BlueCross BlueShield
Federal Employee Program

LUMRYZ
(sodium oxybate)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Lumryz (sodium oxybate) is a central nervous system depressant used for the treatment of cataplexy or excessive daytime sleepiness in patients with narcolepsy. The mechanism of action of Lumryz in the treatment of narcolepsy is unknown. Sodium oxybate is the sodium salt of gamma-hydroxybutyrate (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 patients 7 years of age and older 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 7 years of age have not been established (1).

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Summary

Lumryz (sodium oxybate) is a central nervous system depressant used for the treatment of cataplexy or excessive daytime sleepiness in patients 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 7 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; October 2024.