Pharmacy Policy Bulletin

Category:	Prior Authorization
Number:	J-129
Subject:	Xyrem (sodium oxybate)
Effective Date Begin:	September 2, 2009
Effective Date End:	
Original Date:	September 2, 2009
Review Date(s):	September 1, 2010 September 2, 2009

Policy Applies to: *Commercial* plans only

Background: Xyrem (sodium oxybate) is a central nervous system depressant that has been shown in clinical studies to reduce excessive daytime sleepiness and cataplexy in patients with narcolepsy. However, the precise mechanism by which sodium oxybate produces an effect on cataplexy is unknown.

Sodium oxybate is GHB, a known drug of abuse. Abuse has been associated with some important central nervous system (CNS) adverse events (including death). Even at recommended doses, use has been associated with confusion, depression and other neuropsychiatric events. Reports of respiratory depression occurred in clinical trials. Almost all of the patients who received sodium oxybate during clinical trials were receiving CNS stimulants. Xyrem is available through the Xyrem Success Program®.

Xyrem® (sodium oxybate) oral solution is indicated for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy.

Sodium oxybate is also being studied for use in chronic insomnia (from a variety of sources including PTSD, in patients with schizophrenia, and chronic fatigue syndrome), fibromyalgia, Parkinson's disease, and obstructive sleep apnea. To date, sufficient evidence does not exist to suggest that sodium oxybate is safe or effective in treating any disease or condition outside of its FDA labeled indication.

Approval Criteria: When a benefit, sodium oxybate may be approved when the following criteria are met:

- Sodium oxybate is used to treat excessive daytime sleepiness in patients with narcolepsy, as documented in clinical notes and by MSLT or other appropriate testing **OR**
- Sodium oxybate is used to treat cataplexy associated with narcolepsy, as documented in clinical notes and by MSLT or other appropriate testing.

Use of sodium oxybate for disease states outside of its FDA-approved indications should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.

Duration of Authorization:
If approved, up to a lifetime authorization may be granted

References:
Xyrem® (sodium oxybate) prescribing information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. September 2008.