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Sunosi (solriamfetol) Prior Authorization with Quantity Limit Program Summary

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent(s)	Indication(s)	Dosage
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.	**Narcolepsy:** **Initial dose:** 75 mg once in the morning **OSA:** **Initial dose:** 37.5 mg once in the morning **Max dose:** 150 mg once in the morning

CLINICAL RATIONALE

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 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]

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The American Academy of Sleep Medicine (AASM) 2021 guidelines combined the recommendations for narcolepsy with cataplexy and EDS associated with narcolepsy. The AASM recommend the following for the pharmacologic treatment of narcolepsy:

- Strong treatment recommendations:[8]
  - 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

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] The American Academy of Sleep Medicine (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]

Safety[1]

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.

References

1. Sunosi prescribing Information. Jazz Pharmaceuticals. June 2019.
2. National Institute of Neurological Disorders and Stroke. Narcolepsy Fact Sheet. NIH Publication No. 17-1637. Available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet. Last updated March 2020. Accessed August 2020.

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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.

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Sunosi (solriamfetol) Prior Authorization with Quantity Limit

TARGET AGENT(S)
Sunosi™ (solriamfetol)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Sunosi (solriamfetol)			
75 mg tablet	61370070200320	M, N, O, or Y	1 tablet
150 mg tablet	61370070200340	M, N, O, or Y	1 tablet

PRIOR AUTHORIZATION 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:
        i. 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
        ii. 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
        iii. ONE of the following:
            a. The patient has tried and had an inadequate response to armodafinil OR modafinil after an adequate trial of at least 1-month
            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

    B. The patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND ONE of the following:
        i. The patient has tried and had an inadequate response to armodafinil OR modafinil after an adequate trial of at least 1-month
        OR
        ii. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil
        OR
        iii. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil

AND

2. ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication
    OR
    B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication

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AND

3. The patient will NOT be using the requested agent in combination with armodafinil OR modafinil
   AND
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, 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
   AND
6. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit
      OR
   B. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose (for the requested indication)
         AND
      iii. 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: 3 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
   AND
5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, 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
   AND
7. ONE of the following:
   A. The requested quantity (dose) does NOT exceed the program quantity limit
      OR
   B. ALL of the following:

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i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose (for the requested indication)
AND
iii. 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

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