BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.60.059

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	June 2, 2023
Subject:	Lumryz	**Page:**	1 of 5

Last Review Date: June 13, 2024

Lumryz

Description

Lumryz (sodium oxybate)

Background
Lumryz (sodium oxybate) is a central nervous system depressant used for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy. The mechanism of action of Lumryz in the treatment of narcolepsy is unknown. Sodium oxybate is the sodium salt of gamma-hydroxyburtyrate (GHB) an endogenous compound and metabolite of the neurotransmitter GABA. It is hypothesized that the therapeutic effects of Lumryz on cataplexy and excessive daytime sleepiness are mediated through $GABA_B$ actions at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons (1).

Regulatory Status
FDA-approved indications: Lumryz is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy (1).

Lumryz includes a boxed warning citing the risks of central nervous system (CNS) depression and abuse and misuse. Use caution when considering the concurrent use of Lumryz with other CNS depressants. Because of the risks of CNS depression, abuse, and misuse Lumryz is available only through a restricted program called the Lumryz REMS (1).

Lumryz has warnings for depression and suicidality, confusion/anxiety, parasomnias, and high sodium content in Lumryz. In addition, patients should be instructed to not engage in activities requiring mental alertness or motor coordination, including operating hazardous machinery, for

at least 6 hours of dosing or after first initiating treatment until certain that Lumryz does not affect them adversely (1).

Lumryz is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency and in combination with sedative hypnotics or alcohol (1).

Safety and effectiveness of Lumryz in patients less than 18 years of age have not been established (1).

Related policies
Hetlioz, Orexin Antagonists, Rozerem, Sedative Hypnotics, Xyrem, Xywav

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lumryz may be considered **medically necessary** if the conditions indicated below are met.

Lumryz may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:
1. Cataplexy in narcolepsy
2. Excessive daytime sleepiness (EDS) in narcolepsy

AND ALL of the following:
1. Patient and prescriber are both enrolled in the Lumryz REMS Program
2. Prescriber will monitor for signs of misuse, abuse, and addiction during therapy

AND NONE of the following:
1. Succinic semialdehyde dehydrogenase deficiency

2. Concurrent therapy with a Prior Authorization (PA) sleep aid (see Appendix 1) or with another oxybate product (see Appendix 2)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:
1. Cataplexy in narcolepsy
2. Excessive daytime sleepiness (EDS) in narcolepsy

AND ALL of the following:
1. Prescriber will continue to monitor for signs of misuse, abuse, and addiction during therapy
2. **NO** concurrent therapy with another Prior Authorization (PA) sleep aid (see Appendix 1) or with another oxybate product (see Appendix 2)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 810 grams (90 packets) per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 810 grams (90 packets) per 90 days

Duration 12 months

Rationale

Summary
Lumryz (sodium oxybate) is a central nervous system depressant used for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy. Lumryz includes a boxed warning citing the risks of central nervous system depression and abuse and misuse. Lumryz has warnings for depression and suicidality, confusion/anxiety, parasomnias, and high sodium content in Lumryz. Lumryz is available only through a restricted distribution program called the Lumryz REMS. Safety and effectiveness of Lumryz in patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Lumryz while maintaining optimal therapeutic outcomes.

References

1. Lumryz [package insert]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.

Policy History

Date	Action
June 2023	Addition to PA
September 2023	Annual review
December 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.

Appendix 1 - List of Prior Authorization (PA) Sleep Aids

Generic Name	Brand Name
daridorexant	Quviviq
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
quazepam	Doral
ramelteon	Rozerem
tasimelteon	Hetlioz
suvorexant	Belsomra
temazepam	Restoril
triazolam	Halcion
zaleplon	Sonata
zolpidem	Ambien
zolpidem extended-release	Ambien CR
zolpidem oral spray	Zolpimist
zolpidem sublingual	Edluar
zolpidem sublingual	Intermezzo

Appendix 2 - List of Oxybate Products

Generic Name	Brand Name
sodium oxybate	Lumryz
sodium oxybate	Xyrem
calcium, magnesium, potassium, sodium oxybates	Xywav