Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 14, 2023

Lumryz™ (sodium oxybate extended release)*

LENGTH OF AUTHORIZATION: Initial Therapy: Up to 3 months
Continuation of Therapy: Up to 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- The medication must be prescribed by a physician specializing in narcolepsy or neurologist; **AND**
- Prescriber and patient must be enrolled in and meet the conditions of the REMS program; **AND**
- Patient must NOT have succinic semialdehyde dehydrogenase deficiency; **AND**
- Patient will NOT concurrently use sedative hypnotics (e.g., opioids; muscle relaxants; zolpidem; benzodiazepines) or alcohol during sodium oxybate treatment; **AND**
- Patient will NOT use concurrently with other forms of sodium oxybate (Xyrem or Xywav).

Cataplexy in narcolepsy

- Patient must have a diagnosis of narcolepsy with cataplexy; **AND**
- Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results; **AND**
- Cataplexy has been present for the last 3 months and average number of weekly cataplexy attacks has been documented at baseline.

Excessive daytime sleepiness in narcolepsy

- Patient must have a diagnosis of narcolepsy with excessive daytime sleepiness; **AND**
- Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the PSG and MSLT results; **AND**
- Submission of progress note indicating that sleepiness is significantly impacting daytime functioning; **AND**
- Must have 60-day trial and failure or intolerance to at least one preferred stimulant treatment (e.g., methylphenidate or dextroamphetamine) at maximally tolerated dosage; **AND**
- Must have 60-day trial and failure of modafinil.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of positive clinical response such as improvement in daytime sleepiness according to a validated scale (e.g., Epworth Sleepiness Scale (ESS) and/or the Maintenance of Wakefulness Test (MWT)); **AND**
- Patient has experienced reduced frequency in cataplexy attacks from baseline (as applicable); **AND**

* 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. Further information is available at www.LUMRYZREMS.com or by calling 1-877-453-1029.

- Patient has NOT experienced treatment-restricting adverse effects (e.g., severe depression/suicidality, clinically significant respiratory depression, behavioral/psychiatric adverse reactions, worsening of sleep-disordered breathing); **AND**
- Prescriber attests to continued monitoring of mental health, suicidality, psychiatric episodes, sleep-disordered breathing, and risk of abuse/misuse; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 4.5 g, 6 g, 7.5 g, and 9 g extended-release oral suspension packets.

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