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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	August 21, 2020
Subject:	Xywav	**Page:**	1 of 5

Last Review Date: December 12, 2025

Xywav

Description

Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution

Background
Xywav is a central nervous system (CNS) depressant. Xywav is a mixture of calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate (gamma-hydroxybutyrate). Gamma-hydroxybutyrate is an endogenous compound and metabolite of the neurotransmitter GABA. Xywav is thought to exert its therapeutic effects through $GABA_B$ actions during sleep at noradrenergic and dopaminergic neurons, as well as at thalmocortical neurons (1).

Regulatory Status
FDA-approved indications: Xywav is a central nervous system depressant indicated for the treatment of: (1)

1. Cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
2. Idiopathic Hypersomnia (IH) in adults.

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

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

Safety and effectiveness of Xywav for the treatment of cataplexy or EDS in pediatric patients less than 7 years of age have not been established. Safety and effectiveness of Xywav for the treatment of idiopathic hypersomnia in pediatric patients have not been established (1).

Related policies
Hetlioz, Lumryz, Orexin Antagonists, Rozerem, Sedative Hypnotics, Xyrem

Policy

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

Xywav may be considered **medically necessary** if the conditions indicated below are met.

Xywav may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

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

1. Cataplexy in narcolepsy
    a. 7 years of age or older
2. Excessive daytime sleepiness (EDS) in narcolepsy
    a. 7 years of age or older
3. Idiopathic hypersomnia
    a. 18 years of age or older

AND ALL of the following:

1. Patient and prescriber are both enrolled in the Xywav 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) or with another oxybate product (see Appendix 2)

Prior – Approval *Renewal* Requirements

Diagnoses

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

1. Cataplexy in narcolepsy
    a. 7 years of age or older
2. Excessive daytime sleepiness (EDS) in narcolepsy
    a. 7 years of age or older
3. Idiopathic hypersomnia
    a. 18 years of age or older

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) or with another oxybate product (see Appendix 2)

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
Xywav is indicated for use in patients with cataplexy or EDS in narcolepsy and in patients with idiopathic hypersomnia. Due to the potential for abuse and misuse, Xywav is only available through the Xywav and Xyrem REMS program. Safety and effectiveness of Xywav for the treatment of cataplexy or EDS in pediatric patients less than 7 years of age have not been established. Safety and effectiveness of Xywav for the treatment of idiopathic hypersomnia in pediatric patients have not been established (1).

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

References

1. Xywav [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2025.

Policy History

Date	Action
August 2020	Addition to PA
September 2020	Annual review
March 2021	Annual editorial review and reference update
August 2021	Added new indication per PI: idiopathic hypersomnia
December 2021	Annual review
September 2022	Annual editorial review and reference update. Added Quviviq to Appendix 1
September 2023	Annual review and reference update
December 2023	Annual review
December 2024	Annual editorial review
December 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 - List of Prior Authorization (PA) Sleep Aids

Generic Name	Brand Name
daridorexant	Quviviq
estazolam	Prosom
eszopiclone	Lunesta
flurazepam	Dalmane
lemborexant	Dayvigo
quazepam	Doral
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

Appendix 2 - List of Oxybate Products

Generic Name	Brand Name
sodium oxybate	Lumryz
sodium oxybate	Xyrem
calcium, magnesium, potassium, sodium oxybates	Xywav