Pharmacy Policy Bulletin: J-0937 Sunosi (solriamfetol) – Commercial and Healthcare Reform	
Number: J-0937	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0937-008	**Original Date:** 05/01/2019
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Sunosi (solriamfetol)
FDA-Approved Indication(s):	• Improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA)

Background:	• Sunosi is a scheduled controlled substance that is a wakefulness promoting agent for oral administration. The precise mechanism(s) through which Sunosi promotes wakefulness is unknown, however, it may be mediated through its activity as a dopamine and norepinephrine inhibitor (DNRI). • Narcolepsy is a neurological disorder characterized by EDS and abnormal regulation of sleep-wake cycles. EDS is the primary symptom of narcolepsy and is displayed by all patients to some degree. Cataplexy occurs in 70% of patients and is defined as the sudden, often brief (less than 2 minutes) loss of muscle tone with retained consciousness. It is usually triggered by strong emotions. • Apnea-hypopnea index (AHI) indicates the number of apnea or hypopnea events per hour. A score greater than or equal to 15 indicates moderate to severe apnea. Respiratory disturbance index (RDI) includes the total number of apneas, hypopneas, and respiratory effort related arousals (RERAs) during sleep. A score greater than or equal to 15 indicates moderate to severe apnea. Oxygen desaturation index (ODI) indicates the number of times per hour of sleep that the blood oxygen level drops by 4 or more percentage points from baseline. • The American Academy of Sleep Medicine (AASM) 2021 guidelines strongly recommend modafinil, Wakix (pitolisant), Xyrem (sodium oxybate), and Sunosi in the treatment of narcolepsy in adults. They conditionally recommend armodafinil, dextroamphetamine, and methylphenidate. • OSA can cause disruption in sleep patterns, leading to excessive day-time sleepiness and impaired sleep-related quality of life. OSA is also associated with other comorbidities, such as hypertension. Clinical guidelines recommend that positive airway pressure devices (PAP), such as continuous PAP (CPAP) or automatic PAP (APAP), be used in patients with excessive daytime sleepiness

(strong recommendation), impaired sleep-related quality of life (conditional recommendation), or hypertension (conditional recommendation, AASM).

- Oral appliances (OAs) are devices intended to protrude and stabilize the mandible to maintain a patent airway during sleep. The 2015 AASM Clinical Practice Guideline for the Treatment of OSA and Snoring with Oral Appliance Therapy recommends the consideration of OAs for adults with OSA who are intolerant of CPAP therapy or prefer alternate therapy. The guideline states that CPAP should generally still be used first-line as it has been found to be superior to OAs in reducing AHI, arousal index, and oxygen desaturation index and improving oxygen saturation. The guideline recommends that a custom, titratable appliance be used. A custom OA is created using impressions and models of a patient's oral structures. Titratable OAs have a mechanism that allows for varying amounts of mandibular protrusion. A tongue retaining device is not considered to be an OA.
- Diagnostic Criteria
    - The multiple sleep latency test (MSLT) is a day-time sleep study where patients are instructed to try to fall asleep as they take scheduled naps with breaks in between. The time it takes to fall asleep is sleep latency; 97% of people take more than 8 minutes to fall asleep.
    - Polysomnography is an overnight sleep study that measures the amount of time spent in different phases of sleep, in addition to the number of apneic and hypoapneic episodes.
    - Sleep-onset rapid eye movement periods (SOREMPs) define the number of periods with REM sleep and can be calculated with a polysomnography or MSLT. People with narcolepsy have more frequent and shorter periods of REM sleep.
    - Individuals with narcolepsy may have lower levels of hypocretin, a neurotransmitter involved in the sleep-wake cycle. Patients may undergo a lumbar puncture to quantify the amount of hypocretin-1 in their cerebrospinal fluid; levels under 110 pg/mL are indicative of narcolepsy.
    - The Epworth Sleepiness Scale (ESS) is a subject assessment completed by the patient, generating a rating representative of their level of excessive daytime sleepiness (EDS)
    - The maintenance of wakefulness test (MWT) is very similar to the MSLT, but patients are instructed to stay awake rather than fall asleep. Sleep latency is also generated from the MWT.
- Prescriber Considerations
    - In OSA, Sunosi is indicated to treat excessive daytime sleepiness. Sunosi is not indicated to treat the underlying airway obstruction in OSA. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi because Sunosi not a substitute for these modalities.
    - The recommended dosage range in narcolepsy is 75 mg to 150 mg once daily and in OSA is 37.5 mg to 150 mg once daily. Dosages above 150 mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions.
    - Administer Sunosi once daily upon awakening. Avoid administration within 9 hours of planned bedtime because of the potential to interfere with sleep.
    - Prior to initiation of Sunosi, ensure the blood pressure is adequately controlled.

