Reference number(s)
3677-A, 6975-A

Specialty Guideline Management sodium oxybate-Lumryz-Xyrem

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xyrem	sodium oxybate
Lumryz	sodium oxybate

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[1,4,5]

Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

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

Documentation

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

For initial requests, all of the following (if applicable):

- Documentation of a sleep lab evaluation.

- 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.

For continuation requests, documentation to support one of the following:

- 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.
- 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.

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).

Coverage Criteria

Excessive Daytime Sleepiness (EDS) with Narcolepsy[1-7,10]

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

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

Cataplexy with Narcolepsy[1-6,10]

Authorization of 12 months may be granted for treatment of cataplexy with narcolepsy when all of the following criteria are met:

- The member is 7 years of age or older.
- The diagnosis of narcolepsy is confirmed by a sleep lab evaluation.
- The member has a baseline history of at least 3 cataplexy attacks per week.

Continuation of Therapy

Excessive Daytime Sleepiness (EDS) with Narcolepsy[1-5,10]

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.

Cataplexy with Narcolepsy[1-6,10]

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.

Other

Per regulatory guidelines around behavioral health, step therapy restrictions may vary.

References

1. Lumryz [package insert]. Chesterfield, MO: Ayadel CNS Pharmaceuticals, LLC.; October 2024.
2. Nuvigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals; December 2022.
3. Provigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals.; December 2022.
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 December 5, 2024.
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.