

Reference number(s)
3677-A

## SPECIALTY GUIDELINE MANAGEMENT

### XYREM (sodium oxybate) LUMRYZ (sodium oxybate) sodium oxybate

#### 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 Indication

- A. Xyrem/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 adults with narcolepsy.

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial requests, all of the following (if applicable):
  - 1. Documentation of a sleep lab evaluation.
  - 2. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- B. For continuation requests, documentation to support one of the following:
  - 1. For excessive daytime sleepiness with narcolepsy: chart notes or medical record documentation supporting a beneficial response to therapy as demonstrated by a decrease in daytime sleepiness with narcolepsy from baseline.
  - 2. For cataplexy with narcolepsy: chart notes or medical record documentation supporting a beneficial response to therapy as demonstrated by a decrease in cataplexy episodes from baseline.

##### III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a sleep specialist (e.g., neurologist experienced with sleep disorders, physician certified in sleep medicine).

##### IV. CRITERIA FOR INITIAL APPROVAL

###### A. Excessive Daytime Sleepiness with Narcolepsy

Authorization of 12 months may be granted for treatment of excessive daytime sleepiness when all of the following criteria are met:

1. The diagnosis of narcolepsy is confirmed by a sleep lab evaluation.
2. Member meets one of the following:
  - a. Member is 7 years of age or older and less than 18 years of age and meets one of the following (for sodium oxybate and Xyrem only):
    - i. The member has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate).
    - ii. The member has a contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate).
  - b. Member is 18 years of age or older and meets one of the following:
    - i. The member has experienced an inadequate treatment response or intolerance to modafinil or armodafinil.
    - ii. The member has a contraindication to both modafinil and armodafinil.

#### **B. Cataplexy with Narcolepsy**

1. Authorization of 12 months (for sodium oxybate and Xyrem) may be granted for treatment of cataplexy with narcolepsy when all of the following criteria are met:
  - a. The member is 7 years or older.
  - b. The diagnosis of narcolepsy is confirmed by a sleep lab evaluation.
  - c. The member has a baseline history of at least 3 cataplexy attacks per week.
2. Authorization of 12 months for Lumryz may be granted for treatment of cataplexy with narcolepsy when all of the following are met:
  - a. The member is 18 years or older.
  - b. The diagnosis of narcolepsy is confirmed by a sleep lab evaluation.
  - c. The member has a baseline history of at least 3 cataplexy attacks per week.

### **V. CONTINUATION OF THERAPY**

#### **A. Excessive Daytime Sleepiness with Narcolepsy**

Authorization of 12 months may be granted for continued treatment of excessive daytime sleepiness (EDS) with narcolepsy when the member has demonstrated beneficial response to treatment as defined by a decrease in daytime sleepiness with narcolepsy from baseline.

#### **B. Cataplexy with Narcolepsy**

Authorization of 12 months may be granted for continued treatment of cataplexy with narcolepsy when the member has demonstrated beneficial response to treatment as defined by a decrease in cataplexy episodes from baseline.

### **VI. REFERENCES**

1. Lumryz [package insert]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.
2. Nuvigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2022.
3. Provigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; January 2015.
4. Sodium oxybate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; April 2023.
5. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.
6. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed March 1, 2023.

Reference number(s)
3677-A

7. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and Other Hypersomnias of Central Origin. *Sleep* 2007; 30(12):1705-11.
8. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual*. 3<sup>rd</sup> edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
9. Krahn, L, Hershner S, et al. Quality Measures for the Care of Patients with Narcolepsy; *Journal of Clinical Sleep Medicine*; 2015; 11(3): 335-55.
10. Maski K, Trotti LM, Kotagal S, Auger RR, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. Published online September 1, 2021.