Prior Authorization Approval Criteria

Xyrem (sodium oxybate)

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

Criteria for approval: *(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
- Must be prescribed by a neurologist, psychiatrist or sleep medicine specialist
- For cataplexy, must have failure/intolerance/contraindication to tricyclic antidepressants or SSRIs
- For excessive daytime sleepiness, must have failure/intolerance/contraindication to at least one formulary/preferred stimulant treatment, such as methylphenidate or dextroamphetamine AND at least one of the following: modafinil or armodafinil
- Must be older than 16 years old.
- Patient and physician must adhere to all regulations of the Xyrem Success Program.
- Patient should not be currently treated with sedative hypnotic agents, other CNS depressants, or using alcohol.

Criteria for continuation of therapy:
- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment and there continues to be a medical need for the medication.
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition).
- Patient and physician must adhere to all regulations of the Xyrem Success Program.

Caution:
- 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).
- Pharmacokinetics not studied in elderly over 65
- Sleepwalking, defined as confused behavior occurring at night and at times associated with wandering, was reported in 6% of 781 patients with narcolepsy treated with Xyrem in controlled and long-term open-label studies, with < 1% of patients discontinuing due to sleepwalking.

Approval Duration:
- Initial: 1 month
- Renewal: 3 months

Benefit Type:
- Pharmacy
Adopted:
Revised:
Reviewed: 06/14/17 – updated criteria for use, added continuation of therapy, approval duration, cautions & benefit type, removed not approved if & notes