SUNOSI®
(solriamfetol) ℞
75, 150 mg tablets

How-To Guide:
Letter of Medical Necessity for SUNOSI

For patients with excessive daytime sleepiness (EDS) associated with obstructive sleep apnea (OSA).

This How-to-guide will support you in navigating how to properly develop a letter of medical necessity to be submitted with a Prior Authorization (PA) request on behalf of your patient.

- General guidance for developing a letter of medical necessity
- Instructions for completing the letter of medical necessity template
- Sample letter

Indication and Important Safety Information for SUNOSI®

INDICATIONS:

SUNOSI is indicated to improve wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).

Limitations of Use:

SUNOSI is not indicated to treat the underlying 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. SUNOSI is not a substitute for these modalities, and the treatment of the underlying airway obstruction should be continued.

CONTRAINDICATIONS

SUNOSI is contraindicated in patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of an MAOI, because of the risk of hypertensive reaction.

Please see next page for additional Important Safety Information and accompanying full Prescribing Information or click here for full PI.

General Guidance to Developing a Letter of Medical Necessity

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An effective letter is tailored to your patient's needs

Be clear about your patient's individual circumstances. The following are key considerations when writing a Letter of Medical Necessity

Background on your patient's condition

- Summarize their clinical status by citing diagnostic evidence of EDS due to OSA
- If appropriate, list their current and prior treatments and provide reasons why it is not sufficient, including any side effects, lack of response, or disease progression

Why SUNOSI is the appropriate treatment choice for your patient

- Provide clinical justification supporting SUNOSI treatment for your patient and cite any relevant literature
- State any patient-specific reasons for the treatment choice, such as expected effect of treatment
- Review the health plan's criteria and point out the specific criteria that your patient meets. Explain why your patient should be excluded from any criteria that they do not meet

Providing additional documentation that supports your decision may strengthen your request

Be sure to review the health plan's requirements to ensure that the requested information is incorporated. Additional documentation may include

- Patient clinical notes, including relevant medical records and treatment history
- Clinical studies or peer-reviewed journal articles documenting the medical effectiveness of SUNOSI
- SUNOSI full **Prescribing Information**

Indication and Important Safety Information for SUNOSI® (*continued*)

WARNINGS AND PRECAUTIONS

Blood Pressure and Heart Rate Increases: SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion. Epidemiological data show that chronic elevations in blood pressure increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular death. The magnitude of the increase in absolute risk is dependent on the increase in blood pressure and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension, diabetes, hyperlipidemia, and high body mass index (BMI). 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. Patients with moderate or severe renal impairment could be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

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Instructions for Completing the Letter of Medical Necessity Template

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Once you have identified the need for a letter of medical necessity, please follow the steps below using the *EDS in OSA Letter of Medical Necessity Template* and the Sample Letter of Medical Necessity on page 4 of this guide.

STEP 1

Populate the template as medically appropriate

STEP 2

Delete any pre-populated specific instructions for completion, disclaimers, trademarks, and document numbers

STEP 3

Submit the letter of medical necessity with the appropriate form for the PA request and any supplemental documents as appropriate

For independent consideration and review, please make all changes that you believe to be appropriate or disregard these suggestions in their entirety. The medical professional is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. Please see the FDA-approved label for information relevant to any prescribing decisions.

Indication and Important Safety Information for SUNOSI® (*continued*)

WARNINGS AND PRECAUTIONS (*continued*)

Psychiatric Symptoms: Psychiatric adverse reactions have been observed in clinical trials with SUNOSI, including anxiety, insomnia, and irritability. Exercise caution when treating patients with SUNOSI who have a history of psychosis or bipolar disorders, as SUNOSI has not been evaluated in these patients. Patients with moderate or severe renal impairment may be at a higher risk of psychiatric symptoms because of the prolonged half-life of SUNOSI. Observe SUNOSI patients for the possible emergence or exacerbation of psychiatric symptoms. Consider dose reduction or discontinuation of SUNOSI if psychiatric symptoms develop.

Please see next page for additional Important Safety Information and accompanying full Prescribing Information or click here for full PI.

Template Letter of Medical Necessity for Excessive Daytime Sleepiness in Obstructive Sleep Apnea

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Fields required for customization are in brackets

axsome

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Template Letter of Medical Necessity for Excessive Daytime Sleepiness in Obstructive Sleep Apnea

On physician/provider letterhead

Please place template on official letter head, if applicable

Ensure Health Plan information is correct. This can be found on the PA request form or the health plan's website.

[Medical Director]
[Insurance Company]
[Address]
[City, State, ZIP]

RE: [Patient Name]
[Policy ID Number]
[Policy Group]
[Patient Date of Birth]

Fill out patient information completely and accurately. Ensure the policy ID number matches what is on the patient's insurance card.

Dear Dr. [Last Name]

I am writing this letter to appeal the prior authorization denial for my patient, [insert patient name]. The US Food and Drug Administration (FDA) has approved SUNOSI to improve wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).*

Limitations of use: SUNOSI is not indicated to treat the underlying airway obstruction in OSA. The manufacturer recommends ensuring that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating SUNOSI. SUNOSI is not a substitute for these modalities and the treatment of the underlying airway obstruction should be continued.*

Treatment of [insert patient name] with SUNOSI is medically appropriate and necessary. This letter, specifically related to EDS associated with OSA, outlines our treatment rationale along with the patient's medical history and prognosis.

