

# Prior Authorization (PA) Guide

Insurers may require a PA as part of a claim submission.  
This document is for reference only.

**Lumryz**  
(sodium oxybate) for extended-release  
oral suspension  $\text{Ⓢ}$  4.5 | 6 | 7.5 | 9 g

## Common PA Approval Criteria

Each approval criteria is different, please consult patient's plan.

### AGE, DIAGNOSIS, DOSING

- ☐ Patient's age
- ☐ Narcolepsy diagnosis and type
- ☐ Rx details, including dose
- ☐ NDC

### CHART NOTES

- ☐ Date of initial diagnosis
- ☐ Relevant health conditions and/or symptoms
- ☐ Date and results of PSG and MSLT or reason for not taking the MSLT
- ☐ ICD-10 CM Code(s): G47.411 (with cataplexy), G47.419 (without cataplexy)
- ☐ Documentation of previous step through medications tried or reasons contraindicated

### ADDITIONAL INFORMATION

- ☐ **Prescribed by** or in conjunction with **a specialist**
- ☐ **Explanation of medical necessity**
  - Includes why the patient's diagnosis, severity of condition, and impact of disease warrant treatment with LUMRYZ
- ☐ **History prior to your practice's care**, if applicable tried and failed medications for narcolepsy
- ☐ **LUMRYZ Prescribing Information**
- ☐ **Plan for existing medications** (example: if patient is discontinuing or continuing use of any other narcolepsy medications, note this)

**If you are submitting PA for reauthorization** (typically needed every 6 to 12 months)\*:

- Include documentation of efficacy, eg, improvements in ESS scores and/or cataplexy attacks per week
- \*Actual plan criteria may vary; your Alkermes Field Reimbursement Manager can provide specific information.

ESS, Epworth Sleepiness Scale; MSLT, Multiple Sleep Latency Test; NDC, National Drug Code; PSG, polysomnography.

## INDICATIONS AND USAGE

LUMRYZ (sodium oxybate) for extended-release oral suspension is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

## IMPORTANT SAFETY INFORMATION

### WARNING: CENTRAL NERVOUS SYSTEM (CNS) DEPRESSION AND ABUSE AND MISUSE

#### Central Nervous System Depression

LUMRYZ<sup>®</sup> (sodium oxybate) is a CNS depressant. Clinically significant respiratory depression and obtundation may occur in patients treated with LUMRYZ at recommended doses. Many patients who received LUMRYZ during clinical trials in narcolepsy were receiving CNS stimulants.

#### Abuse and Misuse

LUMRYZ (sodium oxybate) is the sodium salt of gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreased consciousness, coma, and death.

Because of the risks of CNS depression and abuse and misuse, LUMRYZ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the LUMRYZ REMS.

## CONTRAINDICATIONS

LUMRYZ is contraindicated for use in:

- combination with sedative hypnotics or alcohol
- patients with succinic semialdehyde dehydrogenase deficiency

Please see Important Safety Information throughout, and full [Prescribing Information](#), including Boxed Warning, or visit [LUMRYZhcp.com](https://www.lumryzhcp.com).

## COMMON REASONS FOR DENIALS

- Incorrect diagnostic code
- Missing ICD-10 Code
- Lack of documentation (eg, PSG, MSLT results)
- Missing clinical rationale for not using covered formulary alternatives
- Missing evidence of step-throughs required by patient's plan (example: generic twice nightly oxybate, stimulants)
- Insufficient information beyond the diagnostic code
- Lack of formulary coverage or plan exclusion

- Please review the insurer's website for PA guidelines, including forms and contacts
- **Offices should send the denial or approval to RYZUP Support Services**



## Offices can utilize CoverMyMeds to provide electronic Prior Authorizations (PA)

- A key code will be provided upon initiation of the electronic PA process
- We will provide Prior Authorization forms if you or your patient's health plan does not participate in CoverMyMeds
- PAs can be submitted through CoverMyMeds or directly to the patient's payer
- Not registered with CoverMyMeds? Sign up for a free account at: [account.covermymeds.com](https://account.covermymeds.com)



### Questions about starting a new patient on LUMRYZ® (sodium oxybate) for extended-release oral suspension (CIII)?

Your Field Reimbursement Manager is available to educate on the LUMRYZ PA process

**IMPORTANT NOTE:** Use of this resource does not guarantee that an insurance company will provide reimbursement for the medicine requested and is not intended to be a substitute for, or an influence on, the independent medical judgment of a healthcare provider. This is a guide and is not to be taken as a specific recommendation.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

#### Central Nervous System Depression

The concurrent use of LUMRYZ with other CNS depressants, including but not limited to opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, sedating antiepileptic drugs, general anesthetics, muscle relaxants, and/or illicit CNS depressants, may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death. If use of these CNS depressants in combination with LUMRYZ is required, dose reduction or discontinuation of one or more CNS depressants (including LUMRYZ) should be considered. In addition, if short-term

use of an opioid (eg, post- or perioperative) is required, interruption of treatment with LUMRYZ should be considered.

