Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCCNS033.1225	**CENTRAL NERVOUS SYSTEM DRUGS** **NARCOLEPSY AGENTS** See Appendix A for medications covered by policy
Effective Date: 2/1/2026	**Review/Revised Date**: 02/13, 08/13, 08/14, 08/15, 07/16, 05/17, 07/17, 07/18, 01/19, 07/19, 07/20, 01/21, 07/21, 04/22, 06/22, 06/23, 06/24, 10/24, 01/25, 06/25, 10/25 (snm)
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Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial
Medicaid – solriamfetol is covered under the Division of Medical Assistance Programs (DMAP)

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met or if the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit applies.

REQUIRED MEDICAL INFORMATION:
For initial authorization, all the following criteria must be met:
1. ONE of the following:
    a. The patient has a diagnosis of **narcolepsy with cataplexy** and all of the following:
        i. Request is for Lumryz, Xyrem, Xywav, generic sodium oxybate, Wakix
        ii. For Brand Xyrem: Medical rationale provided for not using generic sodium oxybate
    b. The patient has a diagnosis of **narcolepsy with excessive daytime sleepiness** and all of the following:
        i. Request is for Lumryz, Xyrem, Xywav, generic sodium oxybate, Wakix, Sunosi
        ii. For all agents: Inadequate response, intolerance, or contraindication to armodafinil or modafinil

iii. For brand Xyrem: Medical rationale provided for not using generic sodium oxybate

c. The patient has a diagnosis of **excessive daytime sleepiness associated with obstructive sleep apnea (OSA)** and all of the following:
   i. Request is for Sunosi
   ii. The underlying airway obstruction has been treated (e.g., continuous positive airway pressure [CPAP]) for at least 1-month prior to initiating therapy with the requested agent
   iii. The modalities to treat the underlying airway obstruction (such as continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent
   iv. Inadequate response, intolerance, or contraindication to armodafinil or modafinil
d. The patient has a diagnosis of **idiopathic hypersomnia** and all of the following:
   i. Request is for Xywav
   ii. The patient has completed a sleep study
   iii. Sleepiness is not due to another medical, behavioral, or psychiatric disorder condition, including but not limited to insufficient sleep (less than seven hours per night), depression, sedating medications, and sleep-related breathing disorders
   iv. Inadequate response, intolerance, or contraindication to modafinil

For reauthorization, must meet indication-specific criteria below:
1. For narcolepsy: Successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness or reduction in frequency of cataplexy attacks
2. For OSA:
   a. Reduction in symptoms of excessive daytime sleepiness
   b. The modalities to treat the underlying airway obstruction (for example, continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent
3. For idiopathic hypersomnia: Successful response to the medication, such as a reduction in symptoms of excessive daytime sleepiness

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a sleep specialist, neurologist, pulmonologist, or psychiatrist

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for one year.

QUANTITY LIMIT:
- Sunosi®: one tablet per day
- Wakix: two tablets per day
- Xyrem®/Xywav™: 9 grams per day, which is 540 mL/30 days. There is no evidence of additional benefit achieved with doses over 9 grams per day.
- Lumryz™: one packet per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved ("off-label") indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), USP-DI, or Drugdex and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Xyrem®/Lumryz™ (sodium oxybate) and Xywav™ (oxybate salts) are central nervous system depressants that reduce excessive daytime sleepiness and cataplexy in patients with narcolepsy. The precise mechanism by which they produce an effect on cataplexy is unknown. Sodium oxybate is the sodium salt of gamma-hydroxybutyrate (GHB) that is a metabolite of the neurotransmitter GABA. The theoretical mechanism is that therapeutic effects are through GABA actions at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons.

The exact mechanism of action of pitolisant (Wakix®) in excessive daytime sleepiness (EDS) and cataplexy in adult patients with narcolepsy is unclear. However, its efficacy could be mediated through its activity as an antagonist/inverse agonist at histamine-3 (H3) receptors. Pitolisant is contraindicated in patients with severe hepatic impairment. A warning and precaution for pitolisant is QT prolongation. The most common adverse reactions (≥ 5% and twice placebo) with pitolisant use were insomnia, nausea, and anxiety.

The mechanism of action of solriamfetol to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea is unclear. However, its efficacy could be mediated through its activity as a dopamine and norepinephrine reuptake inhibitor (DNRI).

FDA APPROVED INDICATIONS:

Lumryz™ (sodium oxybate)

- Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients seven years of age and older with narcolepsy.

