AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Sodium Oxybate Products

Drug Requested: (select **ONE** from below)

❑ **Lumryz™** (sodium oxbyate) **ER oral suspension**	❑ **Sodium Oxybate oral solution**
❑ **Xyrem®** (sodium oxybate) **IR oral solution**	❑ **Xywav®** (sodium oxybate) **low sodium IR oral solution**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- **To guard against diversion and misuse, the drug's distribution is limited and prescribers MUST adhere to a risk management protocol, the Lumryz™/Xyrem®/Xywav® REMS Program**.
- **All diagnosis of narcolepsy and Idiopathic Hypersomnia must be in accordance with the third edition of the International Classification of Sleep Disorders (ICSD-3), which is a fully revised version of the American Academy of Sleep Medicine's manual of sleep disorders nosology, published in cooperation with international sleep societies and is the key reference work for the diagnosis of sleep disorders.**

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- **Lumryz™/Xyrem®/Xywav® for narcolepsy with or without cataplexy will not be approved in conjunction with Sunosi® or Wakix®. The Health Plan considers the use of concomitant therapy with Lumryz™/Xyrem®/Xywav® and Sunosi® or Wakix® to be experimental and investigational. Safety and efficacy of these combinations has not been established and will not be permitted. In the event a member has an active Sunosi® or Wakix® authorization on file, all subsequent requests for Lumryz™/Xyrem®/Xywav® will NOT be approved.**

Recommended Dosage for Xyrem® & Xywav®:

Patient Weight	Initial Dosage		Maximum Weekly Dosage Increase		Maximum Recommended Dosage	
	Take at Bedtime	Take 2.5 to 4 Hours Later	Take at Bedtime	Take 2.5 to 4 Hours Later	Take at Bedtime	Take 2.5 to 4 Hours Later
<20 kg*	There is insufficient information to provide specific dosing recommendations for patients who weigh less than 20 kg					
20 kg to < 30 kg	≤1 g	≤1 g	0.5 g	0.5 g	3 g	3 g
30 kg to < 45 kg	≤1.5 g	≤1.5 g	0.5 g	0.5 g	3.75 g	3.75 g
≥45 kg	≤2.25 g	≤2.25 g	0.75 g	0.75 g	4.5 g	4.5 g

Recommended Dosage for Lumryz™:

- Starting dosage is 4.5 grams (g) once per night administered orally. Increase the dosage by 1.5 g per night at weekly intervals to the recommended dosage range of 6 g to 9 g once per night orally. The dosage may be gradually titrated based on efficacy and tolerability. Doses higher than 9 g per night have not been studied and should not ordinarily be administered.

CLINICAL CRITERIA: Check below all that apply. **All criteria must be met for approval**. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member is 7 years of age or older
- ❑ Member's current weight must be noted if < 18 years old: _____ kg
- ❑ The requested dose and frequency are 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, psychiatrist, or sleep specialist
- ❑ Member is **NOT** receiving treatment with sedative hypnotics or other CNS depressants **(verified by paid pharmacy claims)**
- ❑ Member is **NOT** using alcohol
- ❑ Member does **NOT** have a history of drug abuse

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❑ **DIAGNOSIS: Narcolepsy with Cataplexy –** Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider is requesting **ONE** of the following:
  - ❑ Lumryz™
  - ❑ sodium oxybate
  - ❑ Xyrem® **(This drug is non-formulary: must also meet medical necessity criteria below)**
  - ❑ Xywav®
- ❑ Member has a diagnosis of narcolepsy with cataplexy **(Multiple Sleep Latency Test (MSLT) confirming diagnosis of narcolepsy and chart notes documenting the occurrence of more than one episode of cataplexy at baseline prior to treatment with requested medication must be submitted. If polysomnography required, please submit with MSLT)**
- ❑ Provider has submitted the member's baseline Epworth Sleepiness Scale score **(rating scale must be attached)**
- ❑ Member must have a **2-month** trial and failure of **ONE** of the following anti-cataplectic therapies **(verified by pharmacy paid claims; documentation of intolerance or treatment failure must be submitted, unless use is contraindicated (please attach clinical documentation citing contraindication))**:
  - ❑ SSRI (i.e., fluoxetine)
  - ❑ TCA (i.e., clomipramine, imipramine, desipramine or protriptyline)
  - ❑ SNRI (i.e., venlafaxine or duloxetine)

