

**Louisiana Fee-for-Service Medicaid**

**Sodium Oxybate (Xyrem®) and Calcium, Magnesium, Potassium and Sodium Oxybates (Xywav™)**

**Sodium oxybate (Xyrem®) requires clinical authorization.** The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for sodium oxybate (Xyrem®) and calcium, magnesium, potassium and sodium oxybates (Xywav™).

These agents have Black Box Warnings and are subject to Risk Evaluation and Mitigation Strategy (REMS) under FDA safety regulations. Please refer to individual prescribing information for details.

**Xyrem® (sodium oxybate) has a Black Box Warning and is available only through a Risk Evaluation and Mitigation Strategies (REMS) program. See the full prescribing information for details.**

**Requests will be considered for initial approval if all of the following criteria are met: Approval Criteria**

- The recipient is 7 years of age or older on date of request; AND
- The recipient has a documented diagnosis of narcolepsy or cataplexy; **AND**
- The prescribing provider is a Board-Certified Neurologist or a Board-Certified Sleep Medicine Physician; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the product prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states.

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**Duration of initial authorization approval: 3 months**

**Requests to continue treatment with sodium oxybate will be considered for approval if all of the following criteria are met: Reauthorization Criteria**

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber states on the request that there is evidence of a positive response to therapy as indicated by a reduction in:
  - The frequency of cataplexy attacks associated with sodium oxybate therapy; **OR**

- Symptoms of excessive daytime sleepiness ~~associated with sodium oxybate therapy~~.

**Duration of initial authorization approval: 3 months**

**Duration of ~~renewal authorization~~ reauthorization approval: 12 months**

#### **Point-of-Sale (POS) Edit**

##### Therapeutic Duplication

Incoming prescriptions for Xyrem® (sodium oxybate) ~~or Xywav™ (calcium, magnesium, potassium and sodium oxybates)~~ will deny at Point-of-Sale (POS) when there is at least one active prescription on the recipient's file for a CNS depressant medication, whether as a single entity or as a component of a combination product. An active prescription is a prescription in which the days supply has not expired. Alternately, incoming prescriptions for a CNS depressant medication will deny at POS when there is an active prescription on the recipient's file for Xyrem® (sodium oxybate) ~~or Xywav™ (calcium, magnesium, potassium and sodium oxybates)~~.

CNS depressant medications include but are not limited to the following agents. Additional contraindicated medications may be added to this list.

Alprazolam	Dantrolene	Metaxalone	Quazepam
Baclofen	Diazepam	Methadone	Ramelteon
Buprenorphine	Dihydrocodeine	Methocarbamol	Remifentanil
Buspirone	Doxepin	Midazolam	Secobarbital
Butabarbital	Estazolam	Morphine	Sufentanil
Butalbital	Eszopiclone	Nalbuphine	Suvorexant
Butorphanol	Fentanyl	Opium	Tapentadol
Carisoprodol	Flurazepam	Orphenadrine	Tasimelteon
Chlordiazepoxide	Hydrocodone	Oxazepam	Temazepam
Chlorzoxazone	Hydromorphone	Oxycodone	Tizanidine
Clonazepam	Levorphanol	Oxymorphone	Tramadol
Clorazepate	Lorazepam	Paregoric	Triazolam
Codeine	Meperidine	Pentazocine	Zaleplon
Cyclobenzaprine	Meprobamate	Phenobarbital	Zolpidem

##### References

Xyrem (sodium oxybate) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; September 20182020. <https://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf>

Retrieved from <http://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf> Xywav (calcium, magnesium, potassium and sodium oxybates) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2020. <https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf>

<b><u>Revision</u></b>	<b><u>Date</u></b>
<u>Added Xywav™, modified clinical criteria to include age, formatting changes, updated references</u>	<u>October 2020</u>