Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 28, 2020 November 12, 2021, February 9, 2024, July 1, 2024, October 23, 2024

XYWAV® (calcium, magnesium, potassium, and sodium oxybates)

LENGTH OF AUTHORIZATION: **Initial therapy** may be approved for up to 3 months
Continuation of therapy may be approved for up to 6 months

INITIAL REVIEW CRITERIA:

- The medication must be prescribed by a sleep specialist or neurologist.
- The patient must be enrolled in the Xywav and Xyrem REMS program.
- Patient must not be treated with sedative hypnotics; check clinical notes and paid claim history.
- Patient has had an inadequate response, intolerance, or contraindication to Xyrem except if using for Idiopathic Hypersomnia (clinical documentation must be submitted demonstrating response).

Cataplexy associated with narcolepsy:

- Patient is ≥7 years of age
- Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results.

For excessive daytime sleepiness:

- Patient is ≥7 years of age
- Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results.
- Must have 60-day trial and failure/intolerance to at least one preferred stimulant treatment (e.g., methylphenidate or dextroamphetamine) at maximally tolerated dosage (clinical documentation must be submitted demonstrating response).
- Must have 60-day trial and failure of modafinil - excluding pediatric recipients (clinical documentation must be submitted demonstrating response).

Idiopathic hypersomnia in adults:

- Patient is ≥18 years of age
- Diagnosis must be confirmed by submission of supporting documentation to include the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results.
- Must have 60-day trial and failure/intolerance to at least one preferred stimulant treatment (e.g., methylphenidate or dextroamphetamine) at maximally tolerated dosage (clinical documentation must be submitted demonstrating response).
- Must have 60-day trial and failure of modafinil - excluding pediatric recipients (clinical documentation must be submitted demonstrating response).

CONTINUATION OF THERAPY:

- Patient is appropriate age per indication (or per product labeling).
- The medication must be prescribed by a sleep specialist or neurologist.
- The patient must be enrolled in the Xywav and Xyrem REMS program
- The physician specializing in narcolepsy or neurologist must submit their interpretation of the Epworth Sleepiness Scale (ESS) and/or the Maintenance of Wakefulness Test (MWT) to demonstrate response to current therapy.

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DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Dosage form: 180mL oral solution containing 0.5 g/mL

AVAILABILITY:

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