

**Lumryz (sodium oxybate)**  
**Xyrem (sodium oxybate)**  
**Xywav (oxybate salts [calcium, magnesium, potassium, and sodium])**  
**Wakix (pitolisant)**  
**Effective 01/01/2024**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Lumryz, Xyrem and Xywav are mediated by GABA<sub>B</sub> receptor activity at noradrenergic, dopaminergic, and thalamocortical neurons. Wakix a histamine-3 (H3) receptor antagonist/inverse agonist. These medications are approved for cataplexy or excessive daytime sleepiness in narcolepsy.

### Coverage Guidelines

Authorization may be reviewed for members new to the plan who are currently receiving treatment with Lumryz, Xyrem, Xywav or Wakix excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member has a diagnosis of cataplexy or excessive daytime sleepiness in narcolepsy
2. Member meets ONE of the following:
  - a. For Xyrem or Xywav: the member is 7 years of age or older
  - b. For Lumryz and Wakix: the member is 18 years of age or older
3. The diagnosis is confirmed by sleep lab evaluation.
4. The member has had inadequate response, intolerance, or contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate)
5. For members 18 years of age or older, the member has had an inadequate response, intolerance, or contraindication to at least one CNS wakefulness promoting drug (e.g., modafinil, armodafinil) o
6. For Lumryz, Xyrem, and Xywav: the member has had inadequate response, intolerance, or contraindication to Wakix

### Continuation criteria:

Reauthorization requires physician documentation of continuation of therapy and positive response to therapy. Physician documents decreased daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy.

**Limitations**

1. Initial approvals and reauthorizations will be granted for 12 months.
2. Quantity limits may apply

Drug	Quantity Limit
Xyrem	540mL per 30 days
Xywav	540mL per 30 days
Lumryz	30 tablets per 30 days
Wakix	60 tablets per 30 days

**References**

1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2018.
2. Wakix (pitolisant) [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences LLC; December 2022
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed October 2018.
4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed October 2018.
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]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2018.
9. Provigil [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2018.
10. Xywav (calcium, magnesium, potassium, and sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; July 2020.
11. Lumryz (sodium oxybate) [prescribing information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.

**Review History**

01/23/2020 – Reviewed and Updated Jan P&T, Transitioned from SGM to Custom Criteria, added PA and QL Xywav to criteria.  
 05/01/2021 – Xywav added to specialty.  
 11/17/2022 – Reviewed and Updated November P&T; Added requirement of previous use of Wakix prior to Xyrem or Xywav. Effective Date: 1/1/2022.  
 08/09/2023 – Reviewed and Updated for August P&T; Added new drug Lumryz to criteria. Effective: 10/1/2023  
 12/13/2023- Reviewed and Updated for December P&T; Added Lumryz to overview. Added Wakix to criteria. Effective 2/1/2024

