Clinical Policy: Solriamfetol (Sunosi)
Reference Number: CP.PMN.209
Effective Date: 05.07.19
Last Review Date: 08.19
Line of Business: Commercial, HIM, Medicaid

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;
      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:
Medicaid/HIM – 12 months
Commercial – Length of Benefit
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. 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
   5. Dose does not exceed 150 mg per day.

   Approval duration:
   Medicaid/HIM – 12 months
   Commercial – Length of Benefit

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.PHAR.21 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 per day.

      Approval duration:
      Medicaid/HIM – 12 months
      Commercial – Length of Benefit

   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.PHAR.21 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.PHAR.21 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
- 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>amphetamine/ dextroamphetamine (Adderall®)</td>
<td>Narcolepsy 5 to 60 mg/day PO in divided doses</td>
<td>60 mg/day</td>
</tr>
<tr>
<td>dextroamphetamine (Dexedrine®, ProCentra®, Zenzedi®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evekeo® (amphetamine)</td>
<td></td>
<td></td>
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<tr>
<td>methylphenidate (Ritalin® (LA, SR), Concerta®, Metadate® (CD, ER), Methylin® (ER), Daytrana®)</td>
<td>Narcolepsy Dosing varies; 10-60 mg PO divided 2 to 3 times daily 30-45 min before meals</td>
<td>60 mg/day</td>
</tr>
<tr>
<td>armodafinil (Nuvigil®)</td>
<td>Narcolepsy/OSA 150 mg PO once a day in the morning</td>
<td>250 mg/day</td>
</tr>
<tr>
<td>modafinil (Provigil®)</td>
<td>Narcolepsy/OSA 200 mg PO once a day in the morning</td>
<td>400 mg/day</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narcolepsy</td>
<td>Initiate at 75 mg PO once a day; dose may be doubled at intervals of at least 3 days</td>
<td>150 mg/day</td>
</tr>
<tr>
<td>OSA</td>
<td>Initiate at 37.5 mg PO once a day; dose may be doubled at intervals of at least 3 days</td>
<td>150 mg/day</td>
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</tbody>
</table>

VI. Product Availability

Tablets: 75 mg, 150 mg
VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>05.07.19</td>
<td>08.19</td>
</tr>
<tr>
<td>Finalized line of businesses on policy to include HIM per SDC and prior</td>
<td>12.02.19</td>
<td></td>
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<tr>
<td>clinical guidance.</td>
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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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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