Sunosi™ (solriamfetol)

Policy # 00695
Original Effective Date: 12/11/2019
Current Effective Date: 01/11/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Sunosi™‡ (solriamfetol) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility will be considered for Sunosi (solriamfetol) when the following patient selection criteria are met:

I. Patient has ONE of the following (a or b):
   a) Patient has diagnosis of excessive daytime sleepiness associated with narcolepsy; AND
      1) Patient has tried and failed at least TWO generic alternatives for the treatment of excessive daytime sleepiness associated with narcolepsy unless there is clinical evidence or patient history that suggests the use of the alternative options will be ineffective or cause an adverse reaction to the patient. Generic alternatives include modafinil, armodafinil, amphetamine, methamphetamine, dextroamphetamine, and methylphenidate; OR
      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
   b) Patient has excessive sleepiness due to obstructive sleep apnea (OSA) AND ALL of the following (1, 2, 3, AND 4):

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1) Patient has been adherent to primary OSA therapy (e.g., positive airway pressure treatment, intraoral device, or had previous surgical intervention) for at least one month prior to initiating Sunosi; AND
2) Patient will continue using primary OSA therapy while being treated with Sunosi; AND
3) Alternative causes of excessive daytime sleepiness were excluded or have been addressed (e.g., insufficient sleep, depression, medication side effects, and comorbid medical and psychiatric disorders); AND
   *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
4) Patient has tried and failed at least TWO generic alternatives for the treatment of excessive daytime sleepiness associated with OSA unless there is clinical evidence or patient history that suggests the use of the alternative options will be ineffective or cause an adverse reaction to the patient. Generic alternatives include modafinil and armodafinil.
   *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Sunosi (solriamfetol) for OSA when alternative causes of excessive daytime sleepiness have not been addressed and for both OSA and narcolepsy when the patient has not tried and failed at least TWO generic alternatives to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Sunosi (solriamfetol) when patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational.***

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Background/Overview

Sunosi is a dopamine and norepinephrine reuptake inhibitor indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). It is important to note that the drug does not impact the underlying airway obstruction in OSA, so patients with OSA should be treated with a primary therapy that is effective in treating the underlying airway obstruction for at least one month prior to initiating Sunosi and continued throughout treatment with Sunosi. Examples of these primary therapies include the various types of positive airway pressure (e.g., continuous positive airway pressure [CPAP], bilevel positive airway pressure [BIPAP], auto-adjusting continuous positive airway pressure [APAP]), intraoral devices, and surgical intervention. For patients with narcolepsy, the recommended dose range of Sunosi is 75 mg to 150 mg once daily. For patients with OSA, the recommended dose range of Sunosi is 37.5 mg to 150 mg once daily based on efficacy and tolerability. Sunosi is classified as a schedule IV controlled substance. Additionally, it is contraindicated in combination with (or within 14 days of administration of) monoamine oxidase inhibitors such as selegiline or rasagiline.

Narcolepsy

Narcolepsy is a rare, chronic neurologic disorder that affects the brain's ability to control sleep-wake cycles. Affected individuals typically feel rested after waking, but then feel very sleepy throughout much of the day. The most typical symptoms are excessive daytime sleepiness, cataplexy, sleep paralysis, and hallucinations. If left undiagnosed or untreated, narcolepsy can interfere with psychological, social, and cognitive function and development and can inhibit academic, work, and social activities.

Treatment of narcolepsy includes lifestyle modifications and medications. Lifestyle modifications are a necessary part of treatment and include taking short, regularly scheduled naps, maintaining a regular sleep schedule, avoiding caffeine and alcohol several hours before bedtime, and exercising regularly. Medications used to treat narcolepsy include stimulants such as modafinil and amphetamines for the treatment of daytime sleepiness and Xyrem for the treatment of cataplexy, daytime sleepiness, and disrupted sleep. Tricyclic antidepressants, selective serotonin reuptake inhibitors, and venlafaxine may be effective for the treatment of cataplexy and selegiline may be effective for the treatment of cataplexy and daytime sleepiness. Clinical practice guidelines have not been updated to include Sunosi. However, Sunosi is thought to have a similar mechanism of action as other stimulant therapies such as armodafinil and modafinil.

