Overview
Xyrem and Xywav are mediated by GABA₉ 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 Xyrem or Xywav 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
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>
</tr>
<tr>
<td>Xywav</td>
<td>540mL 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; Added requirement of previous use of Wakix prior to Xyrem or Xywav. Effective Date: 1/1/2022

Disclaimer
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