

Clinical Policy: Solriamfetol (Sunosi)

Reference Number: CP.PMN.209

Effective Date: 05.07.19

Last Review Date: 05.22

Line of Business: Commercial, HIM, 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.

It is the policy of health plans affiliated with Centene Corporation[®] 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 $\geq$ 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 clinically significant adverse effects are experienced or all are contraindicated: amphetamine, dextroamphetamine, or methylphenidate;
**Prior authorization may be required for CNS stimulants*
5. Failure of a 1-month trial of armodafinil or modafinil at up to maximally indicated doses, unless clinically significant side effects are experienced or both are contraindicated;
**Prior authorization may be required for armodafinil and modafinil*
6. Dose does not exceed 150 mg (1 tablet) per day.

Approval duration:**Medicaid/HIM** – 12 months**Commercial** – 12 months or duration of request, whichever is less

B. Obstructive Sleep Apnea (must meet all):

1. Diagnosis of OSA;
2. Age $\geq$ 18 years;
3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy for at least 1 month;
4. Failure of a 1-month trial of armodafinil or modafinil at up to maximally indicated doses, unless clinically significant side effects are experienced or both are contraindicated;
**Prior authorization may be required for armodafinil and modafinil*
5. Dose does not exceed 150 mg (1 tablet) per day.

Approval duration:

Medicaid/HIM – 12 months

Commercial – 12 months or duration of request, whichever is less

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit 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:

Medicaid/HIM – 12 months

Commercial – 12 months or duration of request, whichever is less

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 for all relevant lines of business 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
dextroamphetamine (Dexedrine [®] , ProCentra [®] , Zenzedi [®])		
amphetamine (Evekeo [®])		
methylphenidate (Ritalin [®] LA or SR, Concerta [®] , Metadate [®] CD or ER, Methylin [®] ER, Daytrana [®])	Narcolepsy Dosing varies; 10-60 mg PO divided 2 to 3 times daily 30-45 min before meals	60 mg/day
armodafinil (Nuvigil [®])	Narcolepsy/OSA 150 mg PO once a day in the morning	250 mg/day
modafinil (Provigil [®])	Narcolepsy/OSA 200 mg PO once a day in the morning	400 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.; October 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211230s004lbl.pdf. Accessed February 1, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed February 1, 2022.
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.
5. Bassetti CL, Kallweit U, Vignatelli, et al. European guideline and expert statements on the management of narcolepsy in adults and children. *J Sleep Res*. 2021;00:e13387. DOI: 10.1111/jsr.13387.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.07.19	08.19
Finalized line of businesses on policy to include HIM per SDC and prior clinical guidance.	12.02.19	
2Q 2020 annual review: no significant changes; added Metadate ER as an option for redirection for narcolepsy; references reviewed and updated.	02.25.20	05.20
For narcolepsy indication added sleep medicine specialist as optional prescriber.	06.11.20	11.20
2Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	01.29.21	05.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	09.28.21	02.22
2Q 2022 annual review: no significant changes; references reviewed and updated.	01.31.22	05.22

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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