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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	April 12, 2019
Subject:	Sunosi	**Page:**	1 of 5

Last Review Date: March 12, 2021

Sunosi

Description

Sunosi (solriamfetol)

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

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).

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** in patients 18 years of age and older for the treatment of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea and if the conditions indicated below are met.

Sunosi may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

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)

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

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)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 tablets per 90 days

Duration 12 months

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

1. Sunosi [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2020.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.