

## PHARMACY COVERAGE GUIDELINE

### SUNOSI™ (solriamfetol) oral tablet WAKIX® (pitolisant) oral tablet Generic Equivalent (if available)

#### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

#### **Scope**

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

#### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).

## Medical Necessity Requirements for SUNOSI (solriamfetol)

### Criteria for Initial Therapy:

#### **Prescriber Qualifications**

- Prescribed by a physician specializing in sleep or in consultation with a Pulmonologist or Sleep Medicine Physician

#### **Indication**

- Excessive Daytime Sleepiness (EDS) associated with Narcolepsy
- Excessive Daytime Sleepiness (EDS) associated with Obstructive Sleep Apnea (OSA)

ORIGINAL EFFECTIVE DATE: 04/18/2010 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/19/2026

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#### Age Requirement

- 18 years or older

#### Baseline Clinical Evaluation

- Diagnosis confirmed by clinical symptoms and polysomnography
- Obstructive Sleep Apnea is treated with continuous or bi level positive airway pressure, which is continued throughout therapy
- Epworth Sleep Scale score of 10 or more
- Blood pressure is within normal limits or managed with appropriate medical treatment
- Estimated glomerular filtration rate is greater than 15 mL/min/1.73m<sup>2</sup>

#### Alternative Therapies

- For Narcolepsy: Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **BOTH** of the following options:
  - A trial of modafinil or armodafinil
  - A trial of amphetamine or methylphenidate
- For Obstructive Sleep Apnea: Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for modafinil or armodafinil

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- No end stage renal impairment (estimated glomerular filtration rate less than 15 mL/min/1.73m<sup>2</sup>)
- No unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems
- No concomitant use with: armodafinil, modafinil, pitolisant, oxybate salts
- No concurrent treatment with monoamine oxidase inhibitors or use within the preceding 14 days

#### Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (e.g., Epworth Sleep Scale score, estimated glomerular filtration rate, blood pressure)
  - Supporting clinical documentation

#### Initial Therapy Criteria Approval Duration

- 6 months **OR** end of plan year

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### Criteria for Continuation of Therapy (renewal therapy):

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**Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.**

#### Prescriber Qualification

- Continues to be seen by a physician specializing in sleep or in consultation with a Pulmonologist or Sleep Medicine Physician

#### Clinical Response

- Improvement in **ONE** of the following:
  - No evidence of disease progression
  - Significant improvement or stabilization in clinical signs and symptoms
  - Narcolepsy: Reduced daily periods of uncontrollable need to sleep or daytime lapsing into sleep
  - Obstructive Sleep Apnea: Reduction in apneas, hypopneas, respiratory effort related arousals, and reduced daytime sleepiness

#### Adherence

- Adherence to the prescribed therapy regimen has been documented
- For OSA only: Continuous use of CPAP or BiPAP

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- No end stage renal impairment (estimated glomerular filtration rate less than 15 mL/min/1.73m<sup>2</sup>)
- No unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems
- No new contraindications or significant adverse effects such as:
  - Emergence or worsening of psychiatric symptoms
  - Blood pressure or heart rate cannot be managed with dose reduction or medical intervention
- No concomitant use with: armodafinil, modafinil, pitolisant, oxybate salts

#### Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

#### Continuation Therapy Criteria Approval Duration

- 12 months **OR** end of plan year

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## Medical Necessity Requirements for WAKIX (pitolisant)

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### Criteria for Initial Therapy:

#### Prescriber Qualifications

- Prescribed by a physician specializing in sleep or in consultation with a Pulmonologist or Sleep Medicine Physician

#### Indication

- Excessive Daytime Sleepiness (EDS) or Cataplexy associated with Narcolepsy

#### Age Requirement

- 18 years or older with EDS or Cataplexy with Narcolepsy
- 6 years or older with EDS with Narcolepsy

#### Baseline Clinical Evaluation

- Diagnosis confirmed by clinical symptoms and polysomnography
- Epworth Sleep Scale score of 10 or more
- Estimated glomerular filtration rate is greater than 15 mL/min/1.73m<sup>2</sup>
- No history of cardiac arrhythmias, torsade de pointes, symptomatic bradycardia, hypokalemia, hypomagnesemia, or congenital QT prolongation

