Drug Coverage Policy

Effective Date… ……. 4/1/2026
Coverage Policy Number……IP0103
Policy Title……Oxybate Products

Neurology – Oxybate Products

- Lumryz™ (sodium oxybate extended-release oral suspension – Avadel)
- Xyrem® (sodium oxybate oral solution – Jazz, generic)
- Xywav® (calcium, magnesium, potassium, and sodium oxybates oral solution – Jazz)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Lumryz, sodium oxybate oral solution, and Xywav, central nervous system (CNS) depressants, are indicated for the following uses:[1-3]

- **Cataplexy treatment in patients with narcolepsy**. Lumryz, Sodium oxybate oral solution and Xywav are indicated in patients ≥ 7 years of age.
- **Excessive daytime sleepiness in narcolepsy**. Lumryz, Sodium oxybate oral solution and Xywav are indicated in patients ≥ 7 years of age.

Additionally, Xywav is indicated for the treatment of **idiopathic hypersomnia** in adults.[2]

Two specialized tests, which can be performed in a sleep disorders clinic, are required to establish a diagnosis of narcolepsy or idiopathic hypersomnia.[4] Polysomnography is an overnight recording of brain and muscle activity, breathing, and eye movements. The multiple sleep latency test (MSLT) assesses daytime sleepiness by measuring how quickly a person falls asleep and whether they enter rapid eye movement (REM) sleep. Polysomnography is routinely indicated for the diagnosis of sleep-related breathing disorders; for continuous positive airway pressure titration in patients with sleep-related breathing disorders; with an MSLT in the evaluation of suspected narcolepsy; and in certain atypical or unusual parasomnias.[5] The MSLT is indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis or patients who are thought to have idiopathic hypersomnia to exclude other causes of hypersomnia. Most patients with narcolepsy have objective evidence of hypersomnia as determined by a mean sleep latency < 5 minutes. In studies, the presence of two or more sleep-onset REM episodes (SOREMPs) was associated with a sensitivity of 0.78 and a specificity of 0.93 for the diagnosis of narcolepsy. SOREMPs do not occur exclusively in patients with narcolepsy; thus, it is important to rule out or treat other sleep disorders before evaluating SOREMPs in the diagnosis of narcolepsy. Diagnostic criteria for patients with idiopathic hypersomnia include a mean sleep latency ≤ 8 minutes and MSLT results showing < 2 SOREMPs or no SOREMPs if the REM sleep latency preceding polysomnogram is ≤ 15 minutes; also, these patients do not have cataplexy. For these reasons, polysomnography and an MSLT performed on the day after the polysomnographic evaluation are routinely indicated in the evaluation of suspected narcolepsy or idiopathic hypersomnia.

Guidelines
Pertinent medical guidelines related to oxybate products are summarized below; of note, Lumryz and Xywav are not addressed in any of the guidelines.

Narcolepsy and Cataplexy
The American Academy of Sleep Medicine (AASM) practice parameters for the treatment of central disorders of hypersomnolence were updated in 2021.[6,7]

- Modafinil, Wakix® (pitolisant tablets), sodium oxybate, and Sunosi® (solriamfetol tablets) are recommended as effective treatments for daytime sleepiness due to narcolepsy and reducing disease severity in adults (Strong Recommendation for each).
- Wakix and sodium oxybate have also demonstrated efficacy for the treatment of cataplexy in patients with narcolepsy (Strong Recommendation for each).
- Sodium oxybate and armodafinil have Conditional Recommendations for the treatment of narcolepsy, showing efficacy for daytime sleepiness due to narcolepsy and reducing disease severity.
- Dextroamphetamine has a Conditional Recommendation for the treatment of narcolepsy, showing efficacy for excessive daytime sleepiness and cataplexy.
- Methylphenidate has a Conditional Recommendation for the treatment of narcolepsy, showing efficacy in reducing disease severity.
- There was insufficient and inconclusive evidence to make recommendations for l-carnitine, scheduled naps, selegiline, triazolam, selective serotonin reuptake inhibitors (SSRIs), and serotonin-norepinephrine reuptake inhibitors (SNRIs).
- Modafinil and sodium oxybate have Conditional Recommendations for the treatment of narcolepsy in pediatric patients.

Note: A Strong Recommendation should be followed by clinicians under most circumstances. A Conditional Recommendation requires that the clinician use clinical knowledge and experience and strongly consider the individual patient's values and preferences to determine the best course of action.

