AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Xyrem	Page:	1 of 3
Effective Date:	12/21/2023	Last Review Date:	11/2023

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

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Xyrem (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
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.

Applicable Drug List:

Xyrem
sodium oxybate

Policy/Guideline:

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, chart notes or medical record documentation supporting a beneficial response to therapy (e.g., decrease in daytime sleepiness, 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:
Note: requests for brand Xyrem require trial and failure of the generic product.

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. If the member is 7 years of age or older and less than 18 years of age:
   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) OR
   ii. The member has a contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate)
3. 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
Authorization of 12 months may be granted for treatment of cataplexy with narcolepsy when all of the following criteria are met:
1. The member is 7 years of age or older
2. The diagnosis of narcolepsy is confirmed by a sleep lab evaluation
3. The member has a baseline history of at least 14 cataplexy attacks in a typical 2-week period

Continuation of Therapy:

A. 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.

B. 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.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: Xyrem (sodium oxybate) – 540 mL per 30 days

References:

1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.
2. Sodium oxybate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; April 2023.
3. Lumryz [package insert]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.
4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed March 1, 2023.
5. 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.
6. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual*. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
7. 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.
8. Nuvigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
9. Provigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
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.