UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2171-8
Program	Prior Authorization/Medical Necessity
Medication	Sunosi® (solriamfetol)
P&T Approval Date	7/2019, 8/2019, 8/2020, 8/2021, 8/2022, 9/2022, 11/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

Limitations of Use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one 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 not a substitute for these modalities.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Narcolepsy

1. **Initial Authorization**

   a. **Sunosi** will be approved based on **all** of the following criteria:

      (1) Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

      –AND–

      (2) Symptoms of excessive daytime sleepiness (including but not limited to daily periods of irrepressible need to sleep or daytime lapses into sleep) are present.

      –AND–

      (3) History of failure, contraindication, or intolerance to **both** of the following:

         i. **One** of the following:

            1. Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
            2. Methylphenidate based stimulant

         –AND–

         ii. **One** of the following:

            1. modafanil (Provigil)
            2. armodafanil (Nuvigil)

      Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Sunosi** will be approved for continuation of therapy based on the following criterion:

      (1) Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

      Authorization will be issued for 12 months.

B. Obstructive Sleep Apnea

1. **Initial Authorization**

   a. **Sunosi** will be approved based on **all** of the following criteria:

      (1) Diagnosis of obstructive sleep apnea defined by one of the following:

         i. Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep

study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

–OR–

ii. Both of the following:

1. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

–AND–

2. One or more of the following signs/symptoms are present:

(a) Daytime sleepiness
(b) Nonrestorative sleep
(c) Fatigue
(d) Insomnia
(e) Waking up with breath holding, gasping, or choking
(f) Habitual snoring noted by bed partner or other observer
(g) Observed apnea

–AND–

(2) Both of the following:

i. Standard treatments for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

–AND–

ii. Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

–AND–

(3) History of failure, contraindication, or intolerance to **one** of the following:

i. armodafinil
ii. modafinil

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sunosi** will be approved for continuation of therapy based on **both** the following criteria:

(1) Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

–AND–

(2) Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g. CPAP, BiPAP)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Sunosi [package insert]. New York, NY: Axsome Therapeutics, Inc; June 2023.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
3. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American 4. Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881–1893.
4. 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.

Program	Prior Authorization/Medical Necessity - Sunosi™ (solriamfetol)
Change Control	
7/2019	New program
8/2019	Changed from a trial of two previous medications to a trial of one in Obstructive Sleep Apnea section.
8/2020	Annual review with no changes to clinical coverage criteria. Updated reference.
8/2021	Annual review with no changes to clinical coverage criteria. Updated reference formatting.
8/2022	Annual review with no changes to clinical coverage criteria. Updated references.
9/2022	Updated references.
11/2023	Annual review. Updated references.
9/2024	Updated initial authorization to 12 months.