After first initiating treatment and until certain that LUMRYZ does not affect them adversely (eg, impair judgment, thinking, or motor skills), caution patients against engaging in hazardous activities requiring complete mental alertness or motor coordination such as operating hazardous machinery, including automobiles or airplanes. Also caution patients against engaging in these hazardous activities for at least six (6) hours after taking LUMRYZ. Patients should be queried about CNS depression-related events upon initiation of LUMRYZ therapy and periodically thereafter.

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## IMPORTANT SAFETY INFORMATION (cont'd)

### Abuse and Misuse

LUMRYZ® (sodium oxybate) for extended-release oral suspension (CIII) is a Schedule III controlled substance. The active ingredient of LUMRYZ, sodium oxybate, is the sodium salt of gamma-hydroxybutyrate (GHB), a Schedule I controlled substance. Abuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. The rapid onset of sedation, coupled with the amnesic features of GHB, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (eg, assault victim). Physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely.

### LUMRYZ REMS

LUMRYZ is available only through a restricted distribution program called the LUMRYZ REMS because of the risks of central nervous system depression and abuse and misuse.

Notable requirements of the LUMRYZ REMS include the following:

- Healthcare providers who prescribe LUMRYZ are specially certified.
- LUMRYZ will be dispensed only by pharmacies that are specially certified.
- LUMRYZ will be dispensed and shipped only to patients who are enrolled in the LUMRYZ REMS with documentation of safe use conditions.

Further information is available at [www.LUMRYZREMS.com](http://www.LUMRYZREMS.com) or by calling 1-877-453-1029.

### Respiratory Depression and Sleep-Disordered Breathing

LUMRYZ may impair respiratory drive, especially in patients with compromised respiratory function. In overdoses of oxybate with illicit use of GHB, life-threatening respiratory depression has been reported. Increased apnea and reduced oxygenation may occur with LUMRYZ administration. A significant increase in the number of central apneas and clinically significant oxygen desaturation may occur in patients with obstructive sleep apnea treated with LUMRYZ. Prescribers should be aware that sleep-related breathing disorders tend to be more prevalent in obese patients, in men, in postmenopausal women not on hormone replacement therapy, and among patients with narcolepsy.

### Depression and Suicidality

Depression, and suicidal ideation and behavior, can occur in patients treated with LUMRYZ. In an adult clinical trial in patients with narcolepsy (n=212), there were no suicide attempts, but one patient with a history of depression and anxiety developed suicidal ideation in the LUMRYZ-treated group. In a clinical trial in pediatric narcolepsy patients administered immediate-release sodium oxybate, one patient experienced suicidal ideation and two patients reported depression. The emergence of depression in patients treated with LUMRYZ requires careful and immediate evaluation. Patients with a previous history of a depressive illness and/or a suicide attempt should be monitored carefully for the emergence of depressive symptoms while taking LUMRYZ.

### Other Behavioral or Psychiatric Adverse Reactions

Other behavioral and psychiatric adverse reactions can occur in patients taking LUMRYZ. During adult clinical trials in patients with narcolepsy administered LUMRYZ, 2% of 107 patients treated with LUMRYZ experienced a confusional state. No patients treated with LUMRYZ discontinued treatment because of confusion. Anxiety occurred in 7.5% of 107 patients treated with LUMRYZ in the adult trial in patients with narcolepsy. Other psychiatric reactions reported in adult clinical trials in patients with narcolepsy administered LUMRYZ included irritability, emotional disorder, panic attack, agitation, delirium, and obsessive thoughts. Other neuropsychiatric reactions reported in adult clinical trials in patients with narcolepsy administered immediate-release sodium oxybate and in the postmarketing setting for immediate-release sodium oxybate include hallucinations, paranoia, psychosis, aggression, and agitation. In a clinical trial in pediatric patients administered immediate-release sodium oxybate, neuropsychiatric reactions including acute psychosis, confusion, and anxiety were reported. The emergence or increase in the occurrence of behavioral or psychiatric events in patients taking LUMRYZ should be carefully monitored.