Approval Criteria

I. Narcolepsy

A. Initial Authorization

When a benefit, coverage of Sunosi may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of narcolepsy (ICD-10: G47.41)
3. The member meets one (1) of the following criteria **(a., b., or c.)**:
   - **a.** The prescriber provides a multiple sleep latency test (MSLT) substantiating both of the following **(i. and ii.)**:
     - **i.** Mean sleep latency ≤ 8 minutes.
     - **ii.** ≥ 2 sleep-onset rapid eye movement periods (SOREMPs).
   - **b.** The prescriber provides a polysomnography and an MSLT substantiating all of the following **(i., ii., and iii.)**:
     - **i.** MSLT demonstrating a mean sleep latency ≤ 8 minutes.
     - **ii.** MSLT demonstrating ≥ one (1) SOREMP.
     - **iii.** Polysomnography demonstrating ≥ one (1) SOREMP.
   - **c.** The member has a documented hypocretin-1 deficiency defined as one (1) of the following **(i. or ii.)**:
     - **i.** Cerebrospinal fluid hypocretin-1 < 110 pg/mL.
     - **ii.** Cerebrospinal fluid hypocretin-1 < one-third of the normal value based on laboratory reference range.
4. The prescriber provides documentation of baseline data of one (1) of the following criteria **(a. or b.)**:
   - **a.** Excessive daytime sleepiness (EDS) via the Epworth Sleepiness Scale (ESS)
   - **b.** Maintenance of Wakefulness Test (MWT)
5. The member meets one (1) of the following criteria **(a. or b.)**:
   - **a.** If the member has a diagnosis of narcolepsy with cataplexy, the member has experienced therapeutic failure, contraindication, or intolerance to a generic CNS stimulant (for example, dextroamphetamine).
   - **b.** If the member has a diagnosis of narcolepsy without cataplexy, the member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(i. and ii.)**:
     - **i.** generic modafinil
     - **ii.** generic CNS stimulant (for example, dextroamphetamine, methylphenidate)

B. Reauthorization

When a benefit, reauthorization of Sunosi may be approved when the following criterion is met **(1.)**:

1. The prescriber attests the member experienced a decrease in daytime sleepiness as proven by improvement on the ESS or MWT compared to baseline.

II. Obstructive Sleep Apnea/Hypopnea Syndrome

A. Initial Authorization

When a benefit, coverage of Sunosi may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS) (ICD-10: G47.33).
3. The member meets one (1) of the following **(a. or b.)**:
   - **a.** The member is currently receiving and compliant with positive airway pressure (PAP).
   - **b.** The member meets both of the following **(i. and ii.)**:
     - **i.** The member has experienced therapeutic failure, intolerance, or contraindication to PAP.
     - **ii.** The member is currently using and compliant with a custom, titratable oral appliance.

4. The member meets both of the following **(a. and b.)**:
   a. The member is experiencing persistent daytime sleepiness despite adequate OSA treatment.
   b. The prescriber attests that alternative causes of daytime sleepiness have been excluded.
5. The member has experienced therapeutic failure, contraindication, or intolerance to both of the following **(a. and b.)**:
   a. generic modafinil
   b. generic armodafinil

B. Reauthorization

When a benefit, reauthorization of Sunosi may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member meets one (1) of the following **(a. or b.):**
   a. The member is currently receiving and compliant with positive airway pressure (PAP).
   b. The member meets both of the following **(i. and ii.):**
      i. The member has experienced therapeutic failure, intolerance, or contraindication to PAP.
      ii. The member is currently using and compliant with a custom, titratable oral appliance.
2. The prescriber provides attestation that the member has experienced improvement in daytime sleepiness.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization will be granted.

Automatic Approval Criteria

None

References:

1. Sunosi [package insert]. New York, NY: Axsome Therapeutics, Inc.; June 2023.
2. 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.
3. Sateia MJ. International classification of sleep disorders-third edition: highlights and modifications. *CHEST.* 2014;146(5):1387-1394.
4. Epstein LJ, Kristro D, Strollo PJ Jr., et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med.* 2009;5(3):263-276.
5. 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.
6. UpToDate. Evaluation and Management of Residual Excessive Sleepiness in Adults with Obstructive Sleep Apnea. Available at: htttps://www.uptodate.com. Accessed January 03, 2025.

7. Ramar K, Dort LC, Katz SG, et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015. *J Clin Sleep Med*. 2015 Jul 15;11(7):773-827.
8. Kapur, VK, Auckley DH, Chowduri S, et al. Clinical Practice Guideline for the Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2017;13(3):479-504.