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Obstructive Sleep Apnea (OSA)
OSA is a potentially serious sleep disorder in which the patient's breathing repeatedly starts and stops during sleep. This leads to an impairment in the ability to reach the desired deep, restful phases of sleep, resulting in sleepiness during the waking hours. Signs and symptoms of OSA include excessive daytime sleepiness, loud snoring, observed episodes of breathing cessation during sleep, abrupt awakenings accompanied by gasping or choking, awakening with a dry mouth or sore throat, morning headache, difficulty concentrating during the day, and mood changes.

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure (PAP) therapy (e.g., fixed CPAP, BiPAP, or APAP) during sleep. All guidelines recommend the use of PAP as initial therapy in addition to behavioral modifications. In patients with mild to moderate OSA who prefer not to use PAP or who do not respond to it, oral appliances are an alternative therapy that have been shown to improve signs and symptoms of OSA. Upper airway surgery may also be used in patients with severe, surgically correctible, obstructing lesions of the upper airway. Despite optimal treatment however, some individuals may experience residual sleepiness despite marked improvements in the apnea-hypopnea index. Therefore, stimulant medications may be used in addition to primary therapy for these patients. Although the most current clinical guideline by the American Academy of Sleep Medicine (AASM) was published prior to the availability of any widely effective pharmacotherapy for sleep apnea, it does mention that stimulant therapy can lead to a small, but statistically significant improvement in objective sleepiness. Currently, the only stimulant agents besides Sunosi that have been studied in patients with OSA are modafinil and armodafinil.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Sunosi is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

Rationale/Source

The efficacy of Sunosi in improving wakefulness in patients with narcolepsy was demonstrated in a 12-week, multi-center, randomized, double-blind, placebo-controlled, parallel group study in adult patients with a diagnosis of narcolepsy. In this study, wakefulness and sleepiness were assessed using the Maintenance of Wakefulness Test (MWT) and the Epworth Sleepiness Scale (ESS). The

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MWT measures an individual's ability to remain awake during the daytime in a darkened, quiet environment. Patients were instructed to remain awake for as long as possible during 40-minute test sessions, and sleep latency was determined as the mean number of minutes patients could remain awake in the first four test sessions. The ESS is an 8-item questionnaire by which patients rate their perceived likelihood of falling asleep during usual daily life activities. In this study, change from baseline in MWT and ESS at week 12 were co-primary efficacy endpoints.

A total of 239 patients with narcolepsy were randomized to receive Sunosi 75 mg, 150 mg, 300 mg, or placebo once daily. Patients randomized to the 150-mg dose received 75 mg for the first 3 days before increasing to 150 mg. Compared to the placebo group, patients randomized to 150 mg Sunosi showed statistically significant improvements on the MWT (treatment difference: 7.7 minutes) and on the ESS (treatment effect difference: 3.8 points) at week 12. These effects were apparent at week 1 and consistent with the results at week 12.

The efficacy of Sunosi in improving wakefulness in patients with OSA was demonstrated in a 12-week, multi-center, randomized, double-blind, placebo-controlled study in adults diagnosed with OSA. The co-primary efficacy endpoints were change from baseline in MWT and ESS at week 12.

A total of 476 patients with OSA were randomized to receive Sunosi 37.5 mg, 75 mg, 150 mg, 300 mg, or placebo once daily. Patients randomized to the 150-mg dose received 75 mg for the first 3 days before increasing to 150 mg. Compared to the placebo group, patients randomized to 37.5 mg, 75 mg, and 150 mg Sunosi showed statistically significant improvements on the MWT (treatment effect difference: 4.5 minutes, 8.9 minutes, and 10.7 minutes, respectively) and ESS (treatment effect difference: 1.9 points, 1.7 points, and 4.5 points, respectively) at week 12. These effects were apparent at week 1 and consistent with the results at week 12.

References

1. Sunosi [package insert]. Jazz Pharmaceuticals. Palo Alto, CA. Updated October 2019.
2. Sunosi Drug Evaluation. Express Scripts. Updated May 2019.
3. Management of obstructive sleep apnea in adults. UpToDate. Updated October 2019.

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12/05/2019 Medical Policy Committee review
12/11/2019 Medical Policy Implementation Committee approval. New policy
12/03/2020 Medical Policy Committee review
12/09/2020 Medical Policy Implementation Committee approval. Minor edit to criteria for narcolepsy to clarify that the indication is for excessive daytime sleepiness associated with narcolepsy.
Next Scheduled Review Date: 12/2021

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.