# Pharmacy Prior Authorization Form

**Fax completed form to: 877.974.4411 toll free, or 616.942.8206**

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

# Xyrem® (sodium oxybate)

## Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

## Product Information

☐ New Request ☐ Continuation Request

Drug product: ☐ Xyrem 500 mg/mL

**Start date** (or date of next dose): _____

**Date of last dose** (if applicable): _____

**Dosing frequency:** _____

## Drug cost information

The wholesale acquisition cost for each 1 mL (500 mg) of Xyrem is $23.97. The annual cost of treatment with this drug will vary depending on the patient's circumstances, but may cost more than $165,000.

## Precertification Requirements

**Before this drug is covered, the patient must meet all of the following requirements:**

1. Must be prescribed by a board certified sleep specialist or neurologist
2. Must be at least 7 years of age
3. Patient must have one of the following conditions and meet requirements specific to that condition:

***(Note that Xyrem is only indicated to treat pediatric patients 7 years of age and older for Narcolepsy Type 1 (narcolepsy with cataplexy) and will not be approved for other forms of narcolepsy)***

   a. Cataplexy substantial enough to warrant treatment
      i. Must first try fluoxetine, venlafaxine ER, or Strattera for 6 weeks with continued cataplexy
   b. Excessive daytime sleepiness in patients with narcolepsy
      i. Must have a documented therapeutic trial with one of the following: amphetamine salts, dextroamphetamine or methylphenidate with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others, AND
      ii. Must have documented therapeutic trial of modafinil and armodafinil with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others.
4. MSLT plus polysomnogram must meet requirements according to International Classification of Sleep Disorders – Third Edition (ICSD-3) for the diagnosis of narcolepsy. Must fax MSLT plus polysomnogram results to Priority Health
5. Must not take with sedative hypnotics
6. Must not drink alcohol when using Xyrem



**All fields must be complete and legible for review. Your office will receive a response via fax.**

Updated 12/2018
Last reviewed 01/2019

7. Must not have succinic semialdehyde dehydrogenase deficiency
8. Must not exceed a daily dose of 9 grams (558 mL every 31 days)

**For continuation, patient must meet the following requirements:**

1. Patient continues to meet precertification requirements, AND
2. Absence of unacceptable toxicities, AND
3. Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline OR reduced frequency of cataplexy attacks from pre-treatment baseline if patient has cataplexy

**Note:** Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

## Priority Health Precertification Documentation

**A. What condition is this drug being requested for?**

☐ **Narcolepsy with cataplexy**
What length of time did the patient take the following drugs, if any?
☐ fluoxetine Duration: _____
☐ Strattera Duration: _____
☐ venlafaxine ER Duration: _____

☐ **Narcolepsy with excessive daytime sleepiness**
Which of the following medications has the patient had a therapeutic trial with? Please explain response/outcome of trial.
☐ amphetamine salts, *outcome*: _____
☐ dextroamphetamine, *outcome*: _____
☐ methylphenidate, *outcome*: _____
☐ modafinil, *outcome*: _____
☐ Nuvigil, *outcome*: _____
☐ Other: _____
☐ None of the above – *Rationale for use:* _____

☐ Other – the patient's condition is*:* _____
*Rationale for use:* _____

**B. Fax polysomnography results with this request that shows patient meets requirements according to ICSD3 for the diagnosis of narcolepsy.**

**C. Which, if any, of the following apply to this patient?**
☐ Patient is also taking a sedative hypnotic
☐ Patient drinks alcohol
☐ Patient has semialdehyde dehydrogenase deficiency
☐ None of the above

## Request to continue a previously authorized approval
## Priority Health Precertification Documentation

**A. Please verify that patient continues to meet precertification criteria.**

**B. Has patient had any side effects or toxicities from Xyrem? Please explain:**

_____
_____
_____


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**C. Please provide chart notes or describe patient's response to treatment with Xyrem supporting effectiveness:**

## Additional information

**Note:** The safety and effectiveness of Xyrem at doses more than 9 grams each day has not been investigated and, therefore, should not be given. Authorization for Xyrem must be requested every year.

**ICSD3 Diagnostic criteria**

**Narcolepsy type 1 (criteria A and B must be met):**

A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.
B. The presence of one or both of the following:
    1. Cataplexy and a mean sleep latency of ≤ 8 minutes and two or more SOREMPs on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.
    2. CSF hypocretin-1 concentration, measured by immunoreactivity, is either ≤ 110 pg/mL or < 1/3 of mean values obtained in normal subjects with the same standardized assay.

**Narcolepsy type 2 (criteria A through E must be met):**

A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.
B. A mean sleep latency of ≤8 minutes and two or more SOREMPs are found on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.
C. Cataplexy is absent.*
D. Either CSF hypocretin concentration has not been measured or CSF hypocretin concentration measured by immunoreactivity is either >110 pg/mL or >1/3 of mean values obtained in normal subjects with the same standardized assay.
E. The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal.


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