Effective Date: 5/2020
Reviewed: 2/2020, 2/2021, 2/2022, 4/2023, 3/2024, 4/2025
Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

SUNOSI (solriamfetol)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
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.

All other indications are considered experimental/investigational and are not a covered benefit.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by one of the following:
A. Sleep disorder specialist
B. Neurologist
C. Psychiatrist

III. CRITERIA FOR INITIAL APPROVAL

A. Narcolepsy
Authorization of 12 months may be granted for treatment of excessive daytime sleepiness associated with narcolepsy in patients who are 18 years of age and older when all of the following criteria are met:
1. The patient has narcolepsy confirmed by sleep lab evaluation

2. The patient has experienced an inadequate treatment response, intolerance, or contraindication to a central nervous system (CNS) stimulant drug (e.g., amphetamine/dextroamphetamine, methylphenidate)
3. The patient meets either of the following criteria:
   a. The patient experienced an inadequate treatment response to at least a one month trial of modafinil or armodafinil, unless intolerance experienced
   b. The patient has a contraindication to modafinil and armodafinil, with rationale provided

B. Obstructive sleep apnea (OSA)

Authorization of 12 months may be granted for treatment of excessive daytime sleepiness associated with OSA in patients who are 18 years of age and older when all of the following criteria are met:

1. The patient has OSA confirmed by polysomnography
2. The patient has been receiving treatment for the underlying airway obstruction [e.g., continuous positive airway pressure (CPAP)] for at least one month, and has documented evidence of residual sleepiness despite compliance
3. The patient meets either of the following criteria:
   a. The patient experienced an inadequate treatment response to at least a one-month trial of modafinil or armodafinil after CPAP, unless intolerance experienced
   b. The patient has a contraindication to modafinil and armodafinil, with rationale provided

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of Sunosi when the patient has experienced a decrease in daytime sleepiness (documentation provided to support treatment efficacy).

V. QUANTITY LIMIT

Sunosi 75 mg & 150mg has a quantity limit of 1 tablet per day.

VI. REFERENCES

1. Sunosi [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed April 2019.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed April 2019.
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. 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.