# Prior Authorization and Reauthorization of XYWAV®

xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution

*This form provides criteria to help facilitate the prior authorization or reauthorization of XYWAV, but does not guarantee it.*

1. **Select:** ☐ Prior Authorization ☐ Reauthorization

2. **Dosage:** _____ Maintenance dose: _____ Bedtime dose: _____ 2.5-4 hours later: _____

   *(Please refer to accompanying **Prescribing Information** for dosage instruction.):*[1]

3. **For reauthorizations, many payers will require evidence of symptom improvement over time.**

☐ **Narcolepsy with cataplexy (ICD: G47.411):**

Baseline # of cataplexy attacks per week: _____ Testing Date: _____
# of cataplexy attacks per week at follow-up: _____ Testing Date: _____
# of cataplexy attacks per week at follow-up: _____ Testing Date: _____
# of cataplexy attacks per week at reauthorization: _____ Testing Date: _____

Baseline ESS score: _____ Testing Date: _____
ESS score at follow-up: _____ Testing Date: _____
ESS score at follow-up: _____ Testing Date: _____
ESS score at reauthorization: _____ Testing Date: _____

☐ **Narcolepsy without cataplexy (ICD: G47.419):**

Baseline ESS score: _____ Testing Date: _____
ESS score at follow-up: _____ Testing Date: _____
ESS score at follow-up: _____ Testing Date: _____
ESS score at reauthorization: _____ Testing Date: _____

**Indications and Usage**

XYWAV® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII, 0.5 g/mL total salts (equivalent to 0.413 g/mL of oxybate), is indicated for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy and for the treatment of IH in adults.

**Important Safety Information**

**WARNING: CENTRAL NERVOUS SYSTEM DEPRESSION and ABUSE AND MISUSE.**

- **Central Nervous System Depression**
  **XYWAV is a CNS depressant. Clinically significant respiratory depression and obtundation may occur in patients treated with XYWAV at recommended doses. Many patients who received XYWAV during clinical trials in narcolepsy and idiopathic hypersomnia were receiving CNS stimulants.**
- **Abuse and Misuse**
  **The active moiety of XYWAV is oxybate or gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.**

**Because of the risks of CNS depression and abuse and misuse, XYWAV is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XYWAV and XYREM REMS.**

**Please see next page for additional Important Safety Information and accompanying Prescribing Information, including BOXED Warning.**

# Prior Authorization and Reauthorization of XYWAV®

☐ **Idiopathic hypersomnia (ICD: G47.11 or G47.12):**

Baseline ESS score: _____ Testing Date: _____
ESS score at follow-up: _____ Testing Date: _____
ESS score at follow-up: _____ Testing Date: _____
ESS score at reauthorization: _____ Testing Date: _____

And/Or

Baseline IHSS score: _____ Testing Date: _____
IHSS score at follow-up: _____ Testing Date: _____
IHSS score at follow-up: _____ Testing Date: _____
IHSS score at reauthorization: _____ Testing Date: _____

**4. Confirm diagnosis: patient meets diagnostic criteria for narcolepsy or IH:[2]** ☐ **Yes** ☐ **No**

**5. Attach medical records or list cardiovascular or cardiometabolic comorbidities below that support the patient's need for a low sodium oxybate.***

_____

_____

_____

_____

**With 131 mg of sodium at the maximum recommended nightly dose, XYWAV has 92% less sodium than high sodium oxybates.*[3]

**Important Safety Information (cont.)**

**Contraindications**
XYWAV is contraindicated in combination with sedative hypnotics or alcohol and in patients with succinic semialdehyde dehydrogenase deficiency.

**Warnings and Precautions**
- CNS Depression: Use caution when considering the concurrent use with other CNS depressants. If concurrent use is required, consider dose reduction or discontinuation of one or more CNS depressants (including XYWAV). Consider interrupting XYWAV treatment if short-term opioid use is required. After first initiating treatment and until certain that XYWAV does not affect them adversely, caution patients against hazardous activities requiring complete mental alertness or motor coordination such as operating hazardous machinery, including automobiles or airplanes. Also caution patients against these hazardous activities for at least 6 hours after taking XYWAV. Patients should be queried about CNS depression-related events upon initiation of XYWAV therapy and periodically thereafter.

**Please see next page for additional Important Safety Information and accompanying Prescribing Information, including BOXED Warning.**

6. **Symptoms patient with IH is experiencing:**[4,5]

☐ **EDS** ☐ **Prolonged sleep duration** ☐ **Cognitive impairment** ☐ **Sleep inertia**

7. **Has the patient had an unsatisfactory therapeutic response to other therapies?**[6] ☐ **Yes** ☐ **No**

*Please note if patient is contraindicated or rationale if medication not taken:* _____

8. **Select recommendation(s) for follow-up:**

☐ **Initial XYWAV prescription:** *Next visit date:* _____

☐ **3 month follow-up:** *Next visit date:* _____

☐ **6 month follow-up:** *Next visit date:* _____

☐ **12 month follow-up:** *Next visit date:* _____

☐ **Other:** *Next visit date:* _____

9. **Additional information about patient's experience on this medication** (suggest to attach clinical notes):

_____

_____

**Important Safety Information (cont.)**

**Warnings and Precautions (cont.)**

- Abuse and Misuse: XYWAV is a Schedule III controlled substance. The rapid onset of sedation, coupled with the amnestic features of GHB particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (eg, assault victim).