Xyrem® (sodium oxybate)

- Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients seven years of age and older with narcolepsy.

Xywav™ (oxybate salts):

- Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients seven years of age and older with narcolepsy
- Treatment of idiopathic hypersomnia (IH) in adults

Wakix (pitolisant):

- Treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy
- Treatment of excessive daytime sleepiness (EDS) in pediatric patients six years of age and older with narcolepsy

Sunosi® (solriamfetol)

- Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

  Limitations of Use:

  Solriamfetol is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated [for example, with continuous positive airway pressure (CPAP)] for at least one month prior to initiating solriamfetol for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with solriamfetol. Solriamfetol is not a substitute for these modalities.

POSITION STATEMENT:

Narcolepsy is an incurable chronic neurologic disorder that affects the brain's ability to regulate sleep-wake cycles. In patients with narcolepsy, the boundaries between sleep, dreams, and time awake are blurred. The chief features are daytime somnolence, cataplexy, sleep paralysis, nocturnal sleep disruption, and hypnagogic

hallucinations. These symptoms are often disabling and will require life-long treatment.

Diagnosing narcolepsy is based on screening tools and laboratory testing. Narcolepsy Type 1 (formally known as narcolepsy with cataplexy) is typically diagnosed using the following criteria:

- Criteria A and B must be met:
    a. Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
    b. Presence of one or both of the following:
        - Cataplexy with both of the following: Multiple Sleep Latency Test (MSLT) mean sleep latency of less than eight minutes AND two or more Sleep-onset REM Periods (SOREMPs) between the MSLT and polysomnogram (PSG) or a SOREMP within 15 minutes of sleep-onset on nocturnal PSG
        - Low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay)

Narcolepsy Type 2 (formally known as narcolepsy without cataplexy) is typically diagnosed using the following criteria:

- Criteria A through E must be met:
    a. Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
    b. MSLT mean sleep latency of less than eight minutes AND two or more SOREMPs between the MSLT and PSG.
    c. Cataplexy absent
    d. Orexin/hypocretin levels not measured or were greater than 110 pg/mL or greater than 1/3 of mean values for normal patients
    e. Hypersomnolence and/or MSLT findings rule out other causes (such as obstructive sleep apnea, medication contributors)

The MSLT should be performed after a PSG showing at least six hours of sleep[21]. The preceding PSG and sleep logs for at least one week prior to MSLT can help rule out other causes of abnormal MSLT findings[8,20].

Excessive Daytime Sleepiness is typically assessed using the Epworth Sleepiness Scale (ESS)

- Patient rate's chance of dozing for specific activities on 4-point scale.
- Score of 10 or greater indicates excessive daytime sleepiness (max 24)

Excessive daytime sleepiness (EDS) in Narcolepsy

- Excessive daytime sleepiness (EDS) is defined by ICSD-3 (International Classification of Sleep Disorders, 3rd edition (ICSD-3) as "daily episodes of an irrepressible need to sleep or daytime lapses into sleep." EDS is a prominent symptom of narcolepsy causing significant burden. Patients report that EDS negatively affects activities of daily living, including safety concerns while driving and decreases in quality of life.

- American Academy of Sleep Medicine – Treatment of central disorders of hypersomnolence clinical practice guideline[19]
    - Recommendations for use are compared to no treatment
    - No direct comparisons between agents are made
    - Combination therapy is not discussed
    - The following recommendations are made for adult patients with narcolepsy
        - We recommend that clinicians use modafinil for the treatment of narcolepsy in adults. (STRONG)
        - We recommend that clinicians use pitolisant for the treatment of narcolepsy in adults. (STRONG)
        - We recommend that clinicians use sodium oxybate for the treatment of narcolepsy in adults. (STRONG)
        - We recommend that clinicians use solriamfetol for the treatment of narcolepsy in adults. (STRONG)
        - We suggest that clinicians use armodafinil for the treatment of narcolepsy in adults. (CONDITIONAL)
        - We suggest that clinicians use dextroamphetamine for the treatment of narcolepsy in adults. (CONDITIONAL)
        - We suggest that clinicians use methylphenidate for the treatment of narcolepsy in adults. (CONDITIONAL)
    - The following recommendations are made for pediatric patients with narcolepsy
        - We suggest that clinicians use modafinil for the treatment of narcolepsy in pediatric patients. (CONDITIONAL)
        - We suggest that clinicians use sodium oxybate for the treatment of narcolepsy in pediatric patients. (CONDITIONAL)

