BlueCross BlueShield of Kansas City

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Xyrem® (sodium oxybate)

Policy Number: 5.01.531
Origination: 3/2009
Last Review: 4/2014
Next Review: 4/2015

Policy

BCBSKC will provide coverage for sodium oxybate when it is determined to be medically necessary because the following criteria have been met.

When Policy Topic is covered

Sodium oxybate may be considered medically necessary in patients with documented* narcolepsy when:

- The patient's diagnosis is cataplexy (a sudden loss in muscle tone and deep tendon reflexes). OR
- The patient's diagnosis is excessive daytime sleepiness and Provigil® in doses up to 400 mg daily and at least one other formulary treatment such as methylphenidate or dextroamphetamine have been ineffective, not tolerated, or contraindicated.

*A polysomnogram and multiple sleep latency test (MSLT) is provided as documentation to support the diagnosis.

When Policy Topic is not covered

Sodium oxybate is considered **investigational** for other conditions or applications, including, but not limited to, the treatment of:

- Alcohol dependence and withdrawl,
- Fibromyalgia,
- Opioid dependence and withdrawal,
- Parkinsonism,
- Night eating syndrome,
- Myoclonus and essential tremor.

Description of Procedure or Service

Sodium oxybate (Xyrem®) is a medication used to reduce the number of cataplexy attacks and to reduce excessive daytime sleepiness in patients with narcolepsy. Sodium oxybate is a schedule III controlled substance.

Considerations

Sodium oxybate is available through the Xyrem Success Program, using a centralized pharmacy 1-866-XYREM88® (1-866-997-3688). The Success Program provides educational materials to the prescriber and the patient explaining the risks and proper use of sodium oxybate, and the required prescription form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. The Xyrem Success Program also recommends patient follow-up every 3 months. Physicians are expected to report all serious adverse events to the manufacturer.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Rationale

Sodium oxybate showed a statistically significant reduction in the weekly cataplexy attacks after 4 weeks of treatment, by about 6 to 12 attacks per week, compared to patients receiving placebo. (1-4, 14) Patients with excessive daytime sleepiness randomized to sodium oxybate showed a statistically significant but modest improvement in scores on rating scales to assess sleepiness and maintenance of daytime wakefulness compared to patients taking placebo after 8 weeks of treatment. (1,16,17) Aproximately 80% of patients maintained concomitant stimulant use. There is weak evidence to support use of sodium oxybate in the treatment of conditions other than cataplexy in narcolepsy. (5-13,15,18,19)

Off-Label Uses

ALCOHOL DEPENDENCE AND WITHDRAWAL

- Two small randomized controlled trials have reported reduction of symptoms related to alcohol withdrawal compared to placebo or to clomethiazole. (7,9) Three small randomized controlled trials examined the use of sodium oxybate on alcohol craving, alcohol consumption and/or abstinence. While suggestive of a useful effect, more studies are needed to fully understand the role of sodium oxybate for the management of alcohol abuse. (8, 18-19)

FIBROMYALGIA

Scharf et al. studied 24 women meeting the American College of Rheumatology (ACR) criteria for fibromyalgia. Subjects received sodium oxybate 6 g/day or placebo for one month each in a double-blind, randomized, placebo-controlled crossover fashion. [6] After one month of each treatment, the mean “tender point index” (TPI) was reduced from baseline by 8.5 for sodium oxybate vs. an increase of 0.7 for placebo. While suggestive of an effect, the small size and high rate of patient non-completion in this trial (4/24 or 17%) render it not useful for recommending treatment. Larger, well-designed randomized controlled trials are needed.

OTHER INDICATIONS

Sodium oxybate has been studied in small, preliminary trials for possible efficacy in opiate withdrawal syndrome, parkinsonism, essential tremor, alcohol dependency and night-eating syndrome. Further research is needed to establish the clinical safety and efficacy of sodium oxybate for these indications. [10-13, 15, 19]

Safety

Contraindications to the use of sodium oxybate include: [1]

- Concomitant treatment with sedative hypnotic agents.
- Use in patients with succinic semialdehyde dehydrogenase deficiency. This rare disorder is an inborn error of metabolism variably characterized by mental retardation, hypotonia, and ataxia.

Black-Box Warning [1]

- Sodium oxybate should not be used with alcohol or other central nervous system (CNS) depressants. It is the same chemical as gamma hydroxybutyrate (GHB), a known drug of abuse. Abuse has been associated with some important 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.
- Important CNS adverse events associated with abuse of GHB include seizure, respiratory depression and profound decreases in level of consciousness, with instances of coma and death. For events that occurred outside of clinical trials, in people taking GHB for recreational purposes, the circumstances surrounding the events are often unclear (e.g., dose of GHB taken, the nature and amount of alcohol or any concomitant drugs).

- Sodium oxybate is available through the Xyrem Success Program, using a centralized pharmacy 1-866-XYREM88® (1-866-997-3688). The Success Program provides educational materials to the prescriber and the patient explaining the risks and proper use of sodium oxybate, and the required prescription form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. The Xyrem Success Program also recommends patient follow-up every 3 months. Physicians are expected to report all serious adverse events to the manufacturer.

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Billing Coding/Physician Documentation Information

N/A Xyrem is a pharmacy benefit.

Additional Policy Key Words

N/A

Related Topics

N/A

Policy Implementation/Update Information

03/2009	New policy
04/2010	Reviewed – no changes made.
04/2011	Reviewed – no changes made.
04/2012	Reviewed – no changes made
04/2014	Reviewed – no changes made