PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG (S)	**Xyrem (sodium oxybate)**
POLICY #	**21129**
INDICATIONS	Xyrem® (sodium oxybate) oral solution is indicated for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy.
CRITERIA	**Criteria:** Cataplexy associated with Narcolepsy (all below criteria must be met) • Patient must be 7 years of age and older. • Patient must have a documented diagnosis of narcolepsy • Patient must have cataplexy requiring treatment • 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 • Xyrem is being prescribed by a neurologist or sleep specialist physican Excessive Daytime Sleepiness associated with Narcolepsy (all below criteria must be met) • Patient must be 7 years of age and older. • Patient must have a documented diagnosis of narcolepsy • Patient must have excessive daytime sleepiness as defined by Epworth Sleepiness Scale (ESS) score greater than or equal to 10. • Patient must have had a intolerance to, or treatment failure of an adequate trial of Provigil® (modafanil) or Nuvigil (armodafanil) • Xyrem is being prescribed by a neurologist or sleep specialist physician Patients meeting any of the following criteria should NOT be considered for Xyrem therapy: • 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 drug abuse.
LIMITATIONS	Initial approval for 3 months. Subsequent approval (up to 1 year) will be based on current progress notes from the physician documenting efficacy of treatment. A quantity limit of 540ml per month will apply.

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References	Xyrem® [package insert]. Jazz Pharmaceuticals, Inc., Palo Alto, CA.
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
Revision Record	4/10, 2/17, 5/17, 7/19