MEDICAL MUTUAL®

Drug Policy

Policy:	Sunosi (solriamfetol)	Annual Review Date: 04/17/2025 Last Revised Date: 04/17/2025

OVERVIEW

Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with **excessive daytime sleepiness** associated with the following conditions:

- **Narcolepsy**.
- **Obstructive sleep apnea** (OSA).
  Limitations of Use: Sunosi is not indicated to treat the underlying airway obstruction in OSA.[1]The underlying airway obstruction should be treated (e.g., with continuous positive airway pressure [CPAP]) for at least 1 month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi.

Sunosi is a Schedule IV controlled substance.

POLICY STATEMENT

This policy involves the use of Sunosi. Prior authorization is recommended for pharmacy benefit coverage of Sunosi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sunosi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sunosi be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

AUTOMATION: When available, 1) ICD-10 code G47.41 confirming diagnosis of Narcolepsy AND 2) patient age of 18 years or older AND 3) history of a CNS stimulant (products containing methylphenidate, dexmethylphenidate, and dextroamphetamine), armodafinil or modafinil use within the previous 730 days AND 4) an absence of claims history for Wakix (pitolisant), Xyrem (sodium Oxybate), and Xywav (Oxybate Salts [Calcium, Magnesium, Potassium, and Sodium]) within the last 130 days will be used for automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sunosi is recommended in those who meet the following criteria:

1. **Excessive Daytime Sleepiness Associated with Narcolepsy**
   Criteria. *Patient must meet the following criteria (A, B, C, D, and E)*

   A. The patient is 18 years of age or older; AND
   B. The patient has been evaluated using polysomnography and multiple sleep latency test (MSLT); AND
   C. Diagnosis of narcolepsy has been confirmed, according to the prescriber; AND
   D. Sunosi is prescribed by or in consultation with a sleep disorder specialist, psychiatrist, or neurologist; AND
   E. Patient has tried ONE of the following: central nervous system (CNS) stimulant, generic modafinil, or generic armodafinil.
   Note: Examples of CNS stimulants include methylphenidate, dexmethylphenidate, and dextroamphetamine. An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil.

2. **Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea (OSA)**
   Criteria. *Patient must meet the following criteria (A, B, C, D, and E)*

   A. The patient is 18 years of age or older; AND
   B. Diagnosis of obstructive sleep apnea has been confirmed, according to the prescriber; AND
   C. Sunosi is prescribed by or in consultation with a sleep disorder specialist, psychiatrist, or neurologist; AND
   D. Patient meets one of the following criteria (i or ii):
      i. Sunosi will be used in conjunction with continuous positive airway pressure (CPAP); OR
      ii. Patient is unable to initiate or tolerate CPAP therapy; AND
   E. Patient has tried generic modafinil or generic armodafinil.
   Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or Nuvigil.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sunosi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Primary Treatment of Airway Obstruction in OSA.** Sunosi is NOT indicated to treat the underlying airway obstruction in OSA. Modalities to treat the underlying airway obstruction, such as CPAP, should be continued during

2. **Concomitant use of Sunosi with Xyrem (sodium oxybate oral solution), Xywav (calcium, magnesium, potassium, and sodium oxybates oral solution), and/or Wakix (pitolisant tablets).** 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. Xyrem (sodium oxybate oral solution) and Xywav (calcium, magnesium, potassium, and

sodium oxybates oral solution) have the same active ingredient (oxybate, a central nervous system depressant) and have not been studied for use in combination or as alternating treatments. Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy. Currently, there are no published studies evaluating combination use of these medications.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sunosi® tablets [prescribing information]. Palo Alto, CA: Jazz; October 2021.
2. Provigil® tablets [prescribing information]. North Wales, PA: Cephalon; January 2015.
3. Nuvigil® tablets [prescribing information]. North Wales, PA: Cephalon; February 2017.
4. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(9):1881–1893.
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8. National Institutes of Health. Narcolepsy Fact Sheet. National Institute of Neurological Disorders and Stroke. Date last modified: July 25, 2022. Available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet. Accessed on September 6, 2022.
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10. Xyrem® oral solution [prescribing information]. Palo Alto, CA: Jazz; March 2022.
11. Xywav® oral solution [prescribing information]. Palo Alto, CA: Jazz; March 2022.
12. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences; October 2020.