Sunosi (solriamfetol) Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date
04-01-2024

Date of Origin
01-01-2020

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Sunosi® (solriamfetol) Tablet	Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA) Limitations of Use: 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.		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Excessive daytime sleepiness	Excessive daytime sleepiness (EDS) is characterized by persistent sleepiness regardless of how much sleep an individual gets at night. In between sleep attacks, individuals have normal levels of alertness, particularly if doing activities that keep their attention.(2) The most common causes of EDS include narcolepsy, obstructive sleep apnea, shift work disorder, sleep deprivation, medication effects, and other medical and psychiatric conditions.(5)
Narcolepsy	Narcolepsy is a chronic neurological disorder caused by the inability to regulate sleep-wake cycles. At various times throughout the day, patients with narcolepsy experience irresistible bouts of sleep and could fall asleep. If left undiagnosed or untreated, narcolepsy can interfere with psychological, social, and cognitive function and development and can inhibit academic, work, and social activities. Symptoms may include excessive daytime sleepiness, cataplexy, sleep paralysis, and hallucinations. All patients diagnosed with narcolepsy will have excessive daytime sleepiness. However, sleepiness in narcolepsy is more like a "sleep attack", where an overwhelming sense of sleepiness comes on quickly.(2) There is limited evidence to advise on treatment of special populations such as children, pregnant women, and breastfeeding mothers.(4) The American Family Physician recommends referral to a sleep clinic if narcolepsy is suspected.(3) The American Academy of Sleep Medicine (AASM) indicates treatment goals should be to alleviate daytime sleepiness and produce the fullest possible return of normal function for patients at work, school, home, and socially.(4)

	AASM 2021 guidelines combined the recommendations for narcolepsy with cataplexy and EDS associated with narcolepsy. The AASM recommend the following for the pharmacologic treatment with narcolepsy:(8)
	
	• Strong treatment recommendations:
	  ○ Modafinil
	  ○ Pitolisant
	  ○ Sodium oxybate
	  ○ Solriamfetol
	• Conditional treatment recommendations:
	  ○ Armodafinil
	  ○ Dextroamphetamine
	  ○ Methylphenidate
	• There was insufficient evidence to make recommendations for SSRI and SNRIs for the treatment of narcolepsy.(8)

Obstructive Sleep Apnea (OSA)	Obstructive sleep apnea (OSA) is a prevalent condition with serious health consequences, including EDS, cognitive disturbances, depression, hypertension, and cardiovascular and cerebrovascular disease.(7) Guidelines from the American College of Physicians (ACP) on management of OSA do not include modafinil/armodafinil in their recommendations for treatment. ACP guidelines state that pharmacologic therapy is not currently supported by evidence and should not be prescribed for OSA treatment.(7) AASM practice parameters recommend modafinil in patients with OSA for the treatment of residual excessive daytime sleepiness despite effective positive airway pressure treatment and who are lacking any other identifiable cause for their sleepiness.(7) Both guidelines recommend weight loss for obese and overweight patients and continuous positive airway pressure treatment as initial therapy.(6,7) A review on the treatment of OSA suggested pharmacologic agents play a minimal role in the treatment of breathing itself in patients with a sleep disorder. Modafinil and armodafinil are considered adjunctive therapies to improve wakefulness in these patients. These agents are recommended for patients who experience residual sleepiness despite optimal CPAP therapy, provided CPAP compliance is closely monitored. Modafinil or armodafinil do not treat the OSA itself but only the associated symptoms of sleepiness. The majority of patients (75%) with severe sleepiness at baseline still had mean multiple sleep latency times of less than 10 minutes despite the addition of modafinil to effective therapy with CPAP. This suggests that these drugs do not necessarily eliminate the risk of motor vehicle and other accidents in the OSA population. Concern also exists that the use of pharmacotherapy to treat excessive sleepiness associated with OSA may lead to subsequent reduction in CPAP compliance.(6)
Efficacy	**Excessive Daytime Sleepiness (EDS) in Patients with Narcolepsy** The efficacy of Sunosi in improving wakefulness and reducing excessive daytime sleepiness was demonstrated in a 12-week, multi-center, randomized, double-blind, placebo controlled, parallel-group study (Study 1; NCT02348593) in adult patients with a diagnosis of narcolepsy according to the ICSD-3 or DSM-5 criteria.(1) Wakefulness and sleepiness were assessed using the Maintenance of Wakefulness Test(MWT) and the Epworth Sleepiness Scale (ESS). Compared to the placebo group, patients randomized to 150 mg Sunosi showed statistically significant improvements on the MWT and on the ESS at Week 12.(1) **Excessive Daytime Sleepiness (EDS) in Patients with Obstructive Sleep Apnea (OSA)** The efficacy of Sunosi in improving wakefulness and reducing excessive daytime sleepiness in patients with OSA was demonstrated in a 12-week multi-

