Mass General Brigham
Health Plan

Lumryz (sodium oxybate)
Sodium oxybate
Xyrem (sodium oxybate)
Xywav (oxybate salts [calcium, magnesium, potassium, and sodium])
Wakix (pitolisant)
Effective 04/01/2025

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

Overview
Lumryz, Xyrem and Xywav are mediated by $GABA_B$ 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. Xywav is also approved for the treatment of idiopathic hypersomnia.

FDA-approved age indications are as follows:

Drug Name	Excessive daytime sleepiness (EDS) in narcolepsy	Narcolepsy with cataplexy	Idiopathic hypersomnia
Lumryz	7 years of age and older	7 years of age and older	n/a
Wakix	6 years of age and older	18 years of age and older	n/a
Xyrem, Sodium Oxybate	7 years of age and older	7 years of age and older	n/a
Xywav	7 years of age and older	7 years of age and older	18 years of age and older

Coverage Guidelines
Authorization may be reviewed for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, 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:

<u>Lumryz, Wakix, Xyrem, Sodium Oxybate</u>:
Excessive Daytime Sleepiness Associated with Narcolepsy

1. Member has a diagnosis of excessive daytime sleepiness in narcolepsy
2. Member meets ONE of the following:
    a. **Lumryz, Sodium Oxybate and Xyrem:** Member is 7 years of age or older
    b. **Wakix:** Member is 6 years of age or older
3. Diagnosis is confirmed by sleep lab evaluation.
4. 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, BOTH of the following**:
    a. Member has had an inadequate response, intolerance, or contraindication to at least one CNS wakefulness promoting drug (e.g., modafinil, armodafinil)
    b. Member has had an inadequate response, intolerance, or contraindication to Sunosi
6. **Lumryz, Sodium Oxybate and Xyrem**: member has had inadequate response, intolerance, or contraindication to Wakix

Cataplexy in Narcolepsy:

1. Member has a diagnosis of cataplexy in narcolepsy
2. Member meets ONE of the following:
    a. **Lumryz, Sodium Oxybate and Xyrem:** Member is 7 years of age or older
    b. **Wakix:** 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, BOTH of the following**:
    a. Member has had an inadequate response, intolerance, or contraindication to at least one CNS wakefulness promoting drug (e.g., modafinil, armodafinil)
    b. **Lumryz, Sodium Oxybate and Xyrem:** Member has had an inadequate response, intolerance, or contraindication to Wakix

<u>Xywav</u>:

Excessive Daytime Sleepiness in Narcolepsy

1. Member has a diagnosis of excessive daytime sleepiness in narcolepsy
2. Member is 7 years of age or older
3. Diagnosis is confirmed by a sleep evaluation
4. 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, BOTH of the following**:
    a. Member has had an inadequate response, intolerance, or contraindication to at least one CNS wakefulness promoting drug (e.g., modafinil, armodafinil)
    b. Member has had an inadequate response, intolerance, or contraindication to Sunosi
6. Member has had inadequate response, intolerance, or contraindication to Wakix

Cataplexy in Narcolepsy

1. Member has a diagnosis of cataplexy in narcolepsy
2. Member is 7 years of age or older
3. 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, BOTH of the following**:

a. Member has had an inadequate response, intolerance, or contraindication to at least one CNS wakefulness promoting drug (e.g., modafinil, armodafinil)
b. Member has had an inadequate response, intolerance, or contraindication to Wakix

Idiopathic Hypersomnia

1. Member has a diagnosis of idiopathic hypersomnia
2. Member is 18 years of age or older
3. Diagnosis is confirmed by sleep lab evaluation
4. 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. Member has had an inadequate response, intolerance, or contraindication to at least one CNS wakefulness promoting drug (e.g., modafinil, armodafinil)

Continuation criteria:

Reauthorization requires physician documentation of continuation of therapy and positive response to therapy, as evidenced by:

- **Xyrem, Sodium Oxybate, Xywav, Lumryz, Wakix:**
  - **EDS or cataplexy in narcolepsy:** decreased daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy
- **Xywav:**
  - **Idiopathic hypersomnia:** decrease in daytime sleepiness from baseline

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.
2. The following quantity limits may apply:

Drug Name	Quantity Limit
Xyrem, Sodium Oxybate	540mL per 30 days
Xywav	540mL per 30 days
Lumryz	30 tablets per 30 days
Wakix	60 tablets per 30 days

References

1. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
2. 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.
3. Lumryz (sodium oxybate) [prescribing information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; October 2024.
4. 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.
5. Wakix (pitolisant) [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences LLC; June 2024.
6. Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.
7. Xywav (calcium, magnesium, potassium, and sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; April 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
12/11/2024 – Reviewed and updated for December P&T. Updated age indication for Wakix for treatment of cataplexy to 6 years old. Updated approvable age for Lumryz to 7 years of age. Added criteria for idiopathic hypersomnia for Xywav. Updated Effective 4/1/2025.
01/08/2025 – Reviewed and updated for January P&T. Updated criteria for Lumryz, Xywav, and Xyrem to require step through with Sunosi for members 18 and older with a diagnosis of excessive daytime sleepiness in narcolepsy and specified that step through with Wakix for diagnosis of cataplexy in narcolepsy applies to members 18 years of age and older. Effective 04/01/2025.