axsome

SUNOSI (solriamfetol) IV
75, 150 mg tablets

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

On physician/provider letterhead

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

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

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.

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]**

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,

[Insert health care provider name and participating provider number]

[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

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 the next page for additional Important Safety Information and accompanying full Prescribing Information.

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

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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.

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 see accompanying full Prescribing Information.

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