Sunosi™ (solriamfetol)

FDA INDICATIONS AND USAGE[1]

Sunosi™ is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi™ is not indicated for the treatment of underlying airway obstruction. Sunosi™ has the potential for abuse and is listed as a controlled substance (Schedule IV).

APPROVAL CRITERIA[1,2]

1. Patient is 18 years of age or older **AND;**
2. Patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy or excessive daytime sleepiness associated with obstructive sleep apnea (OSA) **AND**;
3. Is being prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist **AND**;
4. If the patient has underlying airway obstruction it must be treated with a continuous positive airway pressure (CPAP) or similar device for a minimum of 90 days and for the duration of treatment with Sunosi™ **AND;**
5. The patient has tried and failed armodafinil or modafinil for a period of at least 30 days or has an allergy to both agents **AND;**
6. The patient's blood pressure is well controlled.

DENIAL CRITERIA

1. Patient is not 18 years of age or older **OR**;
2. Patient does not have a diagnosis of excessive daytime sleepiness associated with narcolepsy or excessive daytime sleepiness associated with obstructive sleep apnea (OSA) **OR**;
3. Is not being prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist **OR**;
4. The patient has not tried and failed armodafinil or modafinil for a period of at least 30 days or does not have an allergy to both agents **OR**;
5. The patient's blood pressure is not well controlled.

CAUTIONS[1]

- Sunosi™ is contraindicated when used with in 14 days of monoamine oxidase inhibitors.
- Patients should be monitored for an increased heart rate and blood pressure prior to and throughout therapy. Use should be avoided in patients with serious heart problems.

- Doses may need to be reduced or discontinued for patients with a history of psychosis or bipolar disorder if psychiatric symptoms arise.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 30 - 75mg tablets per month
- 30 – 150mg tablets per month

REFERENCES / FOOTNOTES:

1. Sunosi™ (solriamfetol) [package insert]. Palo Alto, CA. Jazz Pharmaceuticals, Inc.; June 2019. Available at: https://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf Accessed July 8, 2019
2. Scammell, T (June 2019) Treatment of narcolepsy in adults. In April F Eichler (Ed.), *UpToDate*. Retrieved July 8, 2019 from https://www.uptodate.com/contents/treatment-of-narcolepsy-in-adults#H3891976135