Effective Date **11/15/2023**
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Coverage Policy Number **IP0102**

Solriamfetol

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for solriamfetol tablets (**Sunosi®**).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Solriamfetol (Sunosi) is considered medically necessary when ONE of the following is met:

1. **Treatment of Excessive Daytime Sleepiness Associated with Narcolepsy (Type 1 or 2).** Individual meets **ALL** of the following criteria:
    A. Age 18 years or older
    B. Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months

C. Documentation of **ONE** of the following:
    i. Diagnosis of **narcolepsy type 1** and **ONE** of the following:
        a. Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness
        b. A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG
    ii. Diagnosis of **narcolepsy type 2** and Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness.
    A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG may replace one of the SOREMPs on the MSLT
D. The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal
E. Documentation of failure, contraindication, or intolerance to **ONE** of the following:
    i. modafinil OR armodafinil
    ii. dextroamphetamine, dexmethylphenidate OR methylphenidate
F. Medication is prescribed by, or in consultation with, a neurologist, pulmonologist or sleep specialist

2. **Treatment of Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea.** Individual meets **ALL** of the following criteria:
    A. Age 18 years or older
    B. Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months
    C. Documentation of diagnosis of Obstructive Sleep Apnea (OSA) is confirmed by sleep study
    D. The hypersomnolence and/or sleep study findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal
    E. Documentation of inadequate response to at least 1 month of non-pharmacologic treatment for OSA (for example, continuous positive airway pressure [CPAP])
    F. Sunosi will be used in combination with non-pharmacologic treatment for obstructive sleep apnea (OSA), unless contraindicated or intolerant
    G. Documentation of failure, contraindication, or intolerance to **ONE** of the following:
        i. armodafinil
        ii. modafinil
    H. Medication is prescribed by, or in consultation with, a neurologist, pulmonologist or sleep specialist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of solriamfetol (Sunosi) is considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Sunosi, a dopamine and norepinephrine reuptake inhibitor, is indicated to improve wakefulness in adults with **excessive daytime sleepiness** associated with the following conditions:[1]

- **Narcolepsy**.
- **Obstructive sleep apnea** (OSA).
  Limitations of Use: Sunosi is not indicated to treat the underlying airway obstruction in OSA.[1] The underlying airway obstruction should be treated (e.g., with continuous positive airway pressure [CPAP]) for at least 1 month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is a Schedule IV controlled substance.

Armodafinil and modafinil are wakefulness-promoting agents with actions similar to sympathomimetic agents (e.g., amphetamine and methylphenidate). They are indicated to improve wakefulness in adults with excessive sleepiness associated with narcolepsy, OSA, or shift work disorder.[2,3] Armodafinil and modafinil are Schedule IV controlled substances. Stimulant medications (e.g., amphetamine, methamphetamine, dextroamphetamine, and methylphenidate) are used off-label for the treatment of daytime sleepiness due to narcolepsy and OSA and are mentioned in guidelines.[4-7]

Two specialized tests, which can be performed in a sleep disorders clinic, are required to establish a diagnosis of narcolepsy.[8] Polysomnogram (PSG) is an overnight recording of brain and muscle activity, breathing, and eye movements. The multiple sleep latency test assesses daytime sleepiness by measuring how quickly a person falls asleep and whether they enter rapid eye movement (REM) sleep. On the day after PSG, the patient is asked to take five short naps separated by two hours over the course of a day. If an individual falls asleep in < 8 minutes on average over the five naps, this indicates excessive daytime sleepiness. However, patients with narcolepsy also have an abnormally quick start to REM sleep. If REM sleep happens within 15 minutes at least two times out of the five naps and the sleep study the night before, this is likely an abnormality caused by narcolepsy.

Guidelines
Narcolepsy and Cataplexy
The American Academy of Sleep Medicine (AASM) practice parameters for the treatment of central disorders of hypersomnolence were updated in 2021.[4,5]

- Modafinil, Wakix® (pitolisant tablet), Xyrem® (sodium oxybate oral solution), and Sunosi are recommended as effective treatments for daytime sleepiness due to narcolepsy and reducing disease severity in adults (Strong Recommendation for each).
- Wakix and Xyrem have also demonstrated efficacy for the treatment of cataplexy in patients with narcolepsy (Strong Recommendation for each).
- Xyrem and armodafinil have Conditional Recommendations for the treatment of narcolepsy, showing efficacy for daytime sleepiness due to narcolepsy and reducing disease severity.
- Dextroamphetamine has a Conditional Recommendation for the treatment of narcolepsy, showing efficacy for excessive daytime sleepiness and cataplexy.
- Methylphenidate has a Conditional Recommendation for the treatment of narcolepsy, showing efficacy in reducing disease severity.
- There was insufficient and inconclusive evidence to make recommendations for l-carnitine, scheduled naps, selegiline, triazolam, selective serotonin reuptake inhibitors (SSRIs), and serotonin-norepinephrine reuptake inhibitors (SNRIs).
- Modafinil and Xyrem have Conditional Recommendations for the treatment of narcolepsy in pediatric patients.

- A Strong Recommendation should be followed by clinicians under most circumstances. A Conditional Recommendation requires that the clinician use clinical knowledge and experience and strongly consider the individual patient's values and preferences to determine the best course of action.

Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea/Hypoapnea Syndrome

- According to the AASM guideline on medical therapy for OSA (2006), CPAP is the most uniformly effective therapy, and, to date, this is the only intervention for OSA shown to have favorable impacts on both cardiovascular and neurobehavioral morbidities.[6,7]
- Modafinil, in patients compliant with nasal CPAP, consistently improved subjective and objective sleepiness, quality of life, and vigilance compared with placebo. Sunosi is not addressed in these guidelines.

References

1. Sunosi® tablets [prescribing information]. Palo Alto, CA: Jazz; October 2021.
2. Provigil® tablets [prescribing information]. North Wales, PA: Cephalon; January 2015.
3. Nuvigil® tablets [prescribing information]. North Wales, PA: Cephalon; February 2017.
4. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(9):1881–1893.
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8. National Institutes of Health. Narcolepsy Fact Sheet. National Institute of Neurological Disorders and Stroke. Date last modified: July 25, 2022. Available at: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Narcolepsy-Fact-Sheet. Accessed on September 6, 2022.
9. Mayo Clinic. Obstructive sleep apnea. Available at: https://www.mayoclinic.org/diseases-conditions/obstructive-sleep-apnea/symptoms-causes/syc-20352090?p=1. Accessed on September 6, 2022.
10. Xyrem® oral solution [prescribing information]. Palo Alto, CA: Jazz; March 2022.
11. Xywav® oral solution [prescribing information]. Palo Alto, CA: Jazz; March 2022.
12. Wakix® tablets [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences; October 2020.

Supplemental References

13. American Academy of Sleep Medicine. International Classification of Sleep Disorders, 3rd ed, text revision, American Academy of Sleep Medicine, 2023.