



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 1285-5 |
| Program | Prior Authorization/Notification |
| Medication | Sunosi [®] (solriamfetol) |
| P&T Approval Date | 7/2019, 7/2020, 8/2021, 9/2022, 11/2023 |
| Effective Date | 2/1/2024 |

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 irrepensible need to sleep or daytime lapses into sleep) are present.

Authorization will be issued for 6 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 as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

–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

Authorization will be issued for 6 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, Medical Necessity 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 Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881–1893.

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| Change Control | |
| 7/2019 | New program |
| 7/2020 | Annual review. Updated references. |
| 8/2021 | Annual review. Updated references. |
| 9/2022 | Annual review. Updated references. Added state mandate footnote. |
| 11/2023 | Annual review. Updated references. |