Idiopathic Hypersomnia
The AASM guideline includes recommendations for the treatment of idiopathic hypersomnia.[6,7]

- Only modafinil has a Strong recommendation for use.

- Clarithromycin, methylphenidate, Wakix, and sodium oxybate have Conditional recommendations for the treatment of idiopathic hypersomnia in adults.

Safety
Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB) and Xywav is a mixed salt formulation of GHB.[1-3] They are both Schedule III controlled substances. Abuse of GHB (a Schedule I controlled substance), 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, abuse, and misuse, sodium oxybate oral solution and Xywav are available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS) called the Xyrem/Xywav Success Program, using a centralized pharmacy. Healthcare professionals who prescribe sodium oxybate oral solution or Xywav and patients must enroll in the Xyrem/Xywav Success Program and must comply with the requirements to ensure the drug's safe use. Similarly, Lumryz is only available through a restricted distribution program under a REMS called the Lumryz REMS. Healthcare providers who prescribe Lumryz must be specially certified; Lumryz will be dispensed only by pharmacies that are specially certified; and Lumryz will be dispensed and shipped only to patients who are enrolled in the Lumryz REMS with documentation of safe use conditions.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Lumryz, sodium oxybate oral solution, and Xywav. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Lumryz, sodium oxybate oral solution, and Xywav as well as the monitoring required for adverse event and long-term efficacy, approval requires these products to be prescribed by a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Lumryz, sodium oxybate oral solution (Xyrem), or Xywav are considered medically necessary when ONE of the following is met (1, 2, or 3):

FDA-Approved Indications

1. **Cataplexy Treatment in a Patient with Narcolepsy.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 7 years of age; AND
   - **B)** Patient has been evaluated using polysomnography and a multiple sleep latency test **[documentation required]**; AND
   - **C)** Diagnosis of narcolepsy has been confirmed **[documentation required]**; AND
   - **D)** The medication has been prescribed by a sleep specialist physician or a neurologist; AND
   - **E)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried dextroamphetamine **[documentation required]**; OR
     - **ii.** Patient has a contraindication or intolerance to dextroamphetamine **[documentation required]**; AND
       Note: Contraindications to dextroamphetamine include a history of substance use disorder; advanced arteriosclerosis, symptomatic cardiovascular disease, and/or

moderate to severe hypertension; hyperthyroidism; known hypersensitivity to sympathomimetic amines; glaucoma; agitated states; and concomitant administration with monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs.

F) Preferred product criteria is met for the products listed in the below table(s)

2. **Excessive Daytime Sleepiness in a Patient with Narcolepsy.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 7 years of age; AND
   - **B)** Patient has been evaluated using polysomnography and a multiple sleep latency test **[documentation required]**; AND
   - **C)** Diagnosis of narcolepsy has been confirmed **[documentation required]**; AND
   - **D)** The medication has been prescribed by a sleep specialist physician or a neurologist; AND
   - **E)** Patient has tried at least one of the following treatments: a central nervous system (CNS) stimulant, modafinil, or armodafinil **[documentation required]**; AND
     Note: Examples of CNS stimulants include methylphenidate, dexmethylphenidate, and dextroamphetamine.
   - **F)** Preferred product criteria is met for the products listed in the below table(s)

3. **Idiopathic Hypersomnia.** Approve Xywav (NOT sodium oxybate oral solution or Lumryz) for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been evaluated using polysomnography and a multiple sleep latency test **[documentation required]**; AND
   - **C)** Results of the polysomnography and a multiple sleep latency test are congruent with a diagnosis of idiopathic hypersomnia **[documentation required]**; AND
   - **D)** The medication has been prescribed by a sleep specialist physician or a neurologist; AND
   - **E)** Patient has tried at least one of modafinil, armodafinil, or methylphenidate **[documentation required]**

Employer Plans:

Product	Criteria
Xyrem (sodium oxybate oral solution)	**Cataplexy Treatment OR Excessive Daytime Sleepiness in Patients with Narcolepsy** Inability to obtain sodium oxybate oral solution due to market availability **[documentation required]**

Individual and Family Plans:

