Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	December 4, 2008 December 11, 2008 June 9, 2011; June 18, 2012, October 25, 2017, November 27, 2018, November 24, 2020

XYREM® (sodium oxybate)

LENGTH OF AUTHORIZATION: Initial therapy may be approved for up to 3 months. Continuation of therapy may be approved for up to 6 months.

REVIEW CRITERIA:

Initiation of Therapy:

1. Patient is ≥ 7 years of age.
2. The medication must be prescribed by a physician specializing in narcolepsy or neurologist.
3. The patient must be enrolled in the Xyrem and Xywav REMS program.
4. For cataplexy in narcolepsy:
    - Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results (reference chart below).
5. For excessive daytime sleepiness:
    - Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results (reference chart below); **AND**
    - Submission of progress notes indicating that sleepiness is significantly impacting daytime functioning; **AND**
    - Must have tried and failed/intolerant to at least one preferred stimulant treatment (e.g. methylphenidate or dextroamphetamine); **AND**
    - Verify that dosage has been maximized (reference chart below for stimulants) **AND**
    - Trial and failure of modafinil for patients 17 years and older; **AND**
    - Trial period is 2 months (60 days) for each required trial; **AND**
    - Supporting documentation must be submitted.
6. Approved for twice nightly dosing (first dose at bedtime then next dose 2.5 – 4 hours later while in bed).

Continuation of Therapy:

1. Patient is ≥ 7 years of age.
2. The medication must be prescribed by a physician specializing in narcolepsy or neurologist.
3. The patient must be enrolled in the Xyrem and Xywav REMS program.
4. The physician specializing in narcolepsy or neurologist must submit their interpretation of the Epworth Sleepiness Scale (**ESS**) and/or the Maintenance of Wakefulness Test (**MWT**) to demonstrate response to current therapy.
    a. **ESS**: a subjective patient questionnaire that evaluates the extent of daytime sleepiness in everyday situations.
    b. **MWT**: an objective measurement of latency to sleep onset (in minutes) or daytime wakefulness following nocturnal polysomnography – higher scores indicate greater wakefulness.
5. Approved for twice nightly dosing (first dose at bedtime then next dose 2.5 – 4 hours later while in bed).

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Availability:
Xyrem is available through the Xyrem and Xywav REMS program, using a centralized pharmacy 1-866-997-3688. The REMS Program provides educational material to the prescriber and the patient explaining the risks and proper use of sodium oxybate, and the required form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. Xyrem and Xywav REMS program also recommends patients follow-up every 3 months. Physicians are expected to report all serious adverse events to the REMS Program.

REFERENCE CHARTS

Medication	Dosage Ranges
Methylphenidate	**10-60 mg/day in 2-3 divided doses**
Dextroamphetamine	**5-60 mg/day in 1-3 divided doses**

	Normal	Narcolepsy
PSG	• Non-rapid eye movement (NREM) and rapid eye movement (REM) sleep alternate through the night, with an approximately 90-minute cycle. • Four to five cycles of REM and non-REM sleep during a night.	• Sleep latency (time it takes from the start of a daytime nap period to the first signs of sleep) < 10 min. • Stage 1 sleep extended. • Disruption of normal sleep pattern with frequent awakenings.
MSLT	• Sleep latency of > 10 min. • REM sleep does not occur at sleep onset.	• Mean sleep latency of ≤ 8 min. • Two or more sleep-onset REM periods (SOREMPs).