



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Sodium Oxybate

Brand Name: Xyrem

Medication Class: central nervous system depressant

FDA Approved Uses: treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy

Available Dosage Form: Oral solution, 500mg/ml, 180ml bottle

Usual Dose: Initial: 4.5g/day in 2 equal doses, first dose given at bedtime after the patient is in bed, and second dose given 2.5 to 4 hours later.
Dose may be increased or adjusted in 2-week intervals.
Average dose 6 – 9 g/day (maximum dose 9 g/day)

Duration of Therapy: indefinite

Approximate monthly cost (based on AWP 2007): \$551.82

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Patient must be clinically diagnosed with narcolepsy and have cataplexy or excessive daytime sleepiness that is substantial enough to warrant treatment
- For cataplexy, must have tried and failed/intolerant to tricyclic antidepressants or SSRIs
- For excessive daytime sleepiness, must have tried and failed/intolerant to at least one formulary/preferred stimulant treatment, such as methylphenidate or dextroamphetamine.
- Must be older than 16. (Safety and effectiveness not established in children under 16.)
- Patient and physician must adhere to all regulations of the *Xyrem Success Program*.
- Initial approval for maximum of 1-month supply. Subsequent renewals for maximum approval period of 3 months at a time. (Patients are to be evaluated by physician no less frequently than every 3 months.)
- Must be prescribed by a neurologist.

Not Approved if:

- Patient is being treated with sedative hypnotic agents, other CNS depressants, or using alcohol.
- Patient has succinic semialdehyde dehydrogenase deficiency (This rare disorder is an in-born error of metabolism and variably characterized by mental retardation, hypotonia, and ataxia.)
- Patient has a history of drug abuse.
- Patient has any contraindications to the use of Xyrem



- Patient does not meet above criteria.

Notes:

- Xyrem should not be used with ethanol or other CNS depressants
- Use caution in patients with compromised respiratory function, history of depression or suicide attempts, psychiatric illness, hepatic dysfunction, heart failure, hypertension, or compromised renal function (contains significant amounts of sodium).
- Almost all patients receiving Xyrem under clinical trials were also receiving CNS stimulants.
- Xyrem, in combination with zolpidem, protriptyline, and modafanil, produced no significant pharmacokinetic changes in either drug. However, pharmacodynamic interactions cannot be ruled out. Xyrem should not be used in combination with sedative hypnotics or other CNS depressants.
- Xyrem rapidly produces deep sedation.
- Since food significantly reduces bioavailability, patients should eat several hours before going to sleep and taking Xyrem.
- Pharmacokinetics not studied in elderly over 65

P&T Approval: _____ Date: _____