

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 1 month 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 one of the following agents: tricyclic antidepressants, SSRIs, 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. 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)

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 (clinical notes provided support treatment efficacy).

V. QUANTITY LIMIT

Xyrem has a quantity limit of 18 ml per day.