PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**NARCOLEPSY AGENTS**
BRAND NAME*	
(generic)	
	SUNOSI
	(solriamfetol)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 2915-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

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
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has excessive daytime sleepiness associated with narcolepsy
  AND
  - The request is for continuation of therapy AND the patient experienced a decrease in daytime sleepiness with narcolepsy

  OR
  - The diagnosis has been confirmed by sleep lab evaluation

  AND
  - The patient has experienced an inadequate treatment response to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
    OR
  - The patient has experienced an intolerance to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)
    OR
  - The patient has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate)

  AND
  - The patient has experienced an inadequate treatment response to armodafinil OR modafinil
    OR
  - The patient has experienced an intolerance to armodafinil OR modafinil
    OR
  - The patient has a contraindication that would prohibit a trial of ALL of the following: A) armodafinil, B) modafinil

OR

- The patient has excessive daytime sleepiness associated with obstructive sleep apnea (OSA)
  AND

- The request is for continuation of therapy AND the patient has experienced a decrease in daytime sleepiness with obstructive sleep apnea (OSA)

OR

- The diagnosis has been confirmed by polysomnography
  AND
- The patient has been receiving treatment for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) for at least one month
  AND
- The patient has experienced an inadequate treatment response to armodafinil OR modafinil
  OR
- The patient has experienced an intolerance to armodafinil OR modafinil
  OR
- The patient has a contraindication that would prohibit a trial of ALL of the following: A) armodafinil, B) modafinil

Quantity Limits Apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Sunosi is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). 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.[1]

According to the American Academy of Sleep Medicine (AASM), successful treatment of hypersomnia of central origin requires an accurate diagnosis, individual tailoring of therapy to produce the fullest possible return of normal function, and regular follow-up to monitor response to treatment. The evaluation should include a thorough evaluation of other possible contributing causes of excessive daytime sleepiness. The International Classification of Sleep Disorders, Third Edition (ICSD-3) specifies necessary diagnostic tests and criteria for each disorder of central origin. For narcolepsy, a sleep lab evaluation consisting of an overnight polysomnography (PSG) and mean sleep latency tests (MSLT) is recommended to confirm the diagnosis. Many other conditions produce such sleepiness and can mimic or coexist with a hypersomnia of central origin.[4,5]

According to AASM guidelines, modafinil is effective for treatment of daytime sleepiness due to narcolepsy. One additional study of 196 subjects involved assessment of armodafinil (the longer half-life enantiomer of modafinil) for treatment of excessive sleepiness in patients with narcolepsy.[4] Subjects receiving armodafinil experienced significant improvement in sleepiness as measured by the Mean Wakefulness Test (MWT) mean sleep latency, and in the Clinical Global Impression of Change.[4] The guidelines also state that amphetamine, dextroamphetamine, and methylphenidate are effective for treatment of daytime sleepiness due to narcolepsy.[4] Therefore, patients with narcolepsy who have an inadequate treatment response, intolerance, or contraindication to a CNS stimulant and either modafinil or armodafinil will be considered for approval.

The presence or absence of obstructive sleep apnea (OSA) must be determined before initiating treatment. Diagnostic criteria for OSA are based on clinical signs and symptoms determined during a comprehensive sleep evaluation, which includes a sleep oriented history and physical examination, and findings defined by sleep testing.[6] Following the history and physical examination, patients can be stratified according to their OSA disease risk. Those patients deemed high risk should have the diagnosis confirmed and severity determined with objective testing such as polysomnography with respiratory monitoring.[5] OSA should be approached as a chronic disease requiring long-term, multidisciplinary management. The patient should be an active participant in the decision on treatment type and taught to contribute to the management of his or her own disease. Positive airway pressure (PAP) is the treatment of choice for mild, moderate, and severe OSA and should be offered as an option to all patients. Alternative therapies may be offered depending on the severity of the OSA and the patient's anatomy, risk factors, and preferences.[6] Oral appliances (OA) may improve upper

airway patency during sleep by enlarging the upper airway and/or by decreasing upper airway collapsibility (e.g., improving upper airway muscle tone). Although not as efficacious as PAP, OAs are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail CPAP or other measures.[6] Patients should be established on effective treatment of the underlying airway obstruction associated with OSA before considering pharmacologic therapy for excessive sleepiness associated with OSA.[6] Patients should be continued on their treatment for the underlying airway obstruction while using pharmacologic treatment for excessive sleepiness due to OSA.[1-3,6] Therefore, patients with OSA must be established on therapy to treat the underlying obstruction for approval of Sunosi.

Modafinil is recommended for the treatment of residual excessive daytime sleepiness in OSA patients who have sleepiness despite effective positive airway pressure (PAP) treatment and who are lacking any other identifiable cause for their sleepiness. Before using modafinil, other causes of residual sleepiness must be ruled out including: suboptimal objective adherence with PAP; ill-fitting PAP masks; insufficient sleep; poor sleep hygiene; other sleep disorders such as narcolepsy or restless legs syndrome/periodic limb movements of sleep; and depression. Modafinil should be used in addition to PAP therapy.[5] Armodafinil (the longer half-life enantiomer of modafinil) is also indicated for the treatment of excessive daytime sleepiness associated with obstructive sleep apnea.[2,3] Patients with OSA who have an inadequate treatment response, intolerance, or contraindication to modafinil or armodafinil will be considered for approval.

