Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Xyrem® (Sodium Oxybate)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***June 2005 (as adopted by UPMC Health Plan)***

Last P & T Committee Approval Date: *August 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for sodium Xyrem® (sodium oxybate).

Xyrem® (sodium oxybate) is the sodium salt of gamma hydroxybutryic acid (GHB), a naturally-occurring central nervous system transmitter with sedative and anesthetic properties and is indicated for the treatment of excessive daytime sleepiness (EDS) and cataplexy in members with narcolepsy.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

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The drug, Xyrem® (sodium oxybate), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a board-certified sleep specialist, a pulmonologist, or a neurologist
- Must be 16 years of age or older
- Must have one of the following diagnoses:
  - Cataplexy associated with narcolepsy
  - Excessive daytime sleepiness (EDS) associated with narcolepsy
- Must not be taking Xyrem with any sedative hypnotic agents or alcohol or have succinic semialdehyde dehydrogenase deficiency
- For a diagnosis of Cataplexy associated with Narcolepsy:
  - Chart documentation of all the following:
    - daily uncontrollable need to sleep for at least 3 months
    - cataplexy episodes (uncontrollable weakness/paralysis)
    - all other causes of sleepiness have been ruled out
  - Copy of sleep study confirming diagnosis of cataplexy with narcolepsy including all the following:
    - mean sleep latency (MSL) of <8 minutes AND at least 2 sudden onset REM periods (SOREMPs) on a multisleep latency test (MSLT)
    - a SOREMP occurring within 15 minutes of sleep onset on a polysomnogram (PSG) can replace one SOREMP on MSLT
  - Must have an adequate trial and failure of: tricyclic antidepressant, venlafaxine, atomoxetine, or fluoxetine
- For a diagnosis of EDS with Narcolepsy:
  - Chart documentation of all the following:
    - daily uncontrollable need to sleep for at least 3 months
    - other causes of sleepiness have been ruled out
    - no evidence of cataplexy
  - Copy of sleep study confirming diagnosis of narcolepsy including all the following:
    - mean sleep latency (MSL) of <8 minutes AND at least 2 sudden onset REM periods (SOREMPs) on a multisleep latency test (MSLT)

        - a SOREMP occurring within 15 minutes of sleep onset on a polysomnogram (PSG) can replace one SOREMP on MSLT
    - Must have an adequate trial and failure of 1 of each of the following classes of central nervous stimulants:
        - modafinil, armodafinil
        - amphetamine, methamphetamine, dextroamphetamine, or methylphenidate

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's Epworth Sleepiness Scale score (ESS) improved while on therapy OR for a diagnosis of narcolepsy associated with cataplexy a decrease in the number of cataplectic instances

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year
Quantity Limits	
Solution	540mL per month

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Updated Clinical Criteria	*08/18*