If available, include most recent Epworth Sleepiness Score showing inadequate response on current or prior use of specific WPAs.

Include CPAP/BIPAP history and compliance rates

Include ANY failures of specific wakefulness promoting agents (WPA) such as modafinil or armodafinil along with any reasoning for **not** prescribing certain medications

1) Medical History and Prognosis

- [Patient's diagnosis, condition, and history]
- [Previous therapies for the symptoms associated with the patient's condition and the patient's response to these therapies]
- [Brief description of the patient's recent symptoms and conditions]

2) Rationale for Treatment

- [Summary of why, based on your clinical judgment, your patient requires treatment with SUNOSI]

Include patient's positive clinical experience using SUNOSI samples and duration of use, if applicable. Capture an Epworth Sleepiness Score while on SUNOSI showing improvements compared to other agents. Note that the need for medication could also include impact on quality of life, and potential safety concerns (operating vehicle, work safety, etc), if applicable.

Please call my office at [insert telephone number] if I can provide you with any additional information. I look forward to receiving your timely response and approval.

Sincerely,

Include your office or clinic's contact information, including a phone number, fax number, and email

[Insert health care provider name and participating provider number]

Please update the list of attachments to only include documents being sent with the request

[Include as appropriate] **Enclosures:** Prior authorization (PA) denial letter, PA form, office notes, documentation of prior medication history, diagnostic test results, clinical peer-reviewed literature, SUNOSI package insert.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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Please see the next page for additional Important Safety Information and click here to read the full Prescribing Information.

Please be sure to remove Important Safety Information related to SUNOSI and branding on pages 1 and 2

*SUNOSI (solriamfetol) [prescribing information]. New York, NY: Axsome Therapeutics, Inc.

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Template Letter of Medical Necessity for Excessive Daytime Sleepiness in Obstructive Sleep Apnea

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axsome

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IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS

Blood Pressure and Heart Rate Increases: SUNOSI increases systolic blood pressure, diastolic blood pressure, and heart rate in a dose-dependent fashion.

Epidemiological data show that chronic elevations in blood pressure increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular death. The magnitude of the increase in absolute risk is dependent on the increase in blood pressure and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension, diabetes, hyperlipidemia, and high body mass index (BMI).

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.

Please be sure to remove Important Safety Information related to SUNOSI and branding on pages 1 and 2

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.

Patients with moderate or severe renal impairment could be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of SUNOSI.

Psychiatric Symptoms: Psychiatric adverse reactions have been observed in clinical trials with SUNOSI, including anxiety, insomnia, and irritability.

Exercise caution when treating patients with SUNOSI who have a history of psychosis or bipolar disorders, as SUNOSI has not been evaluated in these patients.

Patients with moderate or severe renal impairment may be at a higher risk of psychiatric symptoms because of the prolonged half-life of SUNOSI.

Observe SUNOSI patients for the possible emergence or exacerbation of psychiatric symptoms. Consider dose reduction or discontinuation of SUNOSI if psychiatric symptoms develop.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5%) reported more frequently with the use of SUNOSI than placebo in either narcolepsy or OSA were headache, nausea, decreased appetite, anxiety, and insomnia.

Please click here to read the full Prescribing Information.

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Please see next page for additional Important Safety Information and accompanying full Prescribing Information or click here for full PI.

Indication and Important Safety Information for SUNOSI® (*continued*)

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5%) reported more frequently with the use of SUNOSI than placebo in either narcolepsy or OSA were headache, nausea, decreased appetite, anxiety, and insomnia.

Dose-Dependent Adverse Reactions: In the 12-week placebo-controlled clinical trials that compared doses of 37.5 mg, 75 mg, and 150 mg/day of SUNOSI to placebo, the following adverse reactions were dose-related: headache, nausea, decreased appetite, anxiety, diarrhea, and dry mouth.

DRUG INTERACTIONS

Do not administer SUNOSI concomitantly with MAOIs or within 14 days after discontinuing MAOI treatment. Concomitant use of MAOIs and noradrenergic drugs may increase the risk of a hypertensive reaction. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

Concomitant use of SUNOSI with other drugs that increase blood pressure and/or heart rate has not been evaluated, and combinations should be used with caution.

Dopaminergic drugs that increase levels of dopamine or that bind directly to dopamine receptors might result in pharmacodynamic interactions with SUNOSI. Interactions with dopaminergic drugs have not been evaluated with SUNOSI. Use caution when concomitantly administering dopaminergic drugs with SUNOSI.

USE IN SPECIFIC POPULATIONS

Renal Impairment: Dosage adjustment is not required for patients with mild renal impairment (eGFR 60–89 mL/min/1.73 m^2). Dosage adjustment is recommended for patients with moderate to severe renal impairment (eGFR 15–59 mL/min/1.73 m^2). SUNOSI is not recommended for patients with end stage renal disease (eGFR <15 mL/min/1.73 m^2).

ABUSE

SUNOSI contains solriamfetol, a Schedule IV controlled substance. Carefully evaluate patients for a recent history of drug abuse, especially those with a history of stimulant or alcohol abuse, and follow such patients closely, observing them for signs of misuse or abuse of SUNOSI (e.g., drug-seeking behavior).

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Please see accompanying full Prescribing Information or click here for full PI.