



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name:	Sodium oxybate	Page:	1 of 3
Effective Date:	6/9/2025	Last Review Date:	5/27/2025
Applies to:	<input checked="" type="checkbox"/> Maryland		

**Intent:**

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for 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:**

Sodium oxybate

**Policy/Guideline:**

**Documentation:**

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

- A. 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. 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:**

**A. Excessive Daytime Sleepiness with Narcolepsy**



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Authorization of 12 months may be granted for treatment of excessive daytime sleepiness when ALL 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

#### **B. Cataplexy with Narcolepsy**

Authorization of 12 months may be granted for treatment of cataplexy with narcolepsy when ALL 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:**

Sodium oxybate 0.5 g/mL oral solution: 540 mL per 30 days

#### **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.



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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.