Effective Date: 12/2017
Reviewed: 12/2017, 12/2018, 10/2019, 8/2020, 2/2021, 2/2022, 5/2023, 11/2023, 3/2024, 1/2025 Scope: Medicaid

Sodium oxybate (generic Xyrem)
Lumryz (sodium oxybate)
Xywav (calcium, magnesium, potassium, and sodium oxybates)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Sodium oxybate is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
B. Lumryz is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
C. Xywav is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy AND the treatment of idiopathic hypersomnia (IH) in adults.

All other indications are considered experimental/investigational and are not a covered benefit.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by one of the following:

A. Sleep disorder specialist
B. Neurologist

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted when all of the following criteria are met:

1. Documentation that the member is not being treated with sedative hypnotics that will be used concurrently with sodium oxybate
2. Documentation that the member does not have a history of drug or alcohol abuse
3. Member weighs at least 45 kgs if the requested drug is Lumryz.
4. Documentation that the member meets one of the following criteria:
    a. The requested drug is being prescribed for the treatment of cataplexy in narcolepsy in a member 7 years of age or older and all of the following criteria are met:
        i. The diagnosis is confirmed by sleep lab evaluation
        ii. The member has a baseline history of at least 14 cataplexy attacks in a typical 2-week period.
        iii. The member has experienced an inadequate treatment response, intolerance, or contraindication to at least two of the following agents from a different medication class: atomoxetine, fluoxetine, protriptyline, clomipramine and/or venlafaxine

b. The requested drug is being prescribed for the treatment of excessive daytime sleepiness in a member 7 years of age or older with narcolepsy without cataplexy and all of the following criteria are met:
    i. The diagnosis is confirmed by sleep lab evaluation
    ii. The member has experienced an inadequate treatment response, intolerance, or contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
    iii. If the member is 18 years of age or older:
        1. The member experienced an inadequate treatment response or intolerance, to at least one central nervous system (CNS) wakefulness promoting drug (e.g., modafinil, armodafinil) OR
        2. The member has a contraindication to both armodafinil and modafinil
c. The requested drug is being prescribed for the treatment of idiopathic hypersomnia in a member 18 years of age or older and all of the following criteria are met:
    i. Presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months.
    ii. Insufficient sleep syndrome has been ruled out such as by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least a week of sleep log with wrist actigraphy.
    iii. A multiple sleep latency test (MSLT) documents fewer than two sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs if the REM latency on the preceding polysomnogram was less than or equal to 15 minutes.
    iv. Presence of at least one of the following:
        1. Mean sleep latency on MSLT of less than or equal to 8 minutes.
        2. Total 24-hour sleep time of greater than or equal to 660 minutes on 24-hour polysomnographic monitoring after correcting any chronic sleep deprivation or by wrist actigraphy in association with a sleep log and averaged over at least 7 days of unrestricted sleep.
    v. The member does not have cataplexy.
    vi. Hypersomnolence or multiple sleep latency test results are not better explained by another sleep disorder, other medical or psychiatric disorder, or use of drugs or medications.
    vii. The member has experienced an inadequate treatment response, intolerance, or contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
    viii. The member experienced an inadequate treatment response, intolerance or has a contraindication to modafinil.

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted when the request is for continuation of sodium oxybate, Lumryz, or Xywav when the member has documentation of experiencing a decrease in daytime sleepiness with narcolepsy or IH, or a decrease in cataplexy episodes with narcolepsy from baseline (clinical notes provided support treatment efficacy).

V. QUANTITY LIMIT

- Sodium oxybate 500mg/ml oral solution has a quantity limit of 18 ml per day.
- Lumryz 4.5g, 6g, 7.5g, 9g packets have a quantity limit of 1 packet per day.
- Xywav 0.5gm/ml oral solution has a quantity limit of 18 ml per day.

VI. REFERENCES

1. Sodium oxybate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; April 2023
2. Lumryz [package insert]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; November 2024.
3. Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.