CVS Caremark®

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| 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 Indications1,4,5

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 Narcolepsy1-7,10

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 Narcolepsy1-6,10

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 Narcolepsy1-5,10

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 Narcolepsy1-6,10

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.