesium, potassium and sodium oxybates), Xyrem (sodium oxybate), and Lumryz (sodium oxybate)

Website Form – <a href="https://www.highmarkhealthoptions.com">www.highmarkhealthoptions.com</a>
Submit request via: Fax - 1-855-476-4158

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

For all requests for Xywav (calcium, magnesium, potassium, and sodium oxybates), Xyrem (sodium oxybate), and Lumryz (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 <u>diagnosis</u> 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:
  - O Cerebrospinal fluid hypocretin-1 deficiency one-third less than normal or <110 pg/mL
  - o Polysomnography sleep study test with REM sleep latency  $\leq$  15 minutes.
  - $\circ$  Multiple sleep latency testing with a mean sleep latency  $\le 8$  minutes and  $\ge 2$  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 all require a prior authorization)
  - Modafinil
  - o Armodafinil
- If requesting Xywav or Lumryz (sodium oxybate), 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:
  - O Cerebrospinal fluid hypocretin-1 deficiency one-third less than normal or <110 pg/mL
  - $\circ$  Polysomnography sleep study test with REM sleep latency  $\leq 15$  minutes.
  - O Multiple sleep latency testing with a mean sleep latency  $\leq 8$  minutes and  $\geq 2$  sleep onset REM sleep periods



• If requesting Xywav or Lumryz (sodium oxybate), 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:
  - o MSLT shows a mean sleep latency of ≤8 minutes
  - o 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 all require a prior authorization for members 21 years of age and older)
  - Modafinil
  - Armodafinil

#### **Initial Duration of Approval:** 3 months

### Reauthorization criteria

- o For Excessive daytime sleepiness associated with narcolepsy
  - Documentation of an improvement in Epworth Sleepiness Scale score from baseline
- o For cataplexy with narcolepsy
  - Documentation of a decrease in the number of cataplexy attacks from baseline
- o 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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.



## XYWAV (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES) XYREM (SODIUM OXYBATE), AND LUMRYZ 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 Highmark Health Options Pharmacy Services. FAX: (855) 476-4158							
If needed, you may call to speak to a Pharmacy Services Representative.							
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm PROVIDER INFORMATION							
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Requesting Provider: Provider Specialty:		Office Cor	taat.				
Office Address:		Office Pho					
Office Address.		Office Fax					
	MEMBER II	NFORMATION					
Member Name:	N. W.	DOB:					
Member ID:		Member weight:	Height:				
	REQUESTED DR	UG INFORMATION	6				
Medication:		Strength:					
Directions:		Quantity:	Refills:				
Is the member currently receiving re	quested medication? Yes		Medication Initiated:				
			ion may be necessary for the life of the				
patient? Yes No							
		nformation					
	<u> </u>	ically, JCODE:					
Place of Service: Hospital	<b></b>	er's home  Other					
	Place of Serv	ice Information					
Name:		NPI:					
Address:		Phone:					
	Diagnosis:   Excessive daytime sleepiness with narcolepsy   Cataplexy associated with narcolepsy   Idiopathic hypersomnia						
Other:							
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(Please provide chart documentation	to support the above diagnos	sis please include sleep	study results)				
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# XYWAV (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES) XYREM (SODIUM OXYBATE), AND LUMRYZ( SODIUM OXYBATE) (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 Highmark Health Options Pharmacy Services. FAX: (855) 476-4158  If needed, you may call to speak to a Pharmacy Services Representative.  PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm  MEMBER INFORMATION  Member Name:  DOB:  Member ID:  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:  Date:  Date:  Date:  Date:  SUPPORTING INFORMATION or CLINICAL RATIONALE					
If needed, you may call to speak to a Pharmacy Services Representative.  PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm  MEMBER INFORMATION  Member Name:    DOB:	Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation				
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Member Name:    DOB:	If needed, you may call to speak to a Pharmacy Services Representative.				
Member Name:    Member ID:   Member weight:   Height:	PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm				
Member ID:	MEMBER INFORMATION				
Has the member experienced a significant improvement with treatment?	Member Name:	DOB:			
Has the member experienced a significant improvement with treatment?	Member ID:	Member weight:	Height:		
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