- The efficacy of pitolisant for treatment of EDS associated with narcolepsy in adult patients, upon which its FDA approval is based, was established in two phase III clinical trials (HARMONY I and HARMONY Ibis). The primary efficacy endpoint in these trials was the change in Epworth Sleepiness Scale (ESS) Score from baseline between the comparator groups. The ESS score is an 8-point patient-administered questionnaire used to evaluate the likelihood of falling asleep during activities of daily life. The maximum score is 24 with higher scores

indicating higher likelihood of falling asleep. In both studies, patients were randomized to receive pitolisant, placebo, or active control. Pitolisant demonstrated a statistically significant improvement in the least square mean final ESS score vs. placebo. The placebo-subtracted difference at week eight was -3.1 (95% CI: -5.73, -0.46) and -2.2 (95% CI: -4.17, -0.22) for study 1 and study 2, respectively.

- The effectiveness of sodium oxybate in the treatment of excessive daytime sleepiness in narcolepsy was established in two randomized, double-blind, placebo-controlled trials in patients with narcolepsy. The patients in these trials were stable on modafinil before the study began and were randomized to one of four treatment groups: placebo; sodium oxybate; modafinil; and sodium oxybate plus modafinil. Sodium oxybate was administered in a dose of 6 g/night for four weeks, followed by 9 g/night for four weeks. Modafinil was continued at the prior dose. With sodium oxybate treatment, statistically significant Improvements were seen on the Epworth Sleepiness Scale, the Clinical Global Impression of Change, and the Maintenance of Wakefulness Test score, compared to placebo.

A double-blind, placebo controlled parallel group study of 228 patients with narcolepsy by Black and associates indicates that sodium oxybate significantly improves nocturnal awakenings along with a dose-related decrease in the duration of stage 1 and an increase in the duration of stage 3 and 4 sleep, compared to placebo.[2]

Cataplexy in Narcolepsy

- Cataplexy in narcolepsy is defined by ICSD-3 as more than one episode of generally brief (< 2 min), usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness.

The efficacy of pitolisant for treatment of cataplexy in adult patients with narcolepsy was established in two multicenter, randomized, double-blind, placebo-controlled studies (Study 3; NCT 01800045 and Study 1; NCT01067222). For Study 1, that was mentioned earlier for gaining approval of pitolisant for EDS, there was a subgroup analysis for patients with cataplexy (n=49). Patients meeting the ICSD-2 criteria for narcolepsy (with or without cataplexy) and an ESS score of ≥14 were eligible to enroll. Pitolisant demonstrated statistically significantly greater improvement on the secondary endpoint, the change from baseline in geometric mean daily rate of cataplexy at Week eight compared to placebo. In Study 3, patients ≥18 years of age who met the International Classification of Sleep Disorders (ICSD-2) criteria for narcolepsy with cataplexy with at least 3 cataplexy attacks per week and an ESS score of ≥12 were eligible to enroll. Pitolisant demonstrated statistically significantly greater improvement on the primary endpoint, the change in

geometric mean number of cataplexy attacks per week from baseline to the average of the 4-week stable dosing period compared to placebo.

The efficacy of oxybate salts (Xywav™) was established based on a small phase 3, randomized, double-blind, placebo-controlled trial in 201 adult patients with cataplexy and narcolepsy. The study consisted of a 12-week open-label optimized treatment and titration period (OL OTTP), followed by a 2-week stable-dose period (SDP), and finally a 2-week double-blind randomized withdrawal period (DB RWP). Of the 201 patients, 134 were randomized 1:1 in the 2-week DB RWP. Results showed that patients taking stable doses of oxybate salts who discontinued the treatment and were randomized to placebo during the DB RWP experienced a significant worsening in the average weekly number of cataplexy attacks and in ESS score, compared with patients randomized to continue treatment with the active drug.

The efficacy of oxybate salts (Xywav™) in pediatric patients is based on clinical study in patients treated with sodium oxybate (Xyrem®) and pharmacokinetic information.

Lumryz® is an extended-release formulation of sodium oxybate that is indicated to be taken once at bedtime. Xywav and Xyrem are taken twice nightly with one dose at bedtime and then another two and a half to four hours later.

