Applicable Drugs: Wakix (pitolisant), sodium oxybate (authorized generic), Lumryz (sodium oxybate), Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium, sodium oxybate)

VSI Excluded Drugs: Lumryz (sodium oxybate)

Formulary Shield Drugs: Xyrem (sodium oxybate)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/16/2022

Date Last Reviewed / Revised: 10/15/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

I. Documented diagnosis of one of the following conditions A, B, or C, and must meet all criteria listed under applicable diagnosis:

A. Cataplexy associated with narcolepsy

1. Documentation of polysomnogram (PSG) and multiple sleep latency test (MSLT) confirming the diagnosis of narcolepsy (see Appendix Table 1 for diagnostic criteria).
2. Documented treatment failure with or contraindication to dextroamphetamine.
3. For requests for oxybates, there must also be documented treatment failure or contraindication to Wakix (pitolisant).
    a) Wakix may be approved for this diagnosis for patients who meet all other medical necessity criteria in sections I.A and II-VII.

B. Excessive daytime sleepiness (EDS) associated with narcolepsy

1. Documentation of polysomnogram (PSG) and multiple sleep latency test (MSLT) confirming the diagnosis of narcolepsy (see Appendix Table 1 for diagnostic criteria).
2. Documented treatment failure or contraindication to all of the following (a through c):
    a) Amphetamine, amphetamine-dextroamphetamine, or dextroamphetamine
    b) Modafinil or armodafinil
    c) Sunosi (solriamfetol)
        (1) Exception: for patients aged 6 to 18 years, trial of Sunosi (solriamfetol) is not required, as it is not approved for pediatric use.
3. For requests for oxybates, there must also be documented treatment failure or contraindication to Wakix (pitolisant).

C. Idiopathic Hypersomnia (IH)

1. Documentation of all the following (a through c):
    a) Daily periods of irrepressible need to sleep or daytime lapses into sleep for at least three months

b) MSLT with one of the following:

(1) Fewer than two SOREMPs

(2) No SOREMPs and the REM sleep latency on the preceding PSG was ≤ 15 minutes

c) Presence of at least one of the following:

(1) MSLT with a mean sleep latency of ≤ 8 minutes

(2) Total 24-hour sleep time is ≥ 660 minutes on 24-hour PSG or by wrist actigraphy in association with a sleep log

2. There must be documented treatment failure or contraindication to all of the following (a through b):
   a) Methylphenidate
   b) Modafinil or armodafinil
3. Request is for Wakix or Xywav.
4. For requests for Xywav, there must also be documented treatment failure or contraindication to Wakix (pitolisant).
   a) Wakix may be approved for this diagnosis for patients who meet all other medical necessity criteria in sections I.C and II-VII.

II. Minimum age requirements:

b) Lumryz: 18 years old.

c) Sunosi: 18 years old.

d) Wakix (Pitolisant): 6 years old.

e) Xyrem or generic sodium oxybates: 7 years old.

f) Xywav:

(1) When requested for narcolepsy: 7 years old.

(2) When requested for idiopathic hypersomnia (IH): 18 years old.

III. For requests for Lumryz, there must be documented treatment failure or contraindication to both sodium oxybate (authorized generic) and Xywav.

IV. Documentation of PSG (with at least 6 hours of sleep time) that shows the absence of other pathologies which would cause chronic daytime sleepiness or documentation that known contributing pathology is adequately treated.

V. Treatment is prescribed by or in consultation with a neurologist or sleep disorder specialist.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Wakix (pitolisant):
  - End-stage renal disease (ESRD)
  - Severe hepatic impairment
- Oxybates:
  - Documented succinic semialdehyde dehydrogenase deficiency
  - Concurrent use of sedative hypnotic agents
  - Concurrent use of alcohol or opioid narcotics
  - Uncontrolled depressive or neuropsychiatric disorders

OTHER CRITERIA

- Wakix (pitolisant):
  - For patients with eGFR less than 60 mL/min/1.73 m^2, the maximum dosage is 17.8 mg once daily (quantity limit of 30 tablets per 30 days).
  - For patients with moderate hepatic impairment (Child-Pugh Class B), the maximum dose is 17.8 mg once daily (quantity limit of 30 tablets per 30 days).
  - For concomitant use with strong CYP2D6 inhibitors, the maximum dosage is 17.8 mg once daily for adults and pediatric patients weighing ≥40kg, or 8.9 mg for pediatric patients weighing <40 kg.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Wakix (pitolisant): 60 tablets per 30 days
- Sodium oxybate (authorized generic), Lumryz, Xyrem, Xywav:
  - Adults:
    - Xywav, Xyrem, sodium oxybate: 540 mL per 30 days.
    - Lumryz: 30 packets per 30 days.
  - Children (Xywav, Xyrem, or sodium oxybate):
    - Weight 20 kg to < 30 kg: 360 mL per 30 days.
    - Weight 30 kg to < 45 kg: 450 mL per 30 days.
    - Weight ≥ 45 kg: 540 mL per 30 days.

Approval Length

- **Authorization:** 4 months
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

Table 1. Diagnostic criteria for narcolepsy

Narcolepsy type 1 (with cataplexy)
Criteria a and b must be met: a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. b) The presence of one or both of the following: o Cataplexy and a mean sleep latency of ≤8 minutes and ≥2 SOREMPs on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT. o CSF orexin-A concentration, measured by immunoreactivity, is either ≤110 pg/mL or <1/3 of mean values obtained in normal subjects with the same standardized assay.
Narcolepsy type 2
Criteria a through e must be met: a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. b) A mean sleep latency of ≤8 minutes and ≥2 SOREMPs are found on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT. c) Cataplexy is absent. d) Either CSF orexin concentration has not been measured or CSF orexin concentration measured by immunoreactivity is either >110 pg/mL or >1/3 of mean values obtained in normal subjects with the same standardized assay. e) The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal.

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