#### Alternative Therapies

- Excessive Daytime Sleepiness
  - Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for:
    1. **ONE** trial of the following: modafinil or armodafinil
    2. **ONE** trial of the following: amphetamine or methylphenidate
    3. A trial of Sunosi (solriamfetol)
- Cataplexy
  - Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for a trial of **TWO** of the following rapid eye movement (REM) sleep suppressing drugs:
    1. Venlafaxine
    2. Duloxetine
    3. Fluoxetine
    4. Protriptyline
    5. Clomipramine

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#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Ant failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- No end stage renal impairment (estimated glomerular filtration rate less than 15 mL/min/1.73m<sup>2</sup>)
- No unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems
- No severe hepatic impairment (Child Pugh Class C)
- No concomitant use with: armodafinil, modafinil, solriamfetol, oxybate salts
- No significant drug interactions with:
  - First generation antihistamines (e.g., diphenhydramine, promethazine)
  - QT prolonging drugs (e.g., amiodarone, sotalol, levofloxacin, amitriptyline)

#### Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (e.g., Epworth Sleep Scale score, estimated glomerular filtration rate, cardiac history)
  - Supporting clinical documentation

#### Initial Therapy Criteria Approval Duration

- 12 months **OR** end of plan year
- 

### Criteria for Continuation of Therapy (renewal therapy):

**Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.**

#### Prescriber Qualification

- Continues to be seen by a physician specializing in or in consultation with a Pulmonologist or Sleep Medicine Physician

#### Clinical Response

- Improvement in **ONE** of the following:
  - No evidence of disease progression
  - Significant improvement or stabilization in clinical signs and symptoms
  - Narcolepsy with EDS: Reduced daily periods of uncontrollable need to sleep
  - Narcolepsy with Cataplexy: Reduced episodes of sudden bilateral loss of muscle tone with maintained consciousness

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#### Adherence

- Adherence to the prescribed therapy regimen has been documented

#### Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

#### Safety

- No end stage renal impairment (estimated glomerular filtration rate less than 15 mL/min/1.73m<sup>2</sup>)
- No concomitant use with: armodafinil, modafinil, solriamfetol, oxybate salts
- No new contraindications or significant adverse effects such as:
  - QT interval prolongation
  - Torsade de pointes
- No significant drug interactions with:
  - First generation antihistamines
  - QT prolonging drugs

#### Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

#### Continuation Therapy Criteria Approval Duration

- 12 months **OR** end of plan year
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### Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
  2. Off-Label Use of Cancer Medications
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#### Description:

Sunosi (solriamfetol) is indicated to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or OSA. Sunosi (solriamfetol) is not indicated to treat the underlying airway obstruction in OSA. The underlying airway obstruction should be treated (e.g., with continuous positive airway

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pressure (CPAP)) for at least one month prior to initiating Sunosi (solriamfetol) for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi (solriamfetol). Sunosi (solriamfetol) is not a substitute for these modalities.

Wakix (pitolisant) is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy and for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy.

The American Academy of Sleep Medicine has subdivided narcolepsy into two types: narcolepsy type 1 and narcolepsy type 2. In both EDS is an essential feature, with cataplexy a core feature in narcolepsy type 1. Both types require laboratory tests to confirm the diagnosis. Laboratory testing includes sleep laboratory testing with overnight polysomnography (PSG) followed by a multiple sleep latency test (MSLT) and may also include cerebrospinal fluid (CSF) assessment of hypocretin-1 levels.

Narcolepsy is a chronic neurologic disorder of the central nervous system characterized by the brain's inability to control sleep-wake cycles, resulting in EDS and intermittent bouts of rapid eye movement (REM) sleep during wakefulness. At various times throughout the day, individuals with narcolepsy experience irresistible and sudden bouts of sleep, which can last from a few seconds to several minutes. In addition to EDS, other major symptoms of narcolepsy include cataplexy (an emotionally triggered transient sudden loss of voluntary muscle tone), hypnagogic hallucinations (vivid dream-like images often frightening tactile, or auditory hallucinations during sleep onset or upon waking), and sleep paralysis (brief episodes of total paralysis, also during sleep onset or upon waking). Most individuals experience poor sleep quality that can involve frequent awakenings during nighttime sleep, and other sleep disorders. Sleep may be disrupted by insomnia, vivid dreaming, sleep talking, acting out while dreaming, and periodic leg movements. Patients with sleepiness severe enough to require medication can be treated with stimulant medications, such as armodafinil, modafinil, methylphenidate, or amphetamines.

