# Pharmacy Policy Bulletin

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| **Title:** | Sodium Oxybate (Xyrem®) |
| **Policy #:** | Rx.01.124 |

***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

## Intent:

The intent of this policy is to communicate the medical necessity criteria for sodium oxybate (Xyrem®) as provided under the member's prescription drug benefit.

## Description:

Narcolepsy results from the loss of the neuropeptides, orexin-A and orexin-B (also known as hypocretin-1 and hypocretin-2), which have excitatory effects on the ox1 and ox2 receptors on postsynaptic neurons. Narcolepsy is a clinical syndrome of daytime sleepiness with cataplexy, hypnagogic hallucinations, and sleep paralysis. It is the second most common cause of disabling daytime sleepiness after obstructive sleep apnea. Typical age of onset of narcolepsy is teens to twenties.

Sodium oxybate, a CNS depressant, is the sodium salt of gamma hydroxybutyrate, a metabolite of GABA. It is hypothesized that the therapeutic effects of Xyrem® on cataplexy and excessive daytime sleepiness are mediated through GABA-B actions at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons. The exact mechanism of sodium oxybate in narcolepsy is unknown.

**Sodium oxybate (Xyrem®)** is indicated for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness a narcolepsy.

## Policy:

Sodium oxybate (Xyrem®) is approved when there is documentation of ALL of the following:

A. Diagnosis of ONE of the following:

A. Cataplexy in narcolepsy; or

B. Excessive daytime sleepiness in narcolepsy

and

B. Inadequate response or inability to tolerate modafanil or armodafinil (required for members without cataplexy only); and

C. Recommended by a neurologist or sleep specialist

Authorizations will be placed for a period of 12 months

**Reauthorization criteria**

Sodium oxybate (Xyrem®) is approved when there is documentation to support the efficacy associated with the current regimen (including but not limited to reduction in the frequency of cataplexy attacks or an improvement in the Epworth sleepiness scale).

**Black Box Warning as shown in the drug Prescribing Information:**

WARNING: CENTRAL NERVOUS SYSTEM (CNS) DEPRESSION and ABUSE AND MISUSE.

Central Nervous System Depression

Xyrem® is a CNS depressant, and respiratory depression can occur with Xyrem® use

Abuse and Misuse

Xyrem® is the sodium salt of gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB is associated with CNS adverse reactions, including seizure, respiratory depression, decreased consciousness, coma, and death

Xyrem® is available only through a restricted program called the Xyrem® REMS Program

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Scammel TE. Treatment of narcolepsy in adults. UpToDate. January 2019. Available at: https://www.uptodate.com/contents/treatment-of-narcolepsy-in-adults?source=search_result&search=modafinil%20narcolepsy&selectedTitle=1~143#H1. Accessed February 18, 2019.

Xyrem® (sodium oxybate) [package insert]. Palo Alto, CA. Jazz Pharmaceuticals. October 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=926eb076-a4a8-45e4-91ef-411f0aa4f3ca&type=display. Accessed February 18, 2019.

## Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

| Drug name | Generic name |
|---|---|
| Xyrem® | sodium oxybate |

## Cross References:

N/A

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| **Policy Version Number:** | 6.00 |
| **P&T Approval Date:** | January 10, 2019 |
| **Policy Effective Date:** | April 01, 2019 |
| **Next Required Review Date:** | January 10, 2020 |