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.

Document History

Written by: UM Development (KC)

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Revised: (KC) 10/2019, 03/2020 (no clinical changes), 03/2021; (MRS) 03/2022 (added prescriber restriction, removed step through CNS stimulants for narcolepsy, added ongoing PAP requirement for initiation and continuation in OSA), 03/2023 (no clinical changes); (NS/TM) 01/2024 (no clinical changes); KMB/ASA 12/2024 (added HSAT to OSA)

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External Review: 06/2019, 02/2020, 08/2020, 08/2021, 08/2022, 08/2023, 04/2024, 04/2025

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA)? [If Yes, then go to 2. If No, then go to 9.]	Yes	No
2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then go to 5.]	Yes	No
3	Has the patient achieved or maintained a decrease in daytime sleepiness with obstructive sleep apnea (OSA) from baseline? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Is the patient compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
5	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 6. If No, then no further questions.]	Yes	No

6	Is the diagnosis confirmed by polysomnography or home sleep apnea test (HSAT) with a technically adequate device? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Has the patient been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Will the patient continue to use continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP) after the requested drug is started? [If Yes, then go to 14. If No, then no further questions.]	Yes	No
9	Does the patient have a diagnosis of excessive daytime sleepiness associated with narcolepsy? [If Yes, then go to 10. If No, then no further questions.]	Yes	No
10	Is this request for continuation of therapy? [If Yes, then go to 11. If No, then go to 12.]	Yes	No
11	Has the patient achieved or maintained a decrease in daytime sleepiness with narcolepsy from baseline? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
12	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
13	Is the diagnosis confirmed by a sleep study? [If Yes, then go to 14. If No, then no further questions.]	Yes	No
14	Has the patient experienced an inadequate treatment response to armodafinil OR modafinil? [If Yes, then go to 17. If No, then go to 15.]	Yes	No
15	Has the patient experienced an intolerance to armodafinil OR modafinil? [If Yes, then go to 17. If No, then go to 16.]	Yes	No
16	Does the patient have a contraindication that would prohibit a trial of ALL of the following: A) armodafinil, B) modafinil? [If Yes, then go to 17. If No, then no further questions.]	Yes	No

17	Does the patient require MORE than the plan allowance of 30 tablets per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 30 tablets / 25 days or 90 tablets / 75 days.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 9	
2.	Go to 3	Go to 5	
3.	Go to 4	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
4.	Go to 17	Deny	Your plan only covers this drug if you are using it with treatment for airway problems due to obstructive sleep apnea. We have denied your request because you are not using it with treatment for airway problems due to obstructive sleep apnea. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Not on required concurrent therapy with PAP]

5.	Go to 6	Deny	Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Prescriber specialty]
6.	Go to 7	Deny	Your plan only covers this drug when you have a sleep test that shows obstructive sleep apnea (OSA). We denied your request because we did not receive your results, or your test result did not show obstructive sleep apnea (OSA). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Lab/test for OSA]
7.	Go to 8	Deny	Your plan only covers this drug if you have been using treatment for airway problems due to obstructive sleep apnea for at least one month. We have denied your request because you have not been using treatment for airway problems due to obstructive sleep apnea for one month. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Not on required concurrent therapy with PAP for 1 month]
8.	Go to 14	Deny	Your plan only covers this drug if you will be using it with treatment for airway problems due to obstructive sleep apnea. We have denied your request because you will not be using it with treatment

			for airway problems due to obstructive sleep apnea. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Not on required concurrent therapy with PAP]
9.	Go to 10	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are narcolepsy or obstructive sleep apnea (OSA). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
10.	Go to 11	Go to 12	
11.	Go to 17	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
12.	Go to 13	Deny	Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request

			other plan documents for your review. [Short Description: Prescriber specialty]
13.	Go to 14	Deny	Your plan only covers this drug when you have a sleep lab test that shows narcolepsy. We denied your request because we did not receive your results, or your test result did not show narcolepsy. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Lab/test for narcolepsy]
14.	Go to 17	Go to 15	
15.	Go to 17	Go to 16	
16.	Go to 17	Deny	Your plan only covers this drug if you have tried armodafinil or modafinil, and they did not work well for you. We have denied your request because: A) You have not tried armodafinil or modafinil, and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]
17.	Deny	[PA approved for 12 months. Approve 30 tablets / 25 days or 90 tablets / 75	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (30 tablets per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents

		days.]. Approve, 12 Months	for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]