Overview
Xyrem and Xywav are mediated by GABA\textsubscript{B} receptor activity at noradrenergic, dopaminergic, and thalamocortical neurons. These medications are approved for cataplexy or excessive daytime sleepiness in narcolepsy.

Coverage Guidelines
Authorization may be reviewed for members new to AllWays Health Partners 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, and documentation is provided:
1. The member has a diagnosis of cataplexy or excessive daytime sleepiness in narcolepsy
2. The member is 7 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)
6. The member has had inadequate response, intolerance, or contraindication to Wakix

Specialty Medications
| All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |

Non-Specialty Medications
| MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| Exchange   | Phone: 855-582-2022 | Fax: 855-245-2134 |

Medical Specialty Medications (NLX)
| All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |

Exceptions

Specialty (sodium oxybate)
Xywav (oxybate salts [calcium, magnesium, potassium, and sodium])
Wakix (pitolisant)
Effective 01/01/2022
**Wakix (pitolisant)**

Documentation of all of the following is required:

1. Appropriate diagnosis
2. Member is ≥ 18 years of age
3. Medical records documenting the results of the sleep study used to confirm narcolepsy [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]
4. Requested dose does not exceed the quantity limit of two units/day
5. Paid claim or physician attestation of inadequate response or adverse reaction to THREE of the following, or contraindication to ALL of the following:
   a. armodafinil or modafinil
   b. cerebral stimulant agent
   c. Sunosi
   d. Xyrem.

**Xyrem (sodium oxybate) and Xywav (oxybate salts)**

Documentation of all of the following is required:

1. Member has ONE of the following diagnosis:
   a. Narcolepsy with cataplexy
   b. Excessive daytime sleepiness (EDS) due to narcolepsy (without cataplexy):
2. Medical records documenting the results of the sleep study used to confirm narcolepsy [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]
3. prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided
4. For diagnosis of Narcolepsy with cataplexy: paid claims or physician attestation of inadequate response or adverse reaction to one, or contraindication to all of the following: tricyclic antidepressant, SSRI, venlafaxine
5. For diagnosis of EDS due to narcolepsy (without cataplexy) member must meet BOTH of the following:
   a. paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to one cerebral stimulant agent
   b. paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to armodafinil or modafinil
6. requested quantity does not exceed the quantity limit of nine grams (18 mL)/day
7. for Xywav, medical necessity for use instead of Xyrem

**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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity Limit</th>
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<tbody>
<tr>
<td>Xyrem</td>
<td>540mL per 30 days</td>
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AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>Xywav</td>
<td>540mL per 30 days</td>
</tr>
<tr>
<td>Wakix</td>
<td>60 tablets per 30 days</td>
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</tbody>
</table>

**References**

9. Xywav (calcium, magnesium, potassium, and sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; July 2020.

**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; Updated criteria to match MH criteria. Effective Date: 1/1/2022

**Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.