Original Effective Date: 08/15/2019
Current Effective Date: 06/28/2025
Last P&T Approval/Version: 04/30/2025
Next Review Due By: 04/2026
Policy Number: C17632-A

Sunosi (solriamfetol)

PRODUCTS AFFECTED

Sunosi (solriamfetol)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ALL INDICATIONS:
1. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Sunosi (solriamfetol) include: Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the

preceding 14 days, avoid use in patients with unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems]
AND

2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., symptoms of excessive daytime sleepiness, OR Epworth Sleepiness Scale (ESS), Clinical Global Impression of Change or Maintenance of Wakefulness Test (MWT))

B. EXCESSIVE DAYTIME SLEEPINESS WITH NARCOLEPSY:

1. Documented diagnosis of narcolepsy confirmed by polysomnography and multiple sleep latency test (MSLT) [DOCUMENTATION REQUIRED]
AND
2. Documented treatment failure, serious side effects, or FDA labeled contraindication to BOTH of the following for at least 90 days: (i) ONE formulary central nervous system (CNS) stimulant (e.g., methylphenidate, dexmethylphenidate, dextroamphetamine); AND (ii) ONE wakefulness promoting agent (i.e., modafinil, armodafinil)

C. EXCESSIVE DAYTIME SLEEPINESS WITH OBSTRUCTIVE SLEEP APNEA:

1. Documented diagnosis of obstructive sleep apnea (OSA)
AND
2. Documentation that the member's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) or similar for at least one month prior to initiation of Sunosi.
AND
3. Documentation that the member will continue to use this treatment modality (CPAP or similar) for the duration of therapy with Sunosi.
AND
4. Documented treatment failure, serious side effects, or FDA labeled contraindication to modafinil or armodafinil for at least 90 days

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Documentation of positive response as noted by prescriber's assessment (e.g., "normal" alertness during conventional waking hours or maximized alertness at important times of the day [during work, school, or while driving], decrease or reduction in symptoms of excessive daytime sleepiness, OR improvement in the Epworth Sleepiness Scale (ESS), Clinical Global Impression of Change or Maintenance of Wakefulness Test (MWT))
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., emergence or exacerbation of psychiatric symptoms, etc.)

DURATION OF APPROVAL:

Initial Authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a neurologist, sleep disorder specialist, psychiatrist, or pulmonologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:
Maximum dose 150 mg/day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Dopamine and norepinephrine reuptake inhibitor (DNRI)

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Sleep Studies
There are two sleep studies that are used to confirm a diagnosis of narcolepsy. The purpose of the polysomnogram (PSG) is to exclude alternative and coexisting causes of chronic daytime sleepiness. The purpose of the multiple sleep latency test (MSLT) is to measure the mean sleep latency and identify sleep onset rapid eye movement periods (SOREMPs).

Diagnosis of Narcolepsy Per the International Classification of Sleep Disorders Third Edition and the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (ICSD-3 and DSM-5) guidelines, narcolepsy type 1 (narcolepsy with cataplexy) is highly likely in a patient with symptoms of chronic daytime sleepiness and cataplexy since all patients with narcolepsy have chronic daytime sleepiness and cataplexy occurs in almost no other disorder. Narcolepsy type 2 (narcolepsy without cataplexy) is more difficult to diagnose because sleepiness can occur with a variety of sleep disorders, and hypnagogic hallucinations and sleep paralysis can occur with any condition that increases REM sleep pressure.

The diagnosis of narcolepsy type 1 (narcolepsy with cataplexy) requires both of the following: Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months One or both of the following:

Cataplexy and a mean sleep latency of ≤ 8 minutes and two or more sleep onset REM sleep periods (SOREMPs) on a multiple sleep latency test (MSLT).
ASOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT. - Cerebrospinal fluid (CSF) orexin-A concentration is low.

