

Policy Name:	Sodium Oxybate Products	Policy #:	1869P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for sodium oxybate products; Xyrem, Xywav, and Lumryz under the Specialty Pharmacy benefit.

Statement of the Policy

Health Alliance Medical Plans will approve the use of sodium oxybate products; Xyrem, Xywav, and Lumryz under the Specialty Pharmacy benefit if the following criteria for coverage are met.

Criteria

1. Coverage Criteria

- 1.1 Documented diagnosis of narcolepsy, confirmed by sleep lab evaluation
- 1.2 Ordered by a Certified Risk Evaluation and Mitigation Strategy (REMS) provider
- 1.3 Age 7 years or older (for Xyrem) or age 18 years or older (for Xywav/Lumryz)
- 1.4 Documented failure, intolerance, or contraindication to armodafinil or modafinil
- 1.5 Documented failure, intolerance, or contraindication to Sunosi

2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

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HCPCS Codes

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References

1. Roth T, Dauvilliers Y, Guinta D, et al. Effect of sodium oxybate on disrupted nighttime sleep in patients with narcolepsy. *J Sleep Res* 2017; 26:407.
2. Mayer G, Plazzi G, Iranzo Á, et al. Long-term compliance, safety, and tolerability of sodium oxybate treatment in patients with narcolepsy type 1: a postauthorization, noninterventive surveillance study. *Sleep* 2018; 41.
3. Avellar AB, Carvalho LB, Prado GF, Prado LB. Pharmacotherapy for residual excessive sleepiness and cognition in CPAP-treated patients with obstructive sleep apnea syndrome: A systematic review and meta-analysis. *Sleep Med Rev* 2016; 30:9.
4. Maski K, Trotti L, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *Journal of Clinical Sleep Medicine*, Vol. 17, No. 9: 1881-1893.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.