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# 5.60.036

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	October 1, 2024
<b>Subsection:</b>	Central Nervous System Drugs	<b>Original Policy Date:</b>	April 12, 2019
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**Last Review Date:** September 6, 2024

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## Sunosi

### Description

#### Sunosi (solriamfetol)

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#### Background

Sunosi (solriamfetol) is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) used to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi's efficacy is thought to be mediated through its activity as a dopamine and norepinephrine reuptake inhibitor (1).

#### Regulatory Status

FDA-approved indication: Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) that is indicated to improve wakefulness in patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA) (1).

Limitations of use: Sunosi is not indicated to treat underlying airway obstruction in OSA. Underlying airway obstruction must be treated (i.e., with continuous positive airway pressure (CPAP)) for at least one month before initiation of Sunosi for excessive daytime sleepiness. Sunosi is an adjunct treatment for underlying airway obstruction and should not be used in substitution to current treatment (1).

Sunosi increases systolic blood pressure, diastolic blood pressure and heart rate in a dose-dependent manner. Chronic elevations in blood pressure increase the risk of major cardiovascular events including stroke, heart attack, and cardiovascular death. Patients with narcolepsy and OSA have multiple risk factors for major cardiovascular events including hypertension, diabetes, hyperlipidemia and high body mass index (BMI). Blood pressure should

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be monitored regularly during treatment. New-onset hypertension and exacerbations of previously existing hypertension should be treated. Sunosi should be used cautiously with other drugs that can increase blood pressure and heart rate (1).

Psychiatric adverse reactions including anxiety, irritability and insomnia may occur with Sunosi treatment. However, Sunosi has not been evaluated in bipolar disorders or in patients with psychosis, so caution should be exercised with use in this population. Dose reduction or discontinuation of Sunosi should be considered if exacerbations of psychiatric symptoms occur (1).

Sunosi should not be administered with monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuation of MAOI because of the risk of hypertensive reaction (1).

Physicians should evaluate patients carefully for a recent history of drug abuse, stimulant, or alcohol abuse. Physicians should follow such patients closely to observe for signs of misuse and abuse (1).

Sunosi is not recommended for use in patients with end stage renal disease (ESRD) (1).

The safety and effectiveness of Sunosi in pediatric patients less than 18 years of age have not been established (1).

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## Related Policies

Provigil-Nuvigil, Wakix

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Sunosi may be considered **medically necessary** if the conditions indicated below are met.

Sunosi may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

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## Diagnoses

Patient must have **ONE** of the following:

1. Excessive daytime sleepiness due to narcolepsy
  - a. Inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
    - i. Provigil (modafinil) or Nuvigil (armodafinil)
    - ii. Stimulant, such as amphetamine, methylphenidate, or dexmethylphenidate
2. Excessive daytime sleepiness due to obstructive sleep apnea (OSA)
  - a. Compliant with other standard OSA treatments (such as CPAP and oral appliances) for at least one month prior to initiating Sunosi
  - b. Treatment for underlying airway obstruction will be continued during treatment with Sunosi

**AND ALL** of the following for **ALL** indications:

- a. **NO** concomitant use of a MAOI (monoamine oxidase inhibitor) (must be >14 days post discontinuing therapy)
- b. Prescriber agrees to monitor patient's blood pressure and heart rate
- c. **NO** end stage renal disease (ESRD)

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## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

## Diagnoses

Patient must have **ONE** of the following:

1. Excessive daytime sleepiness due to narcolepsy
2. Excessive daytime sleepiness due to obstructive sleep apnea (OSA)
  - a. Compliant with other standard OSA treatments (such as CPAP and oral appliances)
  - b. Treatment for underlying airway obstruction will be continued during treatment with Sunosi

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**AND ALL** of the following for **ALL** indications:

- NO** concomitant use of a MAOI (monoamine oxidase inhibitor) (must be >14 days post discontinuing therapy)
- Prescriber agrees to monitor patient's blood pressure and heart rate
- NO** end stage renal disease (ESRD)

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Quantity** 90 tablets per 90 days

**Duration** 12 months

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### Prior – Approval *Renewal* Limits

Same as above

## Rationale

### Summary

Sunosi (solriamfetol) is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) used to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi's efficacy is thought to be mediated through its activity as a dopamine and norepinephrine reuptake inhibitor. The safety and effectiveness of Sunosi in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sunosi while maintaining optimal therapeutic outcomes.

### References

- Sunosi [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2023.

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## Policy History

Date	Action
April 2019	Addition to PA
June 2019	Annual review
July 2019	Addition of requirement of trial of Provigil, Nuvigil, or stimulant to narcolepsy diagnosis
September 2019	Annual review and reference update. Removed no dual therapy with Provigil or Nuvigil requirement. Addition of requirement of no ESRD per SME
December 2019	Annual review
December 2020	Annual review and reference update
March 2021	Annual review
March 2022	Annual review and reference update
September 2023	Annual review and reference update. Changed policy number to 5.60.036
December 2023	Annual review
September 2024	Annual review

## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.**