Xyrem

Description

Xyrem (sodium oxybate)

Background
Xyrem 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 pediatric patients below the age of 7 years have not been established (1).

Related policies
Amphetamines, Methylphenidates, Provigil Nuvigil

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 is 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 use of sedative hypnotics

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 use of sedative hypnotics

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 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 pediatric patients below the age of 7 years 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

### Policy History

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<td>May 2014</td>
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<td>Age limit decreased to 7 years or older</td>
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### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.