

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

XYREM
(sodium oxybate)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Xyrem oral solution is indicated for the treatment of cataplexy in narcolepsy.

Xyrem oral solution is indicated for the treatment of excessive daytime sleepiness (EDS) in narcolepsy.

Limitations of Use

Xyrem may only be dispensed to patients enrolled in the Xyrem REMS Program.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The request is for continuation of Xyrem (sodium oxybate) AND the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy

OR

- The diagnosis is confirmed by sleep lab evaluation

AND

- The requested drug is being prescribed for the treatment of cataplexy in narcolepsy

OR

- The requested drug is being prescribed for excessive daytime sleepiness in a patient with narcolepsy

AND

- The patient experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) AND one central nervous system (CNS) promoting wakefulness drug (e.g., modafinil, armodafinil)

OR

- The patient has a contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) AND one central nervous system (CNS) wakefulness promoting drug (e.g., modafinil, armodafinil)

Quantity Limits apply.
540 milliliters/month

REFERENCES

1. Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2017.

Xyrem Policy 11-2017

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2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 2017.
3. Micromedex Healthcare Series [database online]. Greenwood Village, CO: Thomson Reuters (Healthcare) Inc. Updated periodically. <http://www.thomsonhc.com> [available with subscription]. Accessed November 2017.
4. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and Other Hypersomnias of Central Origin. *Sleep* 2007; 30(12):1705-11.
5. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual*. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
6. Krahn, L, Hershner S, et al. Quality Measures for the Care of Patients with Narcolepsy; *Journal of Clinical Sleep Medicine*; 2015; 11(3): 335-55.