Reference number(s)
2915-C

Initial Prior Authorization with Quantity Limit Sunosi Narcolepsy Agents

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sunosi	solriamfetol

Indications

FDA-approved Indications

Sunosi is 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.

Coverage Criteria

Narcolepsy

Authorization may be granted for a diagnosis of excessive daytime sleepiness associated with narcolepsy when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis has been confirmed by sleep study.
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response to armodafinil OR modafinil.
    - The patient has experienced an intolerance to armodafinil OR modafinil.
    - The patient has a contraindication that would prohibit a trial of ALL of the following: armodafinil, modafinil.

Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis has been confirmed by polysomnography or home sleep apnea test (HSAT) with a technically adequate device.
- The patient has been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month.
- The patient will continue to use CPAP or BIPAP after the requested drug is started.
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response to armodafinil OR modafinil.
    - The patient has experienced an intolerance to armodafinil OR modafinil.
    - The patient has a contraindication that would prohibit a trial of ALL of the following: armodafinil, modafinil.

Continuation of Therapy

Narcolepsy

Authorization may be granted for a diagnosis of excessive daytime sleepiness associated with narcolepsy when the following criteria is met:

- The patient has achieved or maintained a decrease in daytime sleepiness with narcolepsy from baseline.

Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The patient has achieved or maintained a decrease in daytime sleepiness with OSA from baseline.
- The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP).

Quantity Limits Apply

30 tablets per 25 days or 90 tablets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 2915-C: DOA: 12 months

References

1. Sunosi [package insert]. New York, NY: Axsome Therapeutics, Inc.; June 2023.
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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/19/2024).
4. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for 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.
5. Epstein LJ, Kristo D, Strollo PJ, 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.
6. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
7. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.

8. 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.
9. 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.