### Parasomnias

Parasomnias can occur in patients taking LUMRYZ. Sleepwalking, defined as confused behavior occurring at night and at times associated with wandering, was reported in 3% of 107 adult patients with narcolepsy treated with LUMRYZ. No patients treated with LUMRYZ discontinued due to sleepwalking. Episodes of sleepwalking should be fully evaluated and appropriate interventions considered.

### Use in Patients Sensitive to High Sodium Intake

LUMRYZ has a high sodium content. In patients sensitive to sodium intake (eg, those with heart failure, hypertension, or renal impairment), consider the amount of daily sodium intake in each dose of LUMRYZ.

### MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (incidence  $\geq 5\%$  and greater than placebo) reported for any dose of LUMRYZ in a trial of adults with narcolepsy were nausea, dizziness, enuresis, headache, and vomiting. Similarly, in a trial of pediatric narcolepsy patients receiving immediate-release sodium oxybate, the most commonly observed adverse reactions (incidence  $\geq 5\%$ ) were nausea, enuresis, vomiting, headache, decreased weight, decreased appetite, dizziness, and sleepwalking.

### ADDITIONAL ADVERSE REACTIONS

Additional adverse reactions that occurred in  $\geq 2\%$  of adult patients with narcolepsy treated with LUMRYZ and were more frequent in the LUMRYZ treatment group than with placebo were vomiting, nausea, decreased weight, decreased appetite, dizziness, somnolence, headache, enuresis, anxiety, and somnambulism.

### DRUG INTERACTIONS

LUMRYZ is contraindicated for use in combination with alcohol or sedative hypnotics. Use of other CNS depressants may potentiate the CNS-depressant effects of LUMRYZ.

Please see Important Safety Information throughout, and full [Prescribing Information](#), including Boxed Warning, or visit [LUMRYZhcp.com](http://LUMRYZhcp.com).

**LUMRYZ has strong commercial coverage for commercially insured patients.\***

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**Questions about starting a new patient on LUMRYZ?**

Your Field Reimbursement Manager is available to provide education about the PA process.

**IMPORTANT SAFETY INFORMATION (cont'd)**

**PREGNANCY AND LACTATION**

There are no adequate data on the developmental risk associated with the use of sodium oxybate in pregnant women. LUMRYZ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. GHB is excreted in human milk after oral administration of sodium oxybate. There is insufficient information on the risk to a breastfed infant, and there is insufficient information on milk production in nursing mothers. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LUMRYZ and any potential adverse effects on the breastfed infant from LUMRYZ or from the underlying maternal condition.

**PEDIATRIC USE**

LUMRYZ has not been studied in a pediatric clinical trial for narcolepsy. The safety and effectiveness of LUMRYZ in the treatment of cataplexy or excessive daytime sleepiness in pediatric patients 7 years of age and older with narcolepsy is supported by evidence from a double-blind, placebo-controlled, randomized-withdrawal study of immediate-release sodium oxybate. Safety and effectiveness of LUMRYZ in pediatric patients below the age of 7 years have not been established.

**GERIATRIC USE**

Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

\*This is not a guarantee of payment, coverage, or reimbursement. Actual coverage and reimbursement decisions are made by the health plan. Contact the health plan for complete and current information regarding coverage of LUMRYZ.

**HEPATIC IMPAIRMENT**

LUMRYZ should not be initiated in patients with hepatic impairment because appropriate dosage adjustments for initiation cannot be made with the available dosage strengths. Patients with hepatic impairment who have been titrated to a maintenance dosage of another oxybate product can be switched to LUMRYZ if the appropriate dosage strength is available.

**DEPENDENCE AND TOLERANCE**

There have been case reports of withdrawal, ranging from mild to severe, following discontinuation of illicit use of GHB at frequent repeated doses (18 g to 250 g per day) in excess of the recommended dosage range. Signs and symptoms of GHB withdrawal following abrupt discontinuation included insomnia, restlessness, anxiety, psychosis, lethargy, nausea, tremor, sweating, muscle cramps, tachycardia, headache, dizziness, rebound fatigue and sleepiness, confusion, and, particularly in the case of severe withdrawal, visual hallucinations, agitation, and delirium. These symptoms generally abated in three (3) to fourteen (14) days. In cases of severe withdrawal, hospitalization may be required. The discontinuation effects of LUMRYZ have not been systematically evaluated in controlled clinical trials.

Tolerance to LUMRYZ has not been systematically studied in controlled clinical trials. There have been some case reports of symptoms of tolerance developing after illicit use at dosages far in excess of the recommended LUMRYZ dosage regimen.

Please see full [Prescribing Information](#), including Boxed Warning, or visit [LUMRYZhcp.com](https://www.lumryzhcp.com).



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