Excessive Daytime Sleepiness in patients with Obstructive Sleep Apnea (OSA)

- Solriamfetol efficacy is based on data from the Treatment of Obstructive sleep apnea and Narcolepsy Excessive Sleepiness (TONES) Phase 3 clinical program, which included four randomized placebo-controlled studies that demonstrated superiority of solriamfetol relative to placebo.
- Warnings and precautions of solriamfetol include blood pressure and heart rate increases, and psychiatric symptoms.
- The most common adverse reactions (≥ 5% and > placebo) with solriamfetol use were headache, nausea, decreased appetite, insomnia, and anxiety.

Idiopathic Hypersomnia

- International Classification of Sleep Disorders (3rd edition) core criteria for idiopathic hypersomnia
    - A report of subjective sleepiness
    - MSLT showing a mean latency of < 8 min with fewer than two SOREMPs (including any SOREMP on the PSG from the preceding night)
    - Absence of cataplexy and hypocretin deficiency (if measured)
    - No other identifiable cause

- The American Academy of Sleep Medicine released in 2021 provided guidelines for the treatment of central disorders of hypersomnolence
    - Strong recommendation for modafinil for the treatment of idiopathic hypersomnia
    - Conditional recommendation for clarithromycin for the treatment of idiopathic hypersomnia
    - Conditional recommendation for methylphenidate for the treatment of idiopathic hypersomnia
    - Conditional recommendation for pitolisant for the treatment of idiopathic hypersomnia
    - Conditional recommendation for sodium oxybate for the treatment of idiopathic hypersomnia

- The efficacy of Xywav® in the setting of idiopathic hypersomnia was established in a phase 3, placebo-controlled, double-blind randomized withdrawal study (NCT03533114)
    - Inclusion criteria: Aged 18–75 years with a primary diagnosis of idiopathic hypersomnia (meeting ICSD-2 or ICSD-3 criteria); average nocturnal total sleep time of 7 h or more; Epworth Sleepiness Scale (ESS) score of 11 or more was required at screening and baseline for all participants except those taking sodium oxybate at study entry, who were instead required to have had clinical improvement of excessive daytime sleepiness with sodium oxybate treatment per the investigator's clinical judgment.
    - Exclusion criteria: Hypersomnia due to another medical, behavioral, sleep, or psychiatric disorder; evidence of untreated or inadequately treated sleep-disordered breathing, known or suspected respiratory difficulty, or any condition that might compromise breathing; use of alerting agents in participants who were not on a stable dose of these medications, or any CNS sedating agents was prohibited.
    - Intervention: Participants began lower-sodium oxybate treatment (oral solution once or twice nightly) in an open-label titration and optimization period (10–14 weeks), followed by a 2-week, open-label, stable-dose period. After these open-label periods, participants were randomized (1:1) to either placebo or lower-sodium oxybate during a 2-week, double-blind, randomized withdrawal period.
    - Primary endpoint: Change in Epworth Sleepiness Scale (ESS) score from the end of the stable-dose period to the end of the double-blind, randomized withdrawal period
    - Results: ESS scores decreased from a mean of 15.7 (SD 3.8) at baseline to 6.1 (4.0) by the end of the stable-dose period. After the open-label periods, 115 participants were randomly assigned either placebo (n=59) or lower-sodium oxybate (n=56) and comprised the modified intention-to-

treat population. During the double-blind, randomized withdrawal period, ESS scores increased (worsened) in participants randomly assigned to placebo but remained stable in those assigned to lower-sodium oxybate (least squares mean difference −6·5; 95% CI −8·0 to −5·0; p<0·0001).

Combination Therapy
A variety of combination therapies are possible in narcolepsy although there is little published evidence to provide guidance on clinical choices. More head-to-head comparison trials along with studies that use drug combinations, and a sufficiently long period of follow-up are needed.

BOXED WARNINGS for oxybate sodium and oxybate salts:[1]
Central Nervous System Depression
Oxybate sodium and oxybate salts are central nervous system depressants. Clinically significant respiratory depression and obtundation may occur in patients treated with these agents. Many patients who received treatment during clinical trials in narcolepsy were receiving central nervous system stimulants.

Abuse/Misuse
The active moiety is oxybate or gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. Because of the risks of CNS depression and abuse and misuse, these agents are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review
The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs (Youth with Special Healthcare Needs (YSHCN)) as they turn 21. This benefit applies when a condition is determined to impact the ability to grow, develop or participate in school and the applicable criteria above are met.

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APPENDIX A.

Brand Name	Generic Name
Lumryz™	sodium oxybate (ER suspension)
Sunosi®	solriamfetol
Wakix®	pitolisant
Xyrem®	sodium oxybate (IR solution)
Xywav™	oxybate salts