RXADVANCE
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Clinical Policy Title:	solriamfetol
Policy Number:	RxA.472
Drug(s) Applied:	Sunosi™
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Solriamfetol (Sunosi™) is a wakefulness promoting agent. It 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™. It is not a substitute for these modalities.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
solriamfetol (Sunosi™)	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

Dosage Forms

- Tablets: 75 mg, 150 mg

Clinical Policy

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

I. Initial Approval Criteria

A. Narcolepsy (must meet all)**:**

1. Diagnosis of narcolepsy;

2. Prescribed by or in consultation with a sleep disorder specialist (including pulmonologist) or neurologist;
3. Age ≥ 18 years;
4. Failure of a 1-month trial of one of the following central nervous system stimulants at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: amphetamine immediate-release (IR), amphetamine, dextroamphetamine IR, dextroamphetamine, or methylphenidate IR;
   *Prior authorization may be required for CNS stimulants
5. Failure of a 1-month trial of armodafinil (Nuvigil®) or modafinil (Provigil®) at up to maximally indicated doses, unless clinically significant side effects are experienced;
   *Prior authorization may be required for armodafinil/modafinil
6. Dose does not exceed 150 mg per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

B. Obstructive Sleep Apnea (must meet all)**:**
1. Diagnosis of OSA;
2. Prescribed by or in consultation with a sleep disorder specialist (including pulmonologist) or neurologist;
3. Age ≥ 18 years;
4. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy for at least 1 month;
5. Failure of a 1-month trial of armodafinil (Nuvigil®) or modafinil (Provigil®) at up to maximally indicated doses, unless clinically significant side effects are experienced;
   *Prior authorization may be required for armodafinil/modafinil
6. Dose does not exceed 150 mg per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 150 mg per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CPAP: continuous positive airway pressure
FDA: Food and Drug Administration
MAOI: monoamine oxidase inhibitor
OSA: obstructive sleep apnea

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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 (ProCentra®, Zenzedi®)		
amphetamine) Evekeo®		
methylphenidate (Ritalin® (LA, SR), Concerta®, Daytrana®)	Narcolepsy Dosing varies; 10-60 mg PO divided 2 to 3 times daily 30-45 minutes 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):
  - Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days.
- Boxed warning(s):
  - None reported

APPENDIX D: General Information

- None

References

1. Sunosi™ Prescribing Information. Palo Alto, CA: Jazz Pharma, Inc.; June 2019. Available at: www.sunosi.com. Accessed August 14, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 14, 2020.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 14, 2020.
4. 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. Accessed August 14, 2020.
5. Thorpy MJ, Dauvilliers Y. Clinical and practical considerations in the pharmacologic management of

narcolepsy. Sleep Medicine. 2014;16(1):9:18. doi:10.1016/j.sleep.2014.10.002. Accessed August 14, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Line of Business Policy Applies to was updated to "All lines of business". 3. Initial approval criteria: updated the specialist requirement in Obstructive Sleep Apnea and Narcolepsy Initial approval criteria. 4. Commercial approval duration was updated for initial and Continued approval criteria. 5. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 6. Appendix B language updated to ''Below are suggested therapeutic alternatives….''. 7. Dexedrine, Metadate CD/ER and Methylin ER were removed from Appendix B as they are discontinued. 8. Appendix D was added. 9. Reference was reviewed and updated.	12/03/2020	12/07/2020