OSA is the most common type of sleep apnea and is characterized by repeated episodes of complete or partial obstructions of the upper airway during sleep, despite the effort to breathe, and is usually associated with a reduction in blood oxygen saturation. In the OSA, the episodes of decreased breathing are called "hypopnea" (defined as a  $\geq 30\%$  drop in flow for 10 seconds or longer, associated with  $\geq 3\%$  oxygen desaturation). The episodes of breathing cessations are called "apneas" (literally, "without breath") and are defined, as a  $\geq 90\%$  drop in flow for 10 seconds or longer and associated with  $\geq 3\%$  oxygen desaturation, or an arousal. The number of events per hour are measured and reported as an apnea hypopnea index (AHI).

Moderate to severe OSA, is defined as a respiratory disturbance index [RDI] greater than 15 events per hour. Like the AHI, the RDI reports on respiratory events during sleep, but unlike the AHI, it also includes respiratory-effort related arousals (RERAs). RERAs are arousals from sleep that do not technically meet the definitions of apneas or hypopneas, but do disrupt sleep. They are abrupt transitions from a deeper stage of sleep to a shallower. A RERA is characterized by increasing respiratory effort (and thus decreasing esophageal pressures) for 10 seconds or more leading to an arousal from sleep, but one that does not fulfill the criteria for a hypopnea or apnea.

CPAP is the treatment of choice for a patient with OSA. A maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Sunosi (solriamfetol). Encouragement of and periodic assessment of CPAP compliance is strongly recommended. Certain medications with inhibitory effects on the central nervous system should be avoided if reasonable alternatives exist. Medications that may exacerbate OSA

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and worsen daytime sleepiness include benzodiazepine receptor agonists, barbiturates, other antiepileptic drugs, sedating antidepressants, antihistamines, and opiates. When such medications are felt to be necessary, their use in a patient with OSA should be monitored closely and the dose carefully titrated if possible.

In OSA, Nuvigil (armodafinil), generic armodafinil, or Sunosi (solriamfetol) are indicated as an adjunct to standard treatment(s) for the underlying obstruction. If CPAP is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Nuvigil (armodafinil), generic armodafinil, or Sunosi (solriamfetol). If Nuvigil (armodafinil), generic armodafinil, or Sunosi (solriamfetol) are used adjunctively with CPAP, the encouragement of and periodic assessment of CPAP compliance is strongly recommended. Certain medications with inhibitory effects on the central nervous system should be avoided if reasonable alternatives exist. Medications that may exacerbate OSA and worsen daytime sleepiness include benzodiazepine receptor agonists, barbiturates, other antiepileptic drugs, sedating antidepressants, antihistamines, and opiates. When such medications are felt to be necessary, their use in a patient with OSA should be monitored closely and the dose carefully titrated if possible.

The mechanism of action of solriamfetol is unclear, but its efficacy may be related to its activity as a dopamine and norepinephrine reuptake inhibitor (DNRI). Solriamfetol is a derivative of phenylalanine.

The mechanism of action of pitolisant in EDS in adult patients with narcolepsy is unclear. However, its efficacy could be mediated through its activity as an antagonist/inverse agonist at histamine-3 (H3) receptors. An inverse agonist is a drug that binds to the same receptor as an agonist but induces a pharmacological response opposite to that of the agonist. Pitolisant binds to the H3 receptor with high affinity and has no appreciable binding to other histamine (H1, H2, or H4) receptors.

