UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1118-14
Program	Prior Authorization/Notification
Medication	Lumryz™ (sodium oxybate), sodium oxybate [Xyrem authorized generic (manufactured by Amneal)]*, sodium oxybate [Xyrem authorized generic (manufactured by Hikma)], Xyrem®* (sodium oxybate), Xywav® (calcium, magnesium, potassium, and sodium oxybates)
P&T Approval Date	8/2009, 5/11/2010, 1/2011, 1/2012, 2/2013, 8/2013, 8/2014, 8/2015, 7/2016, 7/2017, 7/2018, 8/2019, 8/2020, 12/2020, 11/2021, 11/2022, 11/2023, 9/2024, 9/2025
Effective Date	11/16/2025

1. Background:

Lumryz, Xyrem (sodium oxybate) and Xywav are central nervous system depressants indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in patients with narcolepsy. Xyway is also indicated for idiopathic hypersomnia (IH) in adults.

Lumryz, Xyrem and Xywav are classified as a Schedule III controlled substance by Federal law. The active ingredient, sodium oxybate or gamma-hydroxybutyrate (GHB), is listed in the most restrictive schedule of the Controlled Substances Act (Schedule I). Thus, non-medical uses are classified under Schedule I.

Lumryz, Xyrem and Xywav are available only through a REMS program with restricted distribution. The REMS Program provides educational materials to the prescriber and the patient explaining the risks and proper use of Lumryz, Xyrem and Xywav, and the required prescription form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. The REMS Program also recommends patient follow-up every 3 months. Physicians are expected to report all serious adverse events to the manufacturer.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)

1. **Initial Authorization**

   a. **Lumryz, sodium oxybate [Xyrem authorized generic (manufactured by Amneal)]*, sodium oxybate [Xyrem authorized generic (manufactured by Hikma)], Xyrem*** or **Xywav** will be approved based on **all** of the following criteria:

      (1) Diagnosis of narcolepsy *with* cataplexy (i.e., Narcolepsy Type 1) as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [2]

      –AND–

      (2) Symptoms of excessive daytime sleepiness (including but not limited to daily periods of irrepressible need to sleep or daytime lapses into sleep) are present.

      -AND-

      (3) Cataplexy is present

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **The requested medication** will be approved for continuation of therapy based on **one** of the following criteria:

      (1) Reduction in frequency of cataplexy attacks associated with therapy

      –OR–

      (2) Reduction in symptoms of excessive daytime sleepiness associated with therapy

      Authorization will be issued for 12 months.

B. Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)

1. **Initial Authorization**

   a. **Lumryz, sodium oxybate [Xyrem authorized generic (manufactured by Amneal)]*, sodium oxybate [Xyrem authorized generic (manufactured by Hikma)], Xyrem*** or **Xywav** will be approved based on **all** of the following criteria:

      (1) Diagnosis of narcolepsy *without* cataplexy (i.e., Narcolepsy Type 2) as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [2]

–AND–

(2) Symptoms of excessive daytime sleepiness (including but not limited to daily periods of irrepressible need to sleep or daytime lapses into sleep) are present.

–AND–

(3) Cataplexy is absent

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **The requested medication** will be approved for continuation of therapy based on the following criterion:

(1) Reduction in symptoms of excessive daytime sleepiness associated with therapy

Authorization will be issued for 12 months.

C. Idiopathic Hypersomnia

1. **Initial Authorization**

a. **Xywav** will be approved based **both** of the following criteria:

(1) Diagnosis of idiopathic hypersomnia

–AND–

(2) Symptoms of excessive daytime sleepiness (including but not limited to daily periods of irrepressible need to sleep or daytime lapses into sleep) are present.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Xywav** will be approved for continuation of therapy based on the following criterion:

(1) Reduction in symptoms of excessive daytime sleepiness associated with therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Sodium oxybate [Xyrem authorized generic (manufactured by Amneal)] and brand Xyrem are typically excluded from coverage.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Medical Necessity may be in place.

4. References:

1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; July 2025
2. Maski, K., Trotti, L. M., Kotagal, S., Auger, R. R., Rowley, J. A., Hashmi, S. D., & Watson, N. F. (2021). Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine, 17(9), 1881–1893.
3. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
4. Morgenthaler TI1, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007 Dec;30(12):1705-11.
5. Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; June 2023.
6. Lumryz [package insert]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; October 2024.
7. Sodium Oxybate [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals NY LLC; April 2023.
8. Sodium Oxybate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; April 2023.

Program	Prior Authorization/Notification - Sodium oxybates
Change Control	
8/2013	Reformatted initial authorization criteria language to 'diagnosis of narcolepsy as confirmed by sleep study.' Updated formatting.
8/2014	Annual review with no changes to Coverage Criteria. Updated Background and References.
8/2015	Annual review. Created separate criteria for Narcolepsy with and without Cataplexy. Increased initial authorization to 6 months. Updated references.
7/2016	Annual review with no changes to coverage criteria. Updated background and references.
7/2017	Annual review with no changes to coverage criteria. Updated references.
7/2018	Annual review with no changes to coverage criteria. Updated references.
8/2019	Annual review with no changes to coverage criteria. Updated references.
8/2020	Annual review with no changes to coverage criteria. Updated background.
12/2020	Added Xywav to criteria.
11/2021	Added criteria for idiopathic hypersomnia for Xywav due to new

	labeling.
11/2022	Annual review. Added state mandate footnote. Updated references.
11/2023	Added Lumryz to criteria. Noted sodium oxybate (manufactured by Amneal) and brand Xyrem are typically excluded.
9/2024	Updated initial authorization to 12 months. Updated references.
9/2025	Annual review. Updated references.