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

XYREM (sodium oxybate)

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
Xyrem 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. PRESCRIBER SPECIALTIES

This medication must be prescribed by one of the following:

A. Sleep disorder specialist
B. Neurologist

III. 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, intolerance, or contraindication 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

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted when the request is for continuation of Xyrem (sodium oxybate) 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).

V. QUANTITY LIMIT

Xyrem has a quantity limit of 18 ml per day.