Oscar Clinical Guideline: Lumryz (sodium oxybate) (PG246, Ver. 1)

Lumryz (sodium oxybate)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Narcolepsy is a chronic neurological sleep disorder characterized by excessive daytime sleepiness (EDS) with or without cataplexy (sudden loss of muscle tone). Current treatment options aim to manage symptoms and improve quality of life. Stimulants, wake-promoting agents like modafinil and armodafinil, and antidepressants are often used as first-line therapies. Sodium oxybate, a central nervous system depressant, is recommended for patients with narcolepsy who have an inadequate response to these treatments. Lumryz is an extended-release formulation of sodium oxybate approved for the treatment of cataplexy or EDS in adults with narcolepsy. It offers a once-nightly dosing option as an alternative to the twice-nightly immediate-release formulations.

Definitions

"**Cataplexy**" refers to a sudden, transient episode of muscle weakness accompanied by full conscious awareness, typically triggered by emotions such as laughing, crying, or terror.

"**Excessive daytime sleepiness (EDS)**" is the inability to stay awake and alert during the day, resulting in unintended lapses into drowsiness or sleep.

"Hypocretin-1" is a natural chemical in the brain that helps regulate wakefulness.

"**Multiple Sleep Latency Test (MSLT)**" is a sleep study that measures how quickly a person falls asleep during the day and whether they enter rapid eye movement (REM) sleep.

"**Narcolepsy**" is a chronic neurological sleep disorder characterized by excessive daytime sleepiness, cataplexy, sleep paralysis, and hypnagogic hallucinations.

"Polysomnography (PSG)" is a sleep study used to diagnose sleep disorders by measuring certain components such as brain activity, oxygen levels, heart rate, breathing, eye movements, and leg movements.

"Sleep latency" is the amount of time it takes to fall asleep.

"**Sleep-onset REM periods (SOREMPs)**" are periods of rapid eye movement sleep that occur within 15 minutes of falling asleep, which are characteristic of narcolepsy.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Lumryz (sodium oxybate)** medically necessary when **ALL** of the following criteria are met:

1. The medication is prescribed by or in consultation with a sleep medicine specialist, neurologist, psychiatrist, or pulmonologist with expertise in treating sleep disorders; ***AND***
2. The member is 18 years of age or older; ***AND***
3. The member has a diagnosis of narcolepsy that has been confirmed by sleep lab testing or documented clinical symptoms including excessive daytime sleepiness (EDS) persisting for at least 3 months **AND** at least **ONE** of the following:
    b. Cataplexy episodes (for narcolepsy type 1); ***or***

c. Hypocretin-1 (orexin A) deficiency (≤110 pg/mL or <1/3 of mean values of healthy individuals tested using the same standardized assay); ***or***
d. Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency ≤ 15 minutes, or a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency ≤ 8 minutes and ≥ 2 sleep-onset REM periods (SOREMPs). A SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnography may replace one of the SOREMPs on the MSLT; ***AND***

4. The member is unable to use, or has tried and failed **ALL** of the following for at least 30-days duration each:
    a. Sunosi (solriamfetol); ***and***
    b. Either modafinil or armodafinil; ***and***
    c. At least **ONE** CNS stimulant, such as:
        i. amphetamine-dextroamphetamine; ***or***
        ii. dextroamphetamine; ***or***
        iii. methylphenidate; ***and***
    d. For members with cataplexy - at least **ONE** antidepressant, such as:
        i. SSRIs (such as fluoxetine); ***or***
        ii. SNRIs (such as venlafaxine); ***or***
        iii. Tricyclic Antidepressants (such as clomipramine); ***AND***
5. The member does **NOT** have **ANY** of the following:
    b. Succinic semialdehyde dehydrogenase (SSADH) deficiency; ***or***
    c. Documentation indicating concomitant use with, or inability to abstain from, any of the following while taking Lumryz (sodium oxybate):
        i. Alcohol (e.g., beer, wine, whisky); ***or***
        ii. Sedative hypnotics (e.g., alprazolam, diazepam, lorazepam, zolpidem); ***or***
        iii. Xyrem, Xywav, Wakix, or sodium oxybate products***; or***
    d. A condition that better explains the hypersomnolence and/or MSLT findings, such as:
        i. Insufficient sleep***; or***
        ii. Obstructive sleep apnea***; or***
        iii. Delayed sleep phase disorder***; or***
        iv. The effect of medication or substances or their withdrawal***; AND***
6. Lumryz (sodium oxybate) is being prescribed at a dose and frequency that is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if the member has recent (within the last 3-months) clinical chart documentation demonstrating **ALL** of the following criteria:

1. The member has experienced a positive clinical response to Lumryz (sodium oxybate) therapy as demonstrated by a reduction in symptoms of cataplexy and/or EDS; ***AND***
2. The member continues to abstain from alcohol and sedative hypnotics; ***AND***
3. Lumryz will not be used in combination with Xyrem, Xywav, Wakix, or sodium oxybate products; ***AND***
4. Lumryz continues to be prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

Experimental or Investigational / Not Medically Necessary

Lumryz (sodium oxybate) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- When used in combination with alcohol, sedative hypnotics, or other medications containing sodium oxybate, gamma-hydroxybutyrate (GHB), or GHB precursors.
- When used in members with succinic semialdehyde dehydrogenase deficiency, a rare inborn error of metabolism.
- For members under 18 years of age, safety and efficacy have not been established in pediatric populations.

References

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2. Howell M, Avidan AY, Foldvary-Schaefer N, Malkani RG, During EH, Roland JP, McCarter SJ, Zak RS, Carandang G, Kazmi U, Ramar K. Management of REM sleep behavior disorder: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2023 Apr 1;19(4):759-768. doi: 10.5664/jcsm.10424. PMID: 36515157; PMCID: PMC10071384.
3. Lumryz (sodium oxybate) [prescribing information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.
4. Maski K, Trotti LM, Kotagal S, Robert Auger R, Rowley JA, Hashmi SD, Watson NF. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice

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Clinical Guideline Revision / History Information

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