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### **Definitions:**

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

### **Excessive daytime sleepiness (EDS):**

It is defined as persistent drowsiness and difficulty staying awake during the day. It can manifest as dozing off at inappropriate times or waking up feeling unrefreshed after a night's sleep. According to the International Classification of Sleep Disorders, EDS is characterized by the inability to maintain wakefulness and alertness during the major waking episodes of the day, occurring almost daily for at least three months. Additionally, EDS is often associated with a general lack of energy, even after adequate nighttime sleep.

### **Narcolepsy:**

A disorder of sleep-wake control in which elements of sleep intrude into wakefulness and elements of wakefulness intrude into sleep. The result is the classic tetrad of chronic daytime sleepiness with varying amounts of cataplexy, hypnagogic hallucinations, and sleep paralysis. All patients have sleepiness, but only one-third of patients will have all of these symptoms

### **Cataplexy:**

Sudden loss of muscle tone triggered by strong emotions (fear, surprise, joking or laughing); this is transient (less than 2 minutes); symptoms may involve the entire body, or only the knees, neck, or face

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#### **Epworth Sleepiness Scale (ESS):**

- The ESS subjectively measures sleepiness as it occurs in ordinary life situations
- Can be used to screen for excessive sleepiness or to follow a subjective response to an intervention
- The ESS can be performed in the examination room or waiting room
- It is relatively simple and generally takes only a few minutes to complete
- It should be repeated at subsequent visits to assess for change
- A questionnaire describes eight situations:
  - Sitting and reading
  - Watching television
  - Sitting inactively in a public place
  - Riding as a passenger in a car for one hour without a break
  - Lying down to rest in the afternoon when circumstances permit
  - Sitting and talking with someone
  - Sitting quietly after lunch without alcohol
  - Sitting in a car as the driver, while stopped for a few minutes in traffic
- Each situation receives a score of 0-3, which relates to the likelihood that sleep will be induced:
  - 0 = would never doze
  - 1 = slight chance of dozing
  - 2 = moderate chance of dozing
  - 3 = high chance of dozing
- The total ESS score ranges from 0-24, with higher scores correlating with increasing degrees of sleepiness
  - A score > 10 is consistent with excessive sleepiness

#### **Maintenance of Wakefulness Test (MWT):**

- MWT is the ability to stay awake
- It objectively measures the ability of an individual to remain awake for a defined period of time
- It is based on the premise that individuals with a greater degree of sleepiness are less likely to remain awake than individuals with less sleepiness
- MWT may be used to assess an individual's response to therapy
- It is the direction of change, not the degree of change, that is meaningful
- During the MWT:
  - Sit in a recumbent position
  - Instructed to sit still and try to remain awake for as long as possible
  - Look directly ahead and do not look directly at the light
  - Avoid extraordinary measures to stay awake (e.g., slapping the face, singing)
  - A session is ended after unequivocal sleep, or after 40 minutes if sleep does not occur
  - Sleep is considered unequivocal after three consecutive periods of stage 1 sleep or one period of any other stage of sleep
  - For each session, the sleep latency is recorded
  - It is documented as being 40 minutes if the patient does not fall asleep
  - This is repeated every two hours, until the patient has completed four sessions
- The primary measure from the MWT is the mean sleep latency
- Healthy individuals who complete four 40-minute protocol sessions, the mean sleep latency is approximately 30 minutes, with > 97% of individuals having a mean sleep latency of  $\geq$  8 minutes

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- A mean sleep latency of < 8 minutes is generally considered abnormal
- Staying awake for at least 40 minutes during all four sessions is strong objective evidence that an individual can stay awake
- A mean sleep latency between 8 and 40 minutes has uncertain significance

#### **Multiple sleep latency test (MSLT):**

- MSLT is the tendency to fall asleep
- It tests for excessive daytime sleepiness (EDS) by measuring how quickly one falls asleep in a quiet environment during the day
  - EDS occurs when you are sleepy when you should be awake and alert
- MSLT is the standard tool used to diagnose narcolepsy and idiopathic hypersomnia
- MSLT is a full-day test that consists of five scheduled naps separated by two-hour breaks
- During the MSLT
  - Lying flat in bed for the MSLT
  - Instructed to lie quietly, assume a comfortable position, keep eyes closed, and try to fall asleep
  - The test will measure how long it takes for to fall asleep
  - You will be awakened after sleeping 15 minutes
  - If you do not fall asleep within 20 minutes, the nap trial will end

#### **Residual excessive sleepiness (RES) in patients with obstructive sleep apnea (OSA):**

Subjective complaint of excessive daytime sleepiness (EDS) that is present even when breathing and oxygenation parameters during sleep are normalized by successful use of OSA therapy. EDS is defined as the inability to maintain wakefulness and alertness during the major waking episodes of the day, with sleep occurring unintentionally or at inappropriate times.

