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Last Review Date: March 12, 2021

Xyrem

Description

Xyrem (sodium oxybate)

Background
Xyrem (sodium oxybate) is used to treat patients with narcolepsy. Narcolepsy is a disease where people have problems with falling asleep during the day at unexpected times. Xyrem differs from other treatments for narcolepsy in that it significantly decreases cataplexy episodes in addition to excessive daytime sleepiness (EDS). Cataplexy is characterized by loss of muscle control in response to strong emotions (1).

Regulatory Status
FDA labeled indication: Xyrem is a central nervous system depressant indicated for the treatment of cataplexy in narcolepsy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy (1).

Xyrem includes a boxed warning of central nervous system depression and misuse and abuse. Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem REMS Program, using a centralized pharmacy. Prescribers and patients must enroll in the program (1).

Xyrem is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency and in combination with sedative hypnotics or alcohol (1).

Safety and effectiveness of Xyrem in patients less than 7 years of age have not been established (1).

Related policies
Amphetamines, Hetlioz, Methylphenidates, Orexin Antagonists, Provigil Nuvigil, Rozerem, Sedative Hypnotics

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xyrem may be considered **medically necessary** in patients 7 years of age and older for the treatment cataplexy or excessive daytime sleepiness in narcolepsy and if the conditions indicated below are met.

Xyrem may be considered **investigational** for patients less than 7 years of age and for all other indications.

Prior-Approval Requirements

Age 7 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Cataplexy in narcolepsy
2. Excessive daytime sleepiness (EDS) in narcolepsy

AND ALL of the following:

1. Patient and prescriber are both enrolled in the Xyrem REMS Program
2. Prescriber will monitor for signs of misuse, abuse and addiction during therapy

AND NONE of the following:

1. Succinic semialdehyde dehydrogenase deficiency
2. Concurrent therapy with a Prior Authorization (PA) sleep aid (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 7 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Cataplexy in narcolepsy
2. Excessive daytime sleepiness (EDS) in narcolepsy

AND ALL of the following:

1. Prescriber will continue to monitor for signs of misuse, abuse and addiction during therapy
2. **NO** concurrent therapy with another Prior Authorization (PA) sleep aid (see Appendix 1)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 810 grams (1620 ml) per 90 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 810 grams (1620 ml) per 90 days

Duration 12 months

Rationale

Summary

Xyrem (sodium oxybate) is a central nervous system depressant indicated for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness (EDS) in narcolepsy. Xyrem differs from other stimulant treatments for narcolepsy in that it significantly decreases cataplexy

episodes in addition to excessive daytime sleepiness (EDS). Safety and effectiveness of Xyrem in patients less than 7 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Xyrem while maintaining optimal therapeutic outcomes.

References

1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals Inc.; September 2020.

Policy History

Date	Action
May 2014	New addition to PA
September 2014	Annual review
June 2015	Annual review
September 2016	Annual editorial review and reference update Policy number change from 5.07.11 to 5.60.05
December 2017	Annual editorial review and reference update Addition of age to renewal
November 2018	Annual editorial review and reference update Age limit decreased to 7 years or older
December 2019	Annual review
May 2020	Revised no dual therapy requirement
June 2020	Annual review
March 2021	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of PA Sleep Aids

Generic Name	Brand Name
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
ramelteon	Rozerem
tasimelteon	Hetlioz
suvorexant	Belsomra
temazepam	Restoril
triazolam	Halcion
zaleplon	Sonata
zolpidem	Ambien
zolpidem extended-release	Ambien CR
zolpidem oral spray	Zolpimist
zolpidem sublingual	Edluar
zolpidem sublingual	Intermezzo