Product	Criteria
Lumryz (sodium oxybate extended-release oral suspension)	**Cataplexy Treatment in Patients with Narcolepsy.** **Patient is ≥ 18 years of age.** Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]** **Excessive Daytime Sleepiness in Patients with Narcolepsy.** Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]**
Sodium Oxybate oral solution	**Cataplexy Treatment in Patients with Narcolepsy.** **Patient is ≥ 18 years of age.** Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]** **Excessive Daytime Sleepiness in Patients with Narcolepsy.**

Product	Criteria
	Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]**
Xyrem (sodium oxybate oral solution)	**Cataplexy Treatment in Patients with Narcolepsy.** **Patient is ≥ 18 years of age.** Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]** **Excessive Daytime Sleepiness in Patients with Narcolepsy.** Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]**
Xywav (calcium, magnesium, potassium, and sodium oxybate)	**Cataplexy Treatment in Patients with Narcolepsy.** **Patient is ≥ 18 years of age.** Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]** **Excessive Daytime Sleepiness in Patients with Narcolepsy.** Patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [requires prior authorization] **[documentation required]**

Conditions Not Covered

Lumryz, sodium oxybate oral solution (Xyrem), or Xywav for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Fibromyalgia.** The European League Against Rheumatism (EULAR) issued evidence-based recommendations for the management of fibromyalgia (2016) stating that initial management should involve patient education and focus on non-pharmacological therapies.[8] EULAR's position on sodium oxybate for fibromyalgia is strongly against with 94% agreement. Duloxetine, pregabalin capsules and oral solution, and Savella® (milnacipran tablets) are indicated for the treatment of fibromyalgia.[9-11] Other recommended treatments include tricyclic antidepressants (i.e., amitriptyline), cyclobenzaprine, gabapentin, and selective serotonin reuptake inhibitors (i.e., fluoxetine, sertraline, paroxetine).[12]

2. **Concomitant use of Lumryz, sodium oxybate oral solution, and/or Xywav with each other or an oxybate product used in combination with Wakix (pitolisant tablets) and/or Sunosi (solriamfetol tablets).** Lumryz, sodium oxybate oral solution, and Xywav have the same active ingredient (oxybate, a CNS depressant) and have not been studied for use in combination or as alternating treatments.[1-3] Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with excessive daytime sleepiness due to narcolepsy or obstructive sleep apnea.[13] Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy.[14] Currently, there are no published studies evaluating combination use of these medications.

References

1. Xyrem® oral solution [prescribing information]. Palo Alto, CA: Jazz; April 2023.

2. Xywav® oral solution [prescribing information]. Palo Alto, CA: Jazz; April 2023.
3. Lumryz™ extended-release oral suspension [prescribing information]. Chesterfield, MO: Avadel; October 2024.
4. National Institutes of Health. Narcolepsy. National Institute of Neurological Disorders and Stroke. Last reviewed January 10, 2025. Available at: https://www.ninds.nih.gov/health-information/disorders/narcolepsy?search-term=narcolepsy. Accessed on June 9, 2025.
5. Krahn LE, Arand DL, Avidan AY, et al. Recommended protocols for the multiple sleep latency test and maintenance of wakefulness test in adults: guidance from the American Academy of Sleep Medicine. *J Clin Sleep Med*. 2021;17(12):2489-2498.
6. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. Available at: https://jcsm.aasm.org/doi/10.5664/jcsm.9328. Accessed on June 9, 2025.
7. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med*. 2021;17(9).
8. Macfarlane GJ, Kronisch C, Dean LE, et al. EULAR revised recommendations for the management of fibromyalgia. *Ann Rheum Dis*. 2017;76(2):318-328.
9. Lyrica® capsules and oral solution [prescribing information]. Morgantown, WV: Viatris; April 2025.
10. Cymbalta® delayed-release capsules [prescribing information]. Indianapolis, IN: Lilly; August 2023.
11. Savella® tablets [prescribing information]. North Chicago, IL: AbbVie; May 2024.
12. Clauw DJ. Fibromyalgia: a clinical review. *JAMA*. 2014;311(15):1547-1555.
13. Sunosi® tablets [prescribing information]. New York, NY: Axsome; June 2023.
14. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences; May 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Title:** **Updated from** "Oxybate" **to** "Neurology – Oxybate Products" **Cataplexy Treatment in a Patient with Narcolepsy.** **Updated from** "Narcolepsy Type 1 (Narcolepsy with Cataplexy)" **to** "Cataplexy Treatment in a Patient with Narcolepsy" **Updated '**ONE of the following: (i) Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness, (ii) A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG' TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test' **Removed** 'Cataplexy' **Removed** 'The hypersomnolence and/or MSLT findings are not better explained by other causes such as	10/15/2024

	insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' **Removed** 'No concurrent use with other sedative hypnotic drugs or alcohol' **Added** 'Diagnosis of narcolepsy has been confirmed, according to the prescriber' **Updated** 'Documentation of failure, contraindication or intolerance to **ONE** of the following: (i) Treatment of Cataplexy and **ONE** of the following: (1) dextroamphetamine, (2) a tricyclic antidepressant (TCA) [for example, amitriptyline, desipramine, imipramine], (3) a selective serotonin reuptake inhibitor (SSRI) [for example, fluoxetine, sertraline, paroxetine], (4) venlafaxine; (ii) Treatment of Excessive Daytime Sleepiness and **ONE** of the following: (i) modafinil OR armodafinil, (2) dextroamphetamine, dexmethylphenidate OR methylphenidate' TO 'Patient meets ONE of the following (i or ii); (i) Patient has tried dextroamphetamine; OR (ii) Patient has a contraindication or intolerance to dextroamphetamine, according to the prescriber. Note: Contraindications to dextroamphetamine include a history of substance use disorder; advanced arteriosclerosis, symptomatic cardiovascular disease, and/or moderate to severe hypertension; hyperthyroidism; known hypersensitivity to sympathomimetic amines; glaucoma; agitated states; and concomitant administration with monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs.' **Removed** pulmonologist from 'Medication is prescribed by, or in consultation with' bullet **Excessive Daytime Sleepiness in a Patient with Narcolepsy.** **Updated** description from 'Narcolepsy Type 2 (Narcolepsy without Cataplexy)' to 'Excessive Daytime Sleepiness in a Patient with Narcolepsy' **Removed '**Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' **Updated** 'Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness. A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG may replace one of the SOREMPs on the MSLT' TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test'	

	Removed 'The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' **Removed** 'No concurrent use with other sedative hypnotic drugs or alcohol' **Updated** 'Documentation of failure, contraindication or intolerance to **ONE** of the following: (i) modafinil OR armodafinil, (2) dextroamphetamine, dexmethylphenidate OR methylphenidate' TO 'Patient has tried at least one of the following treatments: a central nervous system (CNS) stimulant, modafinil, or armodafinil. Note: Examples of CNS stimulants include methylphenidate, dexmethylphenidate, and dextroamphetamine.' **Removed** pulmonologist from 'Medication is prescribed by, or in consultation with' bullet **Idiopathic Hypersomnia.** **Removed** 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' **Updated** 'A Multiple Sleep Latency Test (MSLT) performed according to standard techniques demonstrating an average sleep latency of less than or equal to 8 minutes with a total of less than 2 sleep onset rapid eye movement periods (SOREMPs)' TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test' **Removed** 'Absence of cataplexy' **Updated** 'The hypersomnolence and/or MSLT findings are not better explained by other sleep disorders (for example, insufficient sleep syndrome [if deemed necessary, by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed], delayed sleep phase disorder, other medical or psychiatric disorders, the effect of medication or substances or their withdrawal)' TO 'Results of the polysomnography and a multiple sleep latency test are congruent with a diagnosis of idiopathic hypersomnia, according to the prescriber' **Removed** 'No concurrent use with other sedative hypnotic drugs or alcohol' **Updated** 'Documentation of failure, contraindication or intolerance to **ONE** of the following: (i) armodafinil or modafinil, (2) methylphenidate' TO 'Patient has tried at least one of modafinil, armodafinil, or methylphenidate.' **Removed** pulmonologist from 'Medication is prescribed by, or in consultation with' bullet **Preferred Product Criteria Table.**	

