Commercial PA Criteria

Effective: December 2005

Prior Authorization: Sodium oxybate

Products Affected: Xyrem (sodium oxybate), Lumryz (sodium oxybate) oral powder for suspension, Lumryz (sodium oxybate) therapy pack

Medication Description:

Xyrem (Sodium oxybate) is a central nervous system depressant with anti-cataplectic activity in patients with narcolepsy. Although the precise mechanism by which sodium oxybate produces an effect on cataplexy and daytime sleepiness is unknown, its effects are thought to be mediated through gamma-aminobutyric acid (GABA)-B actions at the noradrenergic, dopaminergic, and thalamocortical neurons

Covered Uses:

A) Treatment of cataplexy in patients with narcolepsy
B) Treatment of excessive daytime sleepiness (EDS) in patients with narcolepsy

Exclusion Criteria:

1. Fibromyalgia - The European League Against Rheumatism (EULAR) issued evidence-based recommendations for the management of fibromyalgia (2016) stating that initial management should involve patient education and focus on non-pharmacological therapies. EULAR's sodium oxybate for fibromyalgia is strongly against with 94% agreement. Duloxetine, pregabalin capsules and oral solution, and Savella (milnacipran tablets) are indicated for the treatment of fibromyalgia. Other recommended treatments include tricyclic antidepressants (i.e., amitriptyline), cyclobenzaprine, gabapentin, and selective serotonin reuptake inhibitors (i.e., fluoxetine, sertraline, paroxetine).
2. Concomitant use of Lumryz, sodium oxybate oral solution, and/or Xyrem with each other or an oxybate product used in combination with Wakix (pitolisant tablets) and/or Sunosi (solriamfetol tablets).

Required Medical Information:

1. Diagnosis

Age Restrictions: 7 years of age and older

Prescriber Restrictions: Prescriber must be a neurologist or sleep specialist certified in the Xyrem Risk Evaluation and Mitigation Strategy (REMS) program as required by the FDA.

Coverage Duration:

Initial coverage - will be granted for 3 months
Renewal coverage - will be granted for 1 year

Other Criteria:

1. Cataplexy associated with Narcolepsy

Approve if the patient meets ALL of the following (A, B, C, **and** D):

A. Patient has been evaluated using polysomnography and a multiple sleep latency test; **AND**
B. Diagnosis of narcolepsy has been confirmed, according to the prescriber; **AND**
C. The medication has been prescribed by a sleep specialist physician or a neurologist; **AND**
D. Patient meets ONE of the following (i **or** ii);
    i. Patient has tried dextroamphetamine; **OR**
    ii. Patient has a contraindication or intolerance to dextroamphetamine, according to the prescriber. *Note: Contraindications to dextroamphetamine include a of substance use disorder; advanced arteriosclerosis, symptomatic cardiovascular disease, and/or moderate to severe hypertension; hyperthyroidism; known hypersensitivity to sympathomimetic amines; glaucoma; agitated states; and concomitant administration with monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs.*

2. <u>Excessive Daytime Sleepiness associated with Narcolepsy</u>

Approve if the patient meets ALL of the following (A, B, C, **and** D):

A. Patient has been evaluated using polysomnography and a multiple sleep latency test; **AND**
B. Diagnosis of narcolepsy has been confirmed, according to the prescriber; **AND**
C. The medication has been prescribed by a sleep specialist physician or a neurologist; **AND**
D. Patient has tried at least one of the following treatments: a central nervous system (CNS) stimulant, modafinil, or armodafinil.
    Note: Examples of CNS Subsequent approval (up to 1 year) will be based on current progress notes from the physician documenting efficacy of treatment.

<u>References</u>:

1. Xyrem oral solution [prescribing information]. Palo Alto, CA: Jazz; April 2023.
2. Lumryz™ extended-release oral suspension [prescribing information]. Chesterfield, MO: Avadel; October 2024.
3. Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2017;76(2):318-328.

<u>Policy Revision history</u>

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New policy	New policy	All	12/2005

2	Update	Transferred to new CCI template CCI P&T Review History 12/05, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 2/17, 5/17, 1/18. CCI Revision Record 4/10, 2/17, 5/17, 7/19	All	7/23/2023
3	Update	Added Lumryz (sodium oxybate) To prior authorization and products affected Updated policy name from Xyrem to Sodium Oxybate	Prior authorization Products affected	7/24/2023
4	Update	Added Lumryz (sodium oxybate) therapy pack to prior authorization and products affected Updated criteria and exclusion criteria to label requirements	Prior authorization Products affected	11/25/2024