- Respiratory Depression and Sleep-Disordered Breathing: XYWAV may impair respiratory drive, especially in patients with compromised respiratory function. In overdoses of oxybate and with illicit use of GHB, life-threatening respiratory depression has been reported. Increased apnea and reduced oxygenation may occur with XYWAV administration in adult and pediatric patients. A significant increase in the number of central apneas and clinically significant oxygen desaturation may occur in patients with obstructive sleep apnea treated with XYWAV. Prescribers should be aware that sleep-related breathing disorders tend to be more prevalent in obese patients, in men, in postmenopausal women not on hormone replacement therapy, and among patients with narcolepsy.

**Please see next page for additional Important Safety Information and accompanying Prescribing Information, including BOXED Warning.**

***If you require additional assistance or information, please contact your Jazz Access and Reimbursement Manager. You can also call a Reimbursement Specialist with the Certified Pharmacy at 1-866-997-3688.***

**Important Safety Information (cont.)**

Warnings and Precautions (cont.)

- Depression and Suicidality: In clinical trials in adult patients with narcolepsy and IH, depression and depressed mood were reported in patients treated with XYWAV. In most cases, no change in XYWAV treatment was required. Two suicides and two attempted suicides occurred in adult clinical trials with oxybate (same active moiety as XYWAV). One patient experienced suicidal ideation and two patients reported depression in a pediatric clinical trial with oxybate. Monitor patients for the emergence of increased depressive symptoms and/or suicidality while taking XYWAV, which require careful and immediate evaluation.

- Other Behavioral or Psychiatric Adverse Reactions: Monitor patients for impaired motor/cognitive function or the emergence of or increase in anxiety and/or confusion. The emergence or increase in the occurrence of behavioral or psychiatric events in patients taking XYWAV should be carefully monitored.

- Parasomnias: In clinical trials, parasomnias including sleepwalking were reported in adult patients treated with XYWAV. Parasomnias, including sleepwalking, also have been reported in a pediatric clinical trial with sodium oxybate (same active moiety as XYWAV) and in postmarketing experience with sodium oxybate. Episodes of sleepwalking should be fully evaluated and appropriate interventions considered.

Most Common Adverse Reactions

The most common adverse reactions (occurring in ≥5% of XYWAV-treated patients in adult clinical trials in either narcolepsy or IH) were nausea, headache, dizziness, anxiety, insomnia, decreased appetite, hyperhidrosis, vomiting, diarrhea, dry mouth, parasomnia, somnolence, fatigue, and tremor.

In the pediatric clinical trial with XYREM (same active moiety as XYWAV) in patients 7 years of age and older with narcolepsy, the most common adverse reactions (≥5%) were nausea (20%), enuresis (19%), vomiting (18%), headache (17%), weight decreased (13%), decreased appetite (9%), dizziness (8%), and sleepwalking (6%). The safety profile in pediatric patients with XYWAV is expected to be similar to that of adult patients treated with XYWAV and to that of pediatric patients treated with XYREM.

**Please see full Prescribing Information including BOXED Warning.**

**For more information on XYWAV, visit www.xywavhcp.com.**

**Abbreviations**:
ESS=Epworth Sleepiness Scale; EDS=Excessive Daytime Sleepiness; IHSS=Idiopathic Hypersomnia Severity Scale; PSG=Polysomnography

**References:**
**1.** XYWAV™ (calcium, magnesium, potassium, and sodium oxybates) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; 2021. **2.** American Academy of Sleep Medicine. International Classification of Sleep Disorders, 3rd ed, Text Revision. 2023. **3.** Chen C, Jenkins J, Zomorodi K, Skowronski R. Pharmacokinetics, bioavailability, and bioequivalence of lowersodium oxybate in healthy participants in two open-label, randomized, crossover studies. Clin Transl Sci. 2021;14(6):2278-2287. **4.** Arnulf I, et al. Update on the treatment of ideiopathic hypersomnia: progress, challenges, and expert opinion. Sleep Med Rev. 2023;69:1-10. **5.** Dauvilliers Y, et al. Clinical considerations for the diagnosis of idiopathic hypersomnia. Sleep Med Rev. 2022;66:1-10. **6.** UHC. Program Number 2022 P 2021-16. Prior Authorization/Medical Necessity – Xyrem, Xywav. 2.1.2022.



Jazz Pharmaceuticals


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