#### **Oxygen Desaturation:**

- Reductions in blood oxygen levels (desaturation) are recorded during polysomnography or limited channel monitoring
- At sea level, a normal blood oxygen level (saturation) is usually 96-97%
- Although there are no generally accepted classifications for severity of oxygen desaturation, reductions to not less than 90% usually are considered mild
  - Dips into the 80-89% range can be considered moderate, and those below 80% are severe

#### **Apnea Hypopnea Index (AHI):**

- The AHI is the number of apneas or hypopneas events per hour of sleep (i.e., apneas + hypopneas/total sleep time in hours)
- It is a measure sleep apnea severity; the apnea must last for at least 10 seconds and be associated with a decrease in blood oxygenation
- Based on the AHI, the severity of OSA is classified as follows:
  - None/Minimal: AHI < 5 per hour
  - Mild: AHI ≥ 5, but < 15 per hour
  - Moderate: AHI ≥ 15, but < 30 per hour
  - Severe: AHI ≥ 30 per hour

#### **Respiratory Disturbance (or distress) Index (RDI):**

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- Like the AHI, it reports on respiratory events during sleep, but unlike the AHI, it also includes respiratory-effort related arousals (RERAs) (i.e., (apneas + hypopneas + RERAs/total sleep time in hours)
- RERAs are arousals from sleep that do not technically meet the definitions of apneas or hypopneas but do disrupt sleep. They are abrupt transitions from a deeper stage of sleep to a shallower stage
  - A RERA is characterized by increasing respiratory effort (and thus decreasing esophageal pressures) for 10 seconds or more leading to an arousal from sleep, but one that does not fulfill the criteria for a hypopnea or apnea
- Respiratory Event Index (REI) = apneas + hypopneas/total recording time

Diagnosis obstructive sleep apnea		
Sleep testing device	Index	Diagnostic criteria for OSA
Polysomnography*	Apnea Hypopnea Index (AHI)	AHI 5-14/hour sleep <b>PLUS</b> one or more sleep-associated conditions¶ <b>or</b> AHI ≥15/hour sleep
	Respiratory Disturbance Index (RDI)	RDI 5-14/hour sleep <b>PLUS</b> one or more sleep associated conditions¶ <b>or</b> RDI ≥15/hour sleep
Home sleep apnea device	Respiratory Event Index (REI)	REI ≥15/hour total recording time
<p>* Most polysomnography studies will report AHI, RDI, or both values</p> <p>¶ Sleep-associated conditions include the following:</p> <ul style="list-style-type: none"> <li>• Sleepiness, nonrestorative sleep, fatigue, or insomnia symptoms</li> <li>• Waking up with breath holding, gasping, or choking</li> <li>• Habitual snoring, breathing interruptions, or both noted by a bed partner or other observer</li> <li>• Hypertension, mood disorder, cognitive dysfunction, CAD, stroke, CHF, atrial fibrillation, or type 2 DM</li> </ul>		

### Resources:

Sunosi (solriamfetol) product information, revised by manufacturer Axsome Therapeutics, Inc 06-2023. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed October 26, 2025.

Wakix (pitolisant) product information, revised by manufacturer Harmony Biosciences, LLC 06-2025. Available. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed October 27, 2025..

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Scammell TE. Treatment of narcolepsy in adults. In: UpToDate, Benca R, Eichler AF (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through September 2025. Topic last updated June 25, 2025. Accessed October 27, 2025.

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### **SUNOSI™ (solriamfetol) oral tablet** **WAKIX® (pitolisant) oral tablet** **Generic Equivalent (if available)**

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