Effective Date: 12/2017
Reviewed: 12/2017, 12/2018, 10/2019, 8/2020, 2/2021, 2/2022, 5/2023 Scope: Medicaid

Sodium oxybate (generic Xyrem)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Sodium oxybate is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

All other indications are considered experimental/investigational and are not a covered benefit.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests, all of the following (if applicable):
    1. Documentation of a sleep lab evaluation
    2. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy

B. For continuation requests, chart notes or medical record documentation supporting a beneficial response to therapy (e.g., decrease in daytime sleepiness, decrease in cataplexy episodes from baseline)

C. PRESCRIBER SPECIALTIES

This medication must be prescribed by one of the following:

A. Sleep disorder specialist
B. Neurologist

D. CRITERIA FOR INITIAL APPROVAL

Authorization of 6months may be granted when all of the following criteria are met:

1. Member is not being treated with sedative hypnotics that will be used concurrently with sodium oxybate
2. Member does not have a history of drug or alcohol abuse
3. Member meets either of the following criteria:
    a. The requested drug is being prescribed for the treatment of cataplexy in narcolepsy in a member 7 years of age or older and all of the following criteria are met:
        i. The diagnosis is confirmed by sleep lab evaluation
        ii. The member has experienced an inadequate treatment response, intolerance, or contraindication to at least two of the following agents from a different medication class: atomoxetine, fluoxetine, protriptyline, clomipramine and/or venlafaxine
    b. The requested drug is being prescribed for the treatment of excessive daytime sleepiness in a member 7 years of age or older with narcolepsy without cataplexy and all of the following criteria are met:

i. The diagnosis is confirmed by sleep lab evaluation
ii. The member has experienced an inadequate treatment response, intolerance, or contraindication to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
iii. If the member is 18 years of age or older:
    1. The member experienced an inadequate treatment response or intolerance, to at least one central nervous system (CNS) wakefulness promoting drug (e.g., modafinil, armodafinil) OR
    2. The member has a contraindication to both armodafinil and modafinil

E. CONTINUATION OF THERAPY

Authorization of 6 months may be granted when the request is for continuation of sodium oxybate of AND the member experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy from baseline (clinical notes provided support treatment efficacy).

F. QUANTITY LIMIT

Sodium oxybate has a quantity limit of 18 ml per day.

G. REFERENCES

Xyrem [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; December 2020.
Sodium oxybate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; April 2023