

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Oxybate salts (Xywav)

Notes:

- Quantity Limits: Yes

* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation.

Initiation (new start) criteria: Non-formulary **oxybate salts (Xywav)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescribed for the treatment of excessive daytime sleepiness in narcolepsy OR hypersomnia (idiopathic)

-AND-

- Prescribed by a Sleep Specialist
- Patient has failed a trial of, or patient has an allergy or intolerance* to:
 - Modafinil or armodafinil **AND**
 - A stimulant medication (ie methylphenidate, dextroamphetamine, amphetamine salt combination, etc.) **AND**
 - Solriamfetol (Sunosi), unless reason for contraindication is provided **AND**
 - Pitolisant (Wakix), unless reason for contraindication is provided **AND**
 - Sodium oxybate (Xyrem) **AND**
- Patient has an indication for a low sodium product (ie heart failure, renal failure, or uncontrolled hypertension)

-OR-

2. Prescribed for the treatment of cataplexy in narcolepsy

-AND-

- Prescribed by a Sleep Specialist
- Patient has failed a trial of, or patient has an allergy or intolerance* to sodium oxybate (Xyrem)
- Patient has failed a trial of, or patient has an allergy or intolerance* to:
 - A tricyclic antidepressant **OR**
 - A selective serotonin reuptake inhibitor (SSRI) **OR**
 - A serotonin-norepinephrine reuptake inhibitor (SNRI)
- Patient has an indication for a low sodium product (ie heart failure, renal failure, or uncontrolled hypertension)

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All plans offered and underwritten by
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Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary oxybate salts (Xywav) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- See above new start criteria

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary oxybate salts (Xywav) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescribed for the treatment of excessive daytime sleepiness in narcolepsy OR hypersomnia (idiopathic)

-AND-

- Patient has failed a trial of, or patient has an allergy or intolerance* to:
 - Modafinil or armodafinil **AND**
 - A stimulant medication (ie methylphenidate, dextroamphetamine, amphetamine salt combination, etc.) **AND**
 - Solriamfetol (Sunosi), unless reason for contraindication is provided **AND**
 - Pitolisant (Wakix), unless reason for contraindication is provided **AND**
 - Sodium oxybate (Xyrem) **AND**
- Patient has an indication for a low sodium product (ie heart failure, renal failure, or uncontrolled hypertension)

-OR-

2. Prescribed for the treatment of cataplexy in narcolepsy

-AND-

- Patient has failed a trial of, or patient has an allergy or intolerance* to sodium oxybate (Xyrem)
- Patient has failed a trial of, or patient has an allergy or intolerance* to:
 - A tricyclic antidepressant **OR**
 - A selective serotonin reuptake inhibitor (SSRI) **OR**
 - A serotonin-norepinephrine reuptake inhibitor (SNRI)
- Patient has an indication for a low sodium product (ie heart failure, renal failure, or uncontrolled hypertension)

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Continued use criteria for patients stable on the medication: Non-formulary **oxybate salts (Xywav)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Continues to be prescribed by a Sleep Specialist