If there is clinical suspicion for narcolepsy type 2 in a patient with chronic daytime sleepiness, the diagnosis should be confirmed using the following guidelines:

An overnight polysomnogram followed the next day by an MSLT that demonstrates a mean sleep latency ≤ 8 minutes and at least two SOREMPs • The diagnosis of narcolepsy type 2 hinges upon the MSLT, yet the MSLT has several limitations and poor reproducibility in narcolepsy type 2 patients. Consequently, it is sometimes hard to be certain if a patient has narcolepsy type 2 or idiopathic hypersomnia. In the absence of a specific biomarker, clinical judgment is crucial: Does the patient have symptoms suggestive of REM sleep dysfunction (e.g., frequent sleep paralysis or hypnagogic hallucinations) indicative of narcolepsy, or nonrestorative, long sleep with troublesome morning sleep inertia indicative of idiopathic hypersomnia?

Diagnosis of Obstructive Sleep Apnea

In adults, the diagnosis of obstructive sleep apnea is confirmed if either of the following two conditions exists:

There are five or more predominantly obstructive respiratory events per hour of sleep (for polysomnography) or recording time (for home testing) in a patient with one or more of the following: - Sleepiness, nonrestorative sleep, fatigue, or insomnia symptoms - Waking up with breath holding, gasping, or choking - Habitual snoring, breathing interruptions, or both noted by a bed partner or other observer - Hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus

There are 15 or more predominantly obstructive respiratory events (apneas, hypopneas, or respiratory event related arousals) per hour of sleep (for polysomnography) or recording time (for home testing), regardless of the presence of associated symptoms or comorbidities.

Diagnosis can be confirmed by a home sleep apnea test (HSAT):

Patient has a respiratory event index (REI) ≥15 events per hour OR REI 5 to 14 and symptoms

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Sunosi is NOT indicated for the treatment of underlying airway obstruction in OSA and should not be used as a substitute for primary OSA therapy. The active ingredient in Sunosi (solriamfetol) has potential for abuse and is therefore a federally controlled substance.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Sunosi (solriamfetol) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Sunosi (solriamfetol) include: Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days. Avoid use in patients with unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems.

Exclusions/Discontinuation:

Sunosi increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion. Assess blood pressure and control hypertension before initiating treatment with Sunosi. Monitor blood pressure regularly during treatment and treat new-onset hypertension and exacerbations of pre-existing hypertension. Exercise caution when treating patients at higher risk of MACE, particularly patients with known cardiovascular and cerebrovascular disease, pre-existing hypertension, and patients with advanced age. Use caution with other drugs that increase blood pressure and heart rate. Periodically reassess the need for continued treatment with Sunosi. If a patient experiences increases in blood pressure or heart rate that cannot be managed with dose reduction of Sunosi or other appropriate medical intervention, consider discontinuation of Sunosi.

OTHER SPECIAL CONSIDERATIONS:
Sunosi (solriamfetol) is a Schedule IV controlled substance

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Sunosi TABS 75MG
Sunosi TABS 150MG

REFERENCES

1. Sunosi (solriamfetol) tablets, for oral use, CIV [prescribing information]. Palo Alto, CA; Jazz Pharmaceuticals. June 2023.
2. Morgenthaler TI; Kapur VK; Brown TM; Swick TJ; Alessi C; Aurora RN; Boehlecke B; Chesson AL; Friedman L; Maganti R; Owens J; Pancer J; Zak R; Standards of Practice Committee of the AASM. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. SLEEP 2007;30(12):1705-1711.
3. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. 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.
4. Bosco A, Lopez R, Barateau L, et al. Effect of psychostimulants on blood pressure profile and endothelial function in narcolepsy. Neurology 2018; 90:e479.
5. Thorpy MJ, Shapiro C, Mayer G, et al. A randomized study of solriamfetol for excessive sleepiness in narcolepsy. Ann Neurol 2019; 85:359.
6. Maski, K., Trotti, L. M., Kotagal, S., Robert Auger, R., Rowley, J. A., Hashmi, S. D., & Watson, N. F. (2021). Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine, 17(9), 1881–1893. https://doi.org/10.5664/jcsm.9328

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q2 2025

REVISION- Notable revisions: Required Medical Information Continuation of Therapy References	Q2 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q2 2023
REVISION- Notable revisions: Required Medical Information Prescriber Requirements	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file