Clinical Policy: Sodium Oxybate (Xyrem) and Calcium, Magnesium, Potassium, and Sodium Oxybate (Xywav)

Reference Number: IN.CP.PMN.42
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sodium oxybate (Xyrem®) and calcium, magnesium, potassium, and sodium oxybate (Xywav™) are central nervous system (CNS) depressants.

FDA Approved Indication(s)

Xyrem and Xywav are indicated for the treatment of patients 7 years of age and older with:

- Cataplexy in narcolepsy
- Excessive daytime sleepiness (EDS) in narcolepsy

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Xyrem and Xywav are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Xyrem (must meet one of the following)**:**

1. Member is 7 years of age or older and Both of the following
    a. Diagnosis of narcolepsy with cataplexy and excessive daytime sleepiness
    b. Requested dose does not exceed the following:
        i. 12 mL/day for members weighing 20kg to less than 30kg
        ii. 15 mL/day for member weighing 30kg to less than 45kg
        iii. 18 mL/day for members weighing at least 45kg
2. Member is 18 years of age or older AND all of the following
    a. Diagnosis of fibromyalgia
    b. At least one of the following
        i. >90 days of drug therapy with one of the following: amitriptyline, SNRI, SSRI, anticonvulsant (gabapentin/pregabalin), NSAID, acetaminophen
        ii. Prescriber has provided valid medical justification for the use of sodium oxybate over therapy with amitriptyline, SNRI, SSRI, anticonvulsant (gabapentin/pregabalin), NSAID, AND acetaminophen

    c. Requested dose does not exceed 12mL/day

Approval duration: 3 months

B. Xywav Must meet one of the following

1. Member is 7 years of age or older and Both of the following
    a. Diagnosis of narcolepsy with cataplexy and excessive daytime sleepiness
    b. Requested dose does not exceed the following:
        i. 12 mL/day for members weighing 20kg to less than 30kg
        ii. 15 mL/day for member weighing 30kg to less than 45kg
        iii. 18 mL/day for members weighing at least 45kg
2. Member is 18 years of age or older AND both of the following:
    a. Diagnosis of idiopathic hypersomnia
    b. Requested dose does not exceed 18mL/day

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Approval duration: 3 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Xyrem (must meet all)**:**

1. History of the requested agent within the past 90 days
2. Documented attempt to decrease dose or trial and failure of an alternative therapy within the past year
3. Documentation from prescriber indicating continued benefit from the medication (reduction in frequency of cataplexy, reduction in symptoms of excessive daytime sleepiness, etc.) without significant adverse events

Approval duration: 6 months

B. Xywav (must meet all of the following)**:**

1. History of the requested agent within the past 90 days
2. Documented attempt to decrease dose or trial and failure of an alternative therapy within the past year
3. Documentation from prescriber indicating continued benefit from the medication (reduction in frequency of cataplexy, reduction in symptoms of excessive daytime sleepiness, etc.) without significant adverse events

Approval duration: 6 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CNS: central nervous system
EDS: excessive daytime sleepiness
FDA: Food and Drug Administration
IR: immediate-release
MSLT: multiple sleep latency test
PSG: polysomnography

SOREMP: sleep-onset rapid eye movement period

Appendix B: Therapeutic Alternatives

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - In combination with sedative hypnotics or alcohol
  - Succinic semialdehyde dehydrogenase deficiency
- Boxed warning(s):
  - Central nervous system depression: In clinical trials at recommended doses, obtundation and clinically significant respiratory depression occurred in adult patients treated with Xyrem or Xywav.
  - Abuse and misuse: Xyrem and Xywav are a 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.

V. Product Availability

Drug Name	Availability
Xyrem (sodium oxybate)	Oral solution: 0.5 g per mL in 180 mL bottle
Xywav (calcium, magnesium, potassium, and sodium oxybate)	Oral solution: 0.5 g per mL

VI. References

1. Xyrem Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; September 2020. Available at: https://www.xyrem.com/. Accessed January 29, 2021.
2. Xywav Prescribing Information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212690s000lbl.pdf. Accessed January 29, 2021.
3. Morgenthaler TI, Kapur VK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin An American Academy of Sleep Medicine Report: An American Academy of Sleep Medicine Report. Sleep. 2007;30(12):1705-1711.
4. Wise MS, Arand DL, Auger RR, Brooks SN, Watson NF. Treatment of Narcolepsy and other Hypersomnias of Central Origin: An American Academy of Sleep Medicine Review. Sleep. 2007;30(12):1712-1727.
5. Scammell TE. The neurobiology, diagnosis and treatment of narcolepsy. Ann Neurol 2003;53:154 –166.
6. Swick TJ. Treatment paradigms for cataplexy in narcolepsy: past, present, and future. Nat Sci Sleep. 2015; 7:159-169.
7. Billiard M. Narcolepsy: current treatment options and future approaches. Neuropsychiatric Disease and Treatment. 2008;4(3):557-566.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created for Indiana Medicaid Moratorium	12.2021	01.2022

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