Commercial/Healthcare Exchange PA Criteria

Effective: December 2005

Prior Authorization: Sodium oxybate

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

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:

Xyrem has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

- Patient is being treated with sedative hypnotics, other CNS depressants, or using alcohol.
- Patient has succinic semialdehyde dehydrogenase deficiency (This rare disorder is an inborn error of metabolism and variable characterized by mental retardation, hypotonia, and ataxia.)
- Patient has a history of substance abuse.

Required Medical Information:

A) 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 re-evaluated every 3 months for the rest of the coverage year

Other Criteria:

1. Cataplexy associated with Narcolepsy

   Approve if the patient meets the following criteria (A, B **AND** C)

   A. Patient must have a documented diagnosis of narcolepsy **AND**

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B. Patient must have cataplexy requiring treatment **AND**
C. Patient has tried three (3) of the following: modafinil, Nuvigil, a tricyclic antidepressant (TCA) [e.g., amitriptyline, desipramine, imipramine], a selective serotonin reuptake inhibitor (SSRI) [e.g., fluoxetine, sertraline, paroxetine], or venlafaxine

2. Excessive Daytime Sleepiness associated with Narcolepsy
   Approve if the patient meets the following criteria (A, B **AND** C)
   A. Patient must have a documented diagnosis of narcolepsy
   B. Patient must have excessive daytime sleepiness as defined by Epworth Sleepiness Scale (ESS) score greater than or equal to 10.
   C. Patient must have had a intolerance to, or treatment failure of an adequate trial of Provigil® (modafanil) or Nuvigil (armodafanil)

Subsequent approval (up to 1 year) will be based on current progress notes from the physician documenting efficacy of treatment.

References:

1. Xyrem® [package insert]. Jazz Pharmaceuticals, Inc., Palo Alto, CA.

Policy Revision history

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

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