The AASM guidelines for narcolepsy state that the goal of therapy should be to produce the fullest possible return of normal function for patients.[4,7] The guidelines for management of OSA recommend that adjunctive treatment with modafinil should be evaluated to see if symptoms have resolved and that all patients should have ongoing, long-term management for their chronic disorder.[6] If a request is for the continuation of therapy with Sunosi, it should be determined that the patient has experienced a decrease in daytime sleepiness with narcolepsy or a decrease in daytime sleepiness with OSA.

The recommended starting dosage of Sunosi in patients with narcolepsy is 75 mg once daily. Based on efficacy and tolerability, the dosage may be doubled at intervals of at least 3 days to a maximum recommended dose of 150 mg once daily. For OSA, Sunosi should be initiated at 37.5 mg once daily and may be doubled based on efficacy and tolerability at intervals of at least 3 days to a maximum recommended dose of 150 mg daily. Doses above 150 mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions. Sunosi is available as 75 mg tablets that are scored and can be split in half, and as 150 mg tablets. Therefore, the approval will be limited to a maximum of 30 tablets per month.

REFERENCES

1. Sunosi [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed March 12, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed March 12, 2021.
4. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. *Sleep* 2007;30(12):1705-11.
5. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual*. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
6. Epstein LJ, Kristo D, Strollo PJ et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clinical Sleep Medicine 2009:5(3):263-276.
7. Krahn L, Hershner S et al. Quality Measures for the Care of Patients with Narcolepsy. *Journal of Clinical Sleep Medicine* 2015; 11(3):335-55.

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CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of excessive daytime sleepiness associated with narcolepsy? [If no, then skip to question 8.]	Yes	No
2	Is this a request for continuation of therapy with Sunosi (solriamfetol)? [If no, then skip to question 4.]	Yes	No
3	Has the patient experienced a decrease in daytime sleepiness with narcolepsy? [If yes, then skip to question 16.] [If no, then no further questions.]	Yes	No
4	Has the diagnosis been confirmed by sleep lab evaluation? [If no, then no further questions.]	Yes	No
5	Has the patient experienced an inadequate treatment response to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)? [If yes, then skip to question 13.]	Yes	No
6	Has the patient experienced an intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate)? [If yes, then skip to question 13.]	Yes	No
7	Does the patient have a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate)? [If yes, then skip to question 13.] [If no, then no further questions.]	Yes	No
8	Does the patient have a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA)? [If no, then no further questions.]	Yes	No
9	Is this a request for continuation of therapy with Sunosi (solriamfetol)? [If no, then skip to question 11.]	Yes	No
10	Has the patient experienced a decrease in daytime sleepiness with obstructive sleep apnea (OSA)? [If yes, then skip to question 16.] [If no, then no further questions.]	Yes	No
11	Has the diagnosis been confirmed by polysomnography? [If no, then no further questions.]	Yes	No
12	Has the patient been receiving treatment for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) for at least one month? [If no, then no further questions.]	Yes	No

13	Has the patient experienced an inadequate treatment response to armodafinil OR modafinil? [If yes, then skip to question 16.]	Yes	No
14	Has the patient experienced an intolerance to armodafinil OR modafinil? [If yes, then skip to question 16.]	Yes	No
15	Does the patient have a contraindication that would prohibit a trial of ALL of the following: A) armodafinil, B) modafinil? [If no, then no further questions.]	Yes	No
16	Does the patient require MORE than the plan allowance of 30 tablets per month? [RPh Note: If yes, then deny and enter a partial approval for 30 tablets/25 days or 90 tablets/75 days of Sunosi.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Go to 8	
2.	Go to 3	Go to 4	
3.	Go to 16	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using Sunosi and have a decrease in daytime sleepiness with narcolepsy. Your request has been denied based on the information we have. [Short Description: Continuation of therapy, No response to treatment]
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had a sleep lab test to confirm your diagnosis. Your request has been denied based on the information we have. [Short Description: No confirmation of diagnosis (tests, labs, etc.)]
5.	Go to 13	Go to 6	
6.	Go to 13	Go to 7	
7.	Go to 13	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) and it did not work for you, or you cannot use these drugs. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to a CNS stimulant drug]
8.	Go to 9	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet one of these conditions: - You have narcolepsy - You have obstructive sleep apnea Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
9.	Go to 10	Go to 11	

10.	Go to 16	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using Sunosi and have a decrease in daytime sleepiness with obstructive sleep apnea (OSA) Your request has been denied based on the information we have. [Short Description: Continuation of therapy, No response to treatment]
11.	Go to 12	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had a test to confirm your diagnosis. Your request has been denied based on the information we have. [Short Description: No confirmation of diagnosis (tests, labs, etc.)]
12.	Go to 13	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have been on treatment for airway problems due to obstructive sleep apnea for at least one month. Your request has been denied based on the information we have. [Short Description: No underlying treatment for OSA]
13.	Go to 16	Go to 14	
14.	Go to 16	Go to 15	
15.	Go to 16	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried armodafinil or modafinil and it did not work for you, or you cannot use these drugs. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to armodafinil or modafinil]
16.	Deny	Approve, 12 months, 30 tablets/25 days* or 90 tablets/75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 30 tablets/month of the requested drug and strength. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**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.*