❑ **DIAGNOSIS: Excessive Daytime Sleepiness associated with Narcolepsy –** Check below all that apply. **All criteria must be met for approval**. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider is requesting **ONE** of the following:
  - ❑ Lumryz™
  - ❑ sodium oxybate
  - ❑ Xyrem® **(non-formulary: must also meet medical necessity criteria below)**
  - ❑ Xywav®
- ❑ Member has a diagnosis of excessive daytime sleepiness associated with narcolepsy **(MSLT confirming diagnosis of narcolepsy must be submitted. If polysomnography required, please submit with MSLT)**
- ❑ Member must have tried and failed at least 30 days of therapy with modafinil or armodafinil **(verified by pharmacy paid claims; documentation of intolerance or treatment failure must be submitted)**
- ❑ Provider has submitted the member's baseline Epworth Sleepiness Scale score **(rating scale must be attached)**

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❑ **DIAGNOSIS: Idiopathic Hypersomnia –** Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider is requesting **ONE** of the following:
  - ❑ sodium oxybate
  - ❑ Xyrem® **(This drug non-formulary: must also meet medical necessity criteria below)**
  - ❑ Xywav®
- ❑ Member is at least 18 years old
- ❑ Member does **NOT** have cataplexy
- ❑ Member has a diagnosis of idiopathic hypersomnia confirmed by **ALL** the following ICSD-3 criteria **(MSLT confirming diagnosis and polysomnography required, please submit with MSLT)**:
  - ❑ Member has < 2 sleep-onset rapid eye movement periods (SOREMPs) on a MSLT performed according to standard techniques, or has no SOREMPs if the REM sleep latency on the preceding nocturnal polysomnogram (PSG) was ≤ 15 minutes
  - ❑ Member has the presence of at least **ONE** of the following:
    - ❑ Mean sleep latency of ≤ 8 minutes
    - ❑ Total 24-hour sleep time ≥ 660 minutes (typically 12 to 14 hours) on 24-hour polysomnography monitoring or by wrist actigraphy in association with a sleep log
  - ❑ Insufficient sleep syndrome has been ruled out
  - ❑ The hypersomnolence and/or MSLT findings are not better explained by another sleep disorder, other medical or psychiatric disorder, or use of drugs or medications
- ❑ Provider has submitted the member's baseline Epworth Sleepiness Scale score **(rating scale must be attached)**
- ❑ Member must have a **2-month** trial and failure of **ONE** of the following Alerting Agents:
  - ❑ amphetamine-based stimulant
  - ❑ methylphenidate-based stimulant
- ❑ Member must have a **2-month** trial and failure of **ONE** of the following Wake-promoting Agents:
  - ❑ armodafinil (generic Nuvigil)
  - ❑ modafinil (generic Provigil)

❑ **For ALL Xywav® Requests –** Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have a documented diagnosis of heart failure, renal failure or hypertension, are currently on a sodium restricted diet and are taking medications to control applicable diagnosis **(verified by pharmacy paid claims)**

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- ❑ Member must have an unsuccessful 30-day trial of sodium oxybate (failure is defined as an increase from baseline in ESS score and no change in cataplexy events from baseline); **documentation of intolerance or treatment failure must be submitted, unless use is contraindicated (please attach appropriate clinical documentation)**

❑ **For ALL Lumryz™ Requests –** Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have an unsuccessful 30-day trial of sodium oxybate (failure is defined as an increase from baseline in ESS score and no change in cataplexy events from baseline); **documentation of intolerance or treatment failure must be submitted, unless use is contraindicated (please attach appropriate clinical documentation)**

❑ **For ALL Brand Xyrem® Requests –** Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

NOTE: Brand Xyrem® is a non-formulary medication, all requests must meet **ALL** the following criteria for **MEDICAL NECESSITY** of use:

- ❑ Member meets all universal **AND** diagnosis specific criteria above
- ❑ Member must have an unsuccessful 30-day trial of sodium oxybate (failure is defined as an increase from baseline in ESS score and no change in cataplexy events from baseline); **documentation of intolerance or treatment failure must be submitted, unless use is contraindicated (please attach appropriate clinical documentation)**

Medication being provided by a Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*