Oscar Clinical Guideline: Lumryz (sodium oxybate) (PG246, Ver. 3)

Lumryz (sodium oxybate)

Summary

Narcolepsy is a chronic neurological disorder characterized by excessive daytime sleepiness (EDS) and abnormal rapid eye movement (REM) sleep manifestations. It is classified into two types: narcolepsy type 1 (NT1), which includes cataplexy, and narcolepsy type 2 (NT2), without cataplexy. The disorder affects approximately 1 in 2,000 people and is caused by the loss of hypothalamic neurons that produce hypocretin (orexin), a neuropeptide that regulates wakefulness and REM sleep.

The goal of narcolepsy management is to improve the sleep-wake cycle by reducing EDS, improving wakefulness, and maximizing sleep during the nighttime. Treatment options for narcolepsy include central nervous system stimulants (e.g., modafinil, armodafinil, methylphenidate, amphetamines), Z-drugs (e.g., zolpidem, zopiclone), sodium oxybate, Wakix (pitolisant), or Sunosi (solriamfetol) to improve EDS and/or cataplexy. Behavioral modifications, such as scheduled naps and sleep hygiene, are also important components of management.

Lumryz (sodium oxybate) is an oral salt form of gamma-hydroxybutyrate (GHB), approved by the FDA for the treatment of cataplexy or excessive daytime sleepiness in those 7 years of age and older with narcolepsy. It is classified as a central nervous system depressant and is believed to act through GABA-B receptors, although its exact mechanism of action in narcolepsy is not fully understood. Lumryz (sodium oxybate) is typically administered once nightly.

Sodium oxybate products have a boxed warning for the risk of central nervous system depression and abuse and misuse. Because sodium oxybate is a sodium salt of GBH, it can have similar serious and life-threatening adverse reactions including: seizures, respiratory depression, decreased consciousness, coma and death. Because of this, sodium oxybate products are only available through a restricted program - for Lumryz (sodium oxybate) this is called the LUMRYZ REMS.

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.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"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.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"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.

"[s]" indicates state mandates may apply.

"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.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Narcolepsy

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 7 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 (1) of the following:
    a. Cataplexy episodes (for narcolepsy type 1); *or*
    b. Hypocretin-1 (orexin A) deficiency (≤110 pg/mL or <1/3 (one-third) of mean values of healthy individuals tested using the same standardized assay); *or*
    c. Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency ≤ 15 minutes (also known as sleep-onset REM periods [SOREMP]), 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, prior treatments as follows[s]:

a. If the member is 18 years of age and older, the member is unable to use, or has tried and failed ALL of the following[s]:
    i. Sunosi (solriamfetol); *and*
    ii. Either modafinil or armodafinil; *and*
    iii. At least ONE (1) CNS stimulant, such as:
        1. Amphetamine-dextroamphetamine; *or*
        2. Dextroamphetamine; *or*
        3. Methylphenidate; *and*
b. IF the member is 7 to 17 years of age AND does NOT have cataplexy, the member is unable to use, or has tried and failed, at least ONE (1) CNS stimulant, such as[s]:
    i. Methylphenidate; *or*
    ii. Amphetamine-based stimulant; *AND*

5. The member meets ALL of the following:
    a. No evidence of succinic semialdehyde dehydrogenase (SSADH) deficiency; *or*
    b. No evidence of 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 (sodium oxybate), Xywav (calcium, magnesium, potassium, and sodium oxybates), Wakix (pitolisant), or sodium oxybate products*; 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.

<u>If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.</u>[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

<u>Narcolepsy</u>

The Plan considers <u>Lumryz (sodium oxybate)</u> medically necessary when ALL of the following criteria are met (within the last 3-months):

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 (sodium oxybate), Xywav (calcium, magnesium, potassium, and sodium oxybates), Wakix (pitolisant), or sodium oxybate products; *AND*

4. Lumryz (sodium oxybate) 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.

   If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Experimental or Investigational / Not Medically Necessary[s]

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 7 years of age, safety and efficacy have not been established in pediatric populations.

References

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Clinical Guideline Revision / History Information

Original Date: 09/18/2024 Reviewed/Revised: 07/01/2025, 03/02/2026