| 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.

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*. 3rd 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.