PRIOR AUTHORIZATION WITH STEP THERAPY POLICY

POLICY: Wakefulness-Promoting Agents – Sunosi Prior Authorization with Step Therapy Policy
- Sunosi® (solriamfetol tablets – Jazz)

REVIEW DATE: 04/15/2026

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with **excessive daytime sleepiness** associated with the following conditions:[1]

- **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.[1]

Armodafinil and modafinil are wakefulness-promoting agents with actions similar to sympathomimetic agents (e.g., amphetamine and methylphenidate).[2,3] They are indicated to improve wakefulness in adults with excessive sleepiness associated with narcolepsy, OSA, or shift work disorder. Armodafinil and modafinil are Schedule IV controlled substances. Wakix® (pitolisant tablets), an antagonist/inverse agonist of the histamine-3 receptor, is indicated for the treatment of excessive daytime sleepiness or cataplexy in patients ≥ 6 years of age with narcolepsy.[13] Wakix is the only wakefulness-promoting agent that is not a controlled substance. Stimulant medications (e.g., amphetamine, methamphetamine, dextroamphetamine, and methylphenidate) are used off-label for the treatment of daytime sleepiness due to narcolepsy and OSA and are mentioned in guidelines.[4-7]

Two specialized tests, which can be performed in a sleep disorders clinic, are required to establish a diagnosis of narcolepsy.[8] Polysomnogram (PSG) is an overnight recording of brain and muscle activity, breathing, and eye movements. The multiple sleep latency test assesses daytime sleepiness by measuring how quickly a person falls asleep and whether they enter rapid eye movement (REM) sleep. On the day after PSG, the patient is asked to take five short naps separated by 2 hours over the course of a day. If an individual falls asleep in < 8 minutes on average over the five naps, this indicates excessive daytime sleepiness. However, patients with narcolepsy also have an abnormally quick start to REM sleep. If REM sleep happens within 15 minutes at least two times out of the five naps and the sleep study the night before, this is likely an abnormality caused by narcolepsy.

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.[4,5]

- Modafinil, Wakix, sodium oxybate oral solution (Xyrem®, generic), and Sunosi 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.

Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea
AASM guidelines for medical therapy of OSA are dated (2006) and do not address Sunosi.[6] Modafinil is recommended for the treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective positive airway pressure (PAP) treatment and who are lacking any other identifiable cause for their sleepiness. AASM guidelines for treatment of adult OSA with PAP were updated in 2019.[7] PAP is recommended to treat OSA in adults with excessive sleepiness (strong recommendation). Types of PAP cited in the guidelines include auto-adjusting PAP (APAP), continuous PAP (CPAP), and bilevel PAP (BPAP).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Sunosi. This Prior Authorization Policy also contains a Step Therapy component. When clinically appropriate, the patient is directed to try one Step 1 Product (modafinil or armodafinil) prior to Sunosi (Step 2). All approvals are provided for the duration noted below.

- **Sunosi® (solriamfetol tablets – Jazz)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Excessive Daytime Sleepiness Associated with Narcolepsy.** Approve 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; AND
   - **C)** According to the prescriber, diagnosis of narcolepsy has been confirmed; AND
   - **D)** The medication is prescribed by or in consultation with a sleep specialist physician or a neurologist; AND
   - **E)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has tried at least ONE of the following treatments: a central nervous system (CNS) stimulant, generic modafinil, or generic armodafinil; OR
       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 brand Nuvigil.
     - **ii.** Patient is currently receiving Sunosi.

2. **Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):

i. Sunosi will be used in conjunction with positive airway pressure therapy; OR

ii. Patient is unable to initiate or tolerate positive airway pressure therapy; AND

Note: Positive airway pressure can include continuous positive airway pressure (CPAP), auto-titrating positive airway pressure (APAP), or bilevel positive airway pressure (BPAP).

C) Patient meets ONE of the following (i or ii):

i. Patient has tried generic modafinil or generic armodafinil; OR

Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or brand Nuvigil.

ii. Patient is currently receiving Sunosi.

CONDITIONS NOT COVERED

- **Sunosi® (solriamfetol tablets – Jazz)**

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concomitant Use of Sunosi with an Oxybate Product 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.[1] Oxybate products include Xyrem (sodium oxybate oral solution), Lumryz (sodium oxybate extended-release oral suspension), and Xywav (calcium, magnesium, potassium, and sodium oxybate oral solution).[10-12] These 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.[13] Currently, there are no published studies evaluating Sunosi in combination with these medications.

REFERENCES

1. Sunosi® tablets [prescribing information]. New York, NY: Axsome Therapeutics; June 2023.
2. Provigil® tablets [prescribing information]. Parsippany, NJ: Teva; December 2022.
3. Nuvigil® tablets [prescribing information]. Parsippany, NJ: Teva; December 2022.
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.
5. 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):1895-1945.
6. Morgenthaler TI, Kapen S, Lee-Chiong T, et al. Practice parameters for the medical therapy of obstructive sleep apnea. *Sleep*. 2006;29(8):1031-1035.
7. Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2019;15(2):335-343.
8. National Institutes of Health. Narcolepsy. National Institute of Neurological Disorders and Stroke. Last reviewed on March 13, 2026. Available at: Narcolepsy | National Institute of Neurological Disorders and Stroke (nih.gov). Accessed on April 10, 2026.

9. Mayo Clinic. Obstructive sleep apnea. Available at: https://www.mayoclinic.org/diseases-conditions/obstructive-sleep-apnea/symptoms-causes/syc-20352090?p=1. Accessed on April 15, 2026.
10. Xyrem® oral solution [prescribing information]. Palo Alto, CA: Jazz; April 2023.
11. Lumryz™ extended-release oral suspension [prescribing information]. Chesterfield, MO: Avadel; October 2024.
12. Xywav® oral solution [prescribing information]. Palo Alto, CA: Jazz; April 2023.
13. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences; February 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Excessive Daytime Sleepiness Associated with Narcolepsy.** The criteria were updated to include central nervous system (CNS) stimulants as an option for patients to have tried prior to approval of Sunosi. Now a patient needs to have tried a CNS stimulant, generic modafinil, or generic armodafinil prior to approval of Sunosi. Previously, a patient had to have tried one of generic modafinil or generic armodafinil. Additionally, examples CNS stimulants were added to the Note.	09/04/2024
Annual Revision	**Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea.** Requirement regarding use in conjunction with continuous positive airway pressure or patient is unable to initiate or tolerate continuous positive airway pressure was changed to use in conjunction with positive airway pressure or patient is unable to initiate or tolerate positive airway pressure with a Note that positive airway pressure can include continuous positive airway pressure (CPAP), auto-titrating positive airway pressure (APAP), or bilevel positive airway pressure (BPAP).	09/03/2025
Early Annual Revision	**Excessive Daytime Sleepiness Associated with Narcolepsy:** An exception was added such that a patient who is currently receiving Sunosi does not need to try a central nervous system stimulant, modafinil, or armodafinil. **Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea:** An exception was added such that a patient who is currently receiving Sunosi does not need to try modafinil or armodafinil.	04/15/2026