	center, randomized, double-blind, placebo-controlled study (Study 2; NCT02348606) in adults diagnosed with OSA according to ICSD 3 criteria.(1) Compared to the placebo group, patients randomized to 37.5 mg, 75 mg, and 150 mg Sunosi showed statistically significant improvements on the MWT and ESS. At Week 12, 37.5 mg, 75 mg, and 150 mg of Sunosi all demonstrated improvements in wakefulness compared to placebo as assessed in test sessions 1 (approximately 1 hour post-dose) through 5 (approximately 9 hours post-dose) of the MWT.(1)
Safety	Sunosi is contraindicated in patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOI), or within 14 days following discontinuation of MOAI, due to the risk of hypertensive reactions.(1)

REFERENCES

Number	Reference
1	Sunosi prescribing Information. Axsome Therapeutics, Inc. June 2023.
2	National Institute of Neurological Disorders and Stroke. Narcolepsy. NIH Publication No. 17-1637. Available at: https://www.ninds.nih.gov/health-information/disorders/narcolepsy. Last updated September 2023. Accessed October 2023.
3	Ramar, Kannan MD and Olson, Eric MD. Management of Common Sleep Disorders. Am Fam Physician. 2013 Aug 15; 88(4): 231-238.
4	Krahn, Lois MD, et al. Quality Measures for the Care of Patients with Narcolepsy. *Journal of Clinical Sleep Medicine*. 2015; Vol. 11(3).
5	Pagel J. Excessive daytime sleepiness. Am Fam Physician. 2009;79(5): 391-395.
6	Qaseem A, Holty J, Owens D, et al. Management of obstructive sleep apnea in adults: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2013;159:471–483.
7	Morgenthaler TI, Kapen S, Lee-Chiong T, Alessi C, Boehlecke B, Brown T, et al. Practice parameters for the medical therapy of obstructive sleep apnea. Sleep (2006) 29:1031–5.
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.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Sunosi	solriamfetol hcl tab	150 MG ; 75 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Sunosi	Solriamfetol HCl Tab 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS			
Sunosi	Solriamfetol HCl Tab 75 MG (Base Equiv)	75 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Sunosi	solriamfetol hcl tab	150 MG ; 75 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Sunosi	Solriamfetol HCl Tab 150 MG (Base Equiv)	150 MG	Medicaid
Sunosi	Solriamfetol HCl Tab 75 MG (Base Equiv)	75 MG	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   - A. The patient has a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND ALL of the following:
     1. The underlying airway obstruction has been treated (e.g., continuous positive airway pressure [CPAP]) for at least 1-month prior to initiating therapy with the requested agent **AND**
     2. The modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND**
     3. ONE of the following:
        - A. The patient's medication history armodafinil OR modafinil AND ONE of the following:
          1. The patient has had an inadequate response to armodafinil OR modafinil **OR**
          2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH armodafinil AND modafinil **OR**
        - B. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR**
        - C. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR**
        - D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
          1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
          2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
          3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        - E. The prescriber has provided documentation that BOTH armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
   - B. The patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND ONE of the following:
     1. The patient's medication history armodafinil OR modafinil AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has had an inadequate response to armodafinil OR modafinil **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH armodafinil AND modafinil **OR** 2. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** 3. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that BOTH armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with armodafinil OR modafinil for the requested indication **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the diagnosis is excessive daytime sleepiness associated with obstructive sleep apnea (OSA), the modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with armodafinil OR modafinil for the requested indication **AND** 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose (for the requested indication) **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** 12 months