Clinical Policy: Solriamfetol (Sunosi)

Reference Number: IL.ERX.NPA.121
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Solriamfetol (Sunosi™) is a wakefulness-promoting agent.

FDA Approved Indication(s)
Sunosi is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

Limitation(s) 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Sunosi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Narcolepsy (must meet all)**:**
1. Diagnosis of narcolepsy;
2. Prescribed by or in consultation with a neurologist or sleep medicine specialist;
3. Age ≥ 18 years;
4. Failure of a 1-month trial of one of the following generic central nervous system stimulant-containing agent at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: amphetamine, dextroamphetamine IR, or methylphenidate IR;
5. Dose does not exceed 150 mg (1 tablet) per day.

Approval duration: 12 months

B. Obstructive Sleep Apnea (must meet all)**:**
1. Diagnosis of OSA;
2. Age ≥ 18 years;
3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy for at least 1 month;
4. Dose does not exceed 150 mg (1 tablet) per day.

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 150 mg (1 tablet) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CPAP: continuous positive airway pressure
CNS: central nervous system
FDA: Food and Drug Administration
MAOI: monoamine oxidase inhibitor
OSA: obstructive sleep apnea

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
amphetamine/dextroamphetamine (Adderall®)	**Narcolepsy** 5 to 60 mg/day PO in divided doses	60 mg/day
amphetamine		
methylphenidate	**Narcolepsy** Dosing varies; 10-60 mg PO divided 2 to 3 times daily 30-45 min before meals	60 mg/day
dexmethylphenidate	**Narcolepsy** Dosing varies; 2.5 mg PO twice daily to 10 mg PO twice daily	20 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): concomitant treatment with MAOIs, or within 14 days following discontinuation of MAOI
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Narcolepsy	Initiate at 75 mg PO once a day; dose may be doubled at intervals of at least 3 days	150 mg/day
OSA	Initiate at 37.5 mg PO once a day; dose may be doubled at intervals of at least 3 days	150 mg/day

VI. Product Availability

Tablets: 75 mg, 150 mg

VII. References

1. Sunosi Prescribing Information. Palo Alto, CA: Jazz Pharma, Inc.; June 2019. Available at: www.sunosi.com. Accessed January 29, 2021
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed January 29, 2021
3. Morgenthaler TI, Kapur VK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin An American Academy of Sleep Medicine Report: An American Academy of Sleep Medicine Report. *Sleep*. 2007;30(12):1705-1711.
4. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009; 15;5(3):263-76.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.22.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.