	Lumryz. Updated Lumryz from 'There is documentation of failure, contraindication, or intolerance to Wakix (pitolisant) [may require prior authorization]' TO 'Patients ≥ 18 years of age: approve if the patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]' **Xyrem (Individual and Family Plan).** Updated 'Failure, contraindication, or intolerance to Wakix (pitolisant) [may require prior authorization]' TO 'Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization] **Xywav.** Updated 'Failure, contraindication, or intolerance to Wakix (pitolisant) [may require prior authorization]' TO '**1.** patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]' **Conditions Not Covered.** **Updated** 'Concomitant use of Lumryz, sodium oxybate oral solution, Xyrem and/or Xywav' TO 'Concomitant use of Lumryz, sodium oxybate oral solution, and/or Xywav with each other or an oxybate product used in combination with Wakix (pitolisant tablets) and/or Sunosi (solriamfetol tablets)'	
Selected Revision	**Added** "**<u>Documentation</u>**: Documentation is required where noted in the criteria. Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information." **Cataplexy Treatment in a Patient with Narcolepsy** Changed the age requirement for Lumryz from ≥ 18 years of age to ≥ 7 years of age. **Updated** criteria **from** "Patient has been evaluated using polysomnography and a multiple sleep latency test" **to** "Documentation that the patient has been evaluated using polysomnography and a multiple sleep latency test." **Updated** criteria **from** "Diagnosis of narcolepsy has been confirmed, according to the prescriber" **to** "Documented diagnosis of narcolepsy has been confirmed." **Updated** criteria **from** "Patient meets ONE of the following (i <u>or</u> ii):" **to** "Documentation that the patient meets ONE of the following (i <u>or</u> ii):." **Excessive Daytime Sleepiness in a Patient with Narcolepsy**	03/01/2025

	Changed the age requirement for Lumryz from ≥ 18 years of age to ≥ 7 years of age. **Updated** criteria **from** "Patient has been evaluated using polysomnography and a multiple sleep latency test" **to** "Documentation that the patient has been evaluated using polysomnography and a multiple sleep latency test." **Updated** criteria **from** "Diagnosis of narcolepsy has been confirmed, according to the prescriber" **to** "Documented diagnosis of narcolepsy has been confirmed." **Updated** criteria **from** "Patient has tried at least one of the following treatments: a central nervous system (CNS) stimulant, modafinil, or armodafinil" **to** "Documentation that the patient has tried at least one of the following treatments: a central nervous system (CNS) stimulant, modafinil, or armodafinil." **Idiopathic Hypersomnia** **Updated** criteria **from** "Patient has been evaluated using polysomnography and a multiple sleep latency test" **to** "Documentation that the patient has been evaluated using polysomnography and a multiple sleep latency test." **Updated** criteria **from** "Results of the polysomnography and a multiple sleep latency test are congruent with a diagnosis of idiopathic hypersomnia, according to the prescriber" **to** "Documentation that the results of the polysomnography and a multiple sleep latency test are congruent with a diagnosis of idiopathic hypersomnia." **Updated** criteria **from** "Patient has tried at least one of modafinil, armodafinil, or methylphenidate" **to** "Documentation that the patient has tried at least one of modafinil, armodafinil, or methylphenidate." **Preferred Product Table** **Individual and Family Plans:** **Cataplexy Treatment in Patients with Narcolepsy** **Lumryz: Updated** criteria **from** "Patient ≥ 18 years of age: Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]**" to** "Patient is ≥ 18 years of age. Documentation that the patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]." **Xyrem: Updated** criteria **from** "ONE of the following: 1. Less than 18 years of age OR 2. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]" **to** "Patient is	

	≥ 18 years of age. Documentation that the patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]." **Xywav: Updated** criteria **from** "ONE of the following: 1. Less than 18 years of age OR 2. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization" **to** "Patient is ≥ 18 years of age. Documentation that the patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]." **Excessive Daytime Sleepiness in Patients with Narcolepsy** **Lumryz: Updated** criteria **from** "Patients ≥ 18 years of age: Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization" **to** "Documentation that the patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]." **Xyrem: Updated** criteria **from** "ONE of the following: 1. Less than 18 years of age OR 2. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]" **to** "Documentation that the patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]." **Xywav: Updated** criteria **from** "ONE of the following: 1. Less than 18 years of age OR 2. Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization" **to** "Documentation that the patient has tried and has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]."	
Annual Revision	No criteria changes	09/01/2025
Selected Revision	**Updated** policy template.	11/15/2025
Selected Revision	**Individual and Family Plans** **Added** preferred product requirements for Sodium Oxybate oral solution.	01/01/2026
Selected Revision	Update to clarify step therapy requirements for Xyrem, allowing stepping through sodium oxybate products more broadly rather than limiting to a specific generic or manufacturer.	4/1/2026

	Removed the Amneal product from the preferred product criteria box table in acknowledgement of its authorized generic status transitioning to a true generic.	

The policy effective date is in force until updated or retired.