VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY WITH STEP THERAPY

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

**REVIEW DATE:** 08/18/2021; selected revision 02/02/2022

## 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.

Armodafinil and modafinil are wakefulness-promoting agents with actions similar to sympathomimetic agents (e.g., amphetamine and methylphenidate). They are indicated to improve wakefulness in adults with excessive sleepiness associated with narcolepsy, OSA, or shift work disorder.[2,3] Armodafinil and modafinil are Schedule IV controlled substances. 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 two 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® (pitolisant tablet), Xyrem® (sodium oxybate oral solution), 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 Xyrem have also demonstrated efficacy for the treatment of cataplexy in patients with narcolepsy (Strong Recommendation for each).
- Xyrem 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 Xyrem have Conditional Recommendations for the treatment of narcolepsy in pediatric patients.
- 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/Hypoapnea Syndrome**

- According to the AASM guideline on medical therapy for OSA (2006), CPAP is the most uniformly effective therapy, and, to date, this is the only intervention for OSA shown to have favorable impacts on both cardiovascular and neurobehavioral morbidities.[6,7]
- Modafinil, in patients compliant with nasal CPAP, consistently improved subjective and objective sleepiness, quality of life, and vigilance compared with placebo. Sunosi is not addressed in these guidelines.

## 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.

**Automation**: None.

## RECOMMENDED AUTHORIZATION CRITERIA

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

### FDA-Approved Indications

1. **Excessive Daytime Sleepiness Associated with Narcolepsy.** Approve for 1 year if the patient meets the following criteria (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)** Diagnosis of narcolepsy has been confirmed, according to the prescriber; AND
   - **D)** The medication is prescribed by or in consultation with a sleep specialist physician or a neurologist; 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.

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

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sunosi is not recommended in the following situations:

1. **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.[1] 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.[10,11] Wakix, an antagonist/inverse agonist of the histamine-3 receptor, is indicated for excessive daytime sleepiness and cataplexy in adults with narcolepsy.[12] Currently, there are no published studies evaluating combination use of these medications.

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

## REFERENCES

1. Sunosi® tablets [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; June 2019.
2. Provigil® tablets [prescribing information]. North Wales, PA: Cephalon; August 2021.
3. Nuvigil® tablets [prescribing information]. North Wales, PA: Cephalon; February 2017.
4. Morgenthaler TI, Kapur VK, Brown TM, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine Report. Available at: http://www.aasmnet.org/Resources/PracticeParameters/PP_Narcolepsy.pdf. Accessed on August 16, 2021.
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7. 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.
8. National Institutes of Health. Narcolepsy Fact Sheet. National Institute of Neurological Disorders and Stroke. Date last modified: September 30, 2020. Available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet. Accessed on August 16, 2021.
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 August 16, 2021.
10. Xyrem® oral solution [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; September 2020.
11. Xywav™ oral solution [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; August 2021.
12. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences; October 2020.