

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

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®TM).

[Additional Point-of-Sale edits may apply.](#)

*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.*

Calcium, Magnesium, Potassium and Sodium Oxybates (Xywav®)

Approval Criteria

- ONE of the following is true:
 - The recipient is 7 years of age or older on date of request with a documented diagnosis of narcolepsy or cataplexy; **ORAND**
 - The recipient is 18 years of age or older on date of request with ~~has~~ a documented diagnosis of idiopathic hypersomnia (IH) ~~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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.
 - ~~The recipient has no inappropriate concomitant drug therapies or disease states.~~

Duration of initial authorization approval: 3 months

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; **OR**
 - Symptoms of excessive daytime sleepiness.

Duration of reauthorization approval: 12 months

Sodium Oxybate (Xyrem®)

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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial authorization approval: 3 months

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; **OR**
 - Symptoms of excessive daytime sleepiness.

Duration of 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	Remifentanyl
Bupirone	Doxepin	Midazolam	Secobarbital
Butabarbital	Estazolam	Morphine	Sufentanyl
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 2020. <https://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf>

Xywav (calcium, magnesium, potassium and sodium oxybates) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; ~~August 2021~~ ~~October 2020~~.
<https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf>

<u>Revision / Date</u>	<u>Implementation Date</u>
Xyrem policy created	January 2016
Added Xywav™, modified clinical criteria to include age, formatting changes, updated references / <u>October 2020</u>	<u>April 2021</u> <u>October 2020</u>
<u>Added new indication for Xywav®, formatting changes, updated references / August 2021</u>	