AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Xyrem, Lumryz, sodium oxybate	Page:	1 of 4
Effective Date:	11/25/2024	Last Review Date:	10/25/2024

Applies to:	☒Illinois	☒Florida Kids	☒New Jersey
	☐Maryland	☒Pennsylvania Kids	☒Virginia

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Xyrem, Lumryz, sodium oxybate under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Xyrem
Lumryz
sodium oxybate

Policy/Guideline:

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

A. Initial requests, ALL 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. 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. 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 Specialty:
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).

Criteria for Initial Approval:
The patient is unable to take the required formulary alternative, sodium oxybate, due to a trial and inadequate treatment response, or intolerance, or a contraindication. Documentation is required for approval

A. Excessive Daytime Sleepiness with Narcolepsy

Authorization of 12 months may be granted for treatment of excessive daytime sleepiness when ALL 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 (<u>for sodium oxybate and Xyrem only</u>):
      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) If the member is 18 years of age or older:
      i. The member has experienced an inadequate treatment response or intolerance to modafinil or armodafinil OR
      ii. The member has a contraindication to both modafinil and armodafinil
         a. Note: armodafinil is the formulary preferred product for all plans except Illinois. Illinois' formulary preferred product is modafinil.

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 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 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

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.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:

Xyrem (sodium oxybate) 0.5 g/mL oral solution	540 mL per 30 days
sodium oxybate 0.5 g/mL oral solution	540 mL per 30 days
Lumryz (sodium oxybate) granules for extended-release oral suspension 4.5 g packets	30 packets per 30 days
Lumryz (sodium oxybate) granules for extended-release oral suspension 6 g packets	30 packets per 30 days
Lumryz (sodium oxybate) granules for extended-release oral suspension 7.5 g packets	30 packets per 30 days
Lumryz (sodium oxybate) granules for extended-release oral suspension 9 g packets	30 packets per 30 days
Lumryz (sodium oxybate) 28-day starter pack (4.5 g packets, 6 g packets, 7.5 g packets)	28 packets per 28 days

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.