Sunosi (solriamfetol)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Solriamfetol (Sunosi), a dopamine and norepinephrine reuptake inhibitor (DNRI), received FDA approval in 2019 for its efficacy in promoting wakefulness. This drug caters to adults with excessive daytime sleepiness (EDS) resulting from conditions like narcolepsy or obstructive sleep apnea (OSA).

Narcolepsy is a sleep disorder defined by an excessive propensity for sleep, with some individuals experiencing sudden and uncontrollable muscle weakness (cataplexy). Management of narcolepsy typically involves both non-pharmacological interventions (such as good sleep hygiene and psychosocial support) and medications.

On the other hand, OSA involves recurrent start-stop breathing cycles during sleep due to obstruction in the upper airway. Risk factors for OSA encompass old age, male gender, and obesity. Non-pharmacologic treatments for OSA include weight loss, use of continuous positive airway pressure

(CPAP), oral appliances (like mandibular advancement devices), and surgery. In addition, pharmacological strategies, which focus on amplifying respiratory drive and reducing airway collapsibility, are also considered. Due to interrupted sleep at night, patients with OSA often suffer from excessive daytime sleepiness, which is addressed through wakefulness-promoting agents such as modafinil, armodafinil, and Sunosi.

Although the exact mechanism by which solriamfetol enhances wakefulness remains unclear, it is suggested that this drug inhibits the reuptake of stimulatory neurotransmitters dopamine and norepinephrine, thus boosting their synaptic levels and postsynaptic receptor stimulation. Solriamfetol does not impact serotonin reuptake.

Approval for solriamfetol was based on various clinical studies, including two 12-week double-blind efficacy trials conducted on narcolepsy and OSA patients, and two withdrawal trials (one six-week double-blind trial for OSA patients and a 52-week open-label trial for patients with either condition). However, no clinical trials have been conducted comparing solriamfetol to older, less expensive drugs for this indication.

Definitions

"**Actigraphy**" refers to a non-invasive method of monitoring human rest and activity cycles. The device, similar to a watch, is usually worn on the wrist and uses a motion sensor to detect movement.

"**Continuous Positive Airway Pressure (CPAP)**" is a treatment that uses mild air pressure to keep the airways open, primarily utilized for individuals suffering from sleep-related breathing disorders such as obstructive sleep apnea.

"**Hypocretin-1**," also known as orexin-A, is a neuropeptide produced in the brain that plays a crucial role in the regulation of the sleep-wake cycle, appetite, and energy expenditure.

"**Mandibular Advancement Device (MAD)**" refers to an oral appliance, similar to a mouthguard, which is worn during sleep to prevent the collapse of the tongue and soft tissues in the back of the throat, thus keeping the airways open. It is used primarily to treat sleep disorders such as snoring and obstructive sleep apnea.

"**Multiple Sleep Latency Test (MSLT)**" is a diagnostic tool used to measure the speed of falling asleep during a series of planned naps during the day. This test is typically used to diagnose narcolepsy and idiopathic hypersomnia.

"**Non-Rapid Eye Movement (NREM)**" is collectively sleep stages 1-3, each representing a progressively deeper sleep, where the brain activity, heart rate, breathing, and blood pressure gradually decrease.

"**Polysomnography (PSG)**" is a comprehensive sleep study that records a range of physiological variables during sleep, such as brain waves (EEG), eye movements (EOG), muscle activity or skeletal muscle activation (EMG), and heart rhythm (ECG), during sleep. This test helps to diagnose sleep disorders including sleep apnea, restless legs syndrome, insomnia, and other sleep-related conditions.

"**Rapid Eye Movement (REM)**" is a unique phase of mammalian sleep characterized by rapid movement of the eyes, low muscle tone, and the propensity of the sleeper to dream vividly. A disruption in the normal pattern of REM sleep can be indicative of certain neurological disorders.

"**Sleep latency**" refers to the length of time that it takes to transition from full wakefulness to the first stage of sleep. It is a common metric used in sleep research to assess the degree of sleepiness.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Sunosi (solriamfetol)** medically necessary when when the **ALL** the following criteria are met for the applicable indication listed below:

For the treatment of narcolepsy

1. The requested medication is prescribed by or in consultation with a sleep medicine specialist, neurologist, psychiatrist, or pulmonologist with expertise in treating sleep disorders; ***AND***
2. The member is 18 years of age or older; ***AND***
3. The member has a diagnosis of narcolepsy confirmed by Multiple Sleep Latency Test (MSLT), or by a low cerebrospinal fluid (CSF) hypocretin-1 level; ***AND***
4. The member has experienced daily episodes of excessive daytime sleepiness for at least three months; ***AND***
5. The member is unable to use, or has adequately tried and failed the following medications, each trialed for at least a 30-day duration:
    a. At least **TWO** of the following stimulant medications:
        i. amphetamine-dextroamphetamine; ***and/or***

ii. dextroamphetamine; ***and/or***
iii. methylphenidate; ***and***

b. And at least **ONE** of the following wakefulness-promoting agents:
i. armodafinil; ***and/or***
ii. modafinil; ***AND***

6. Chart documentation and supporting laboratory test results are provided for review to validate the above-listed requirements.

For the treatment of Obstructive Sleep Apnea (OSA)

1. The requested medication is prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; ***AND***
2. The member is 18 years of age or older; ***AND***
3. The member has a diagnosis of obstructive sleep apnea, confirmed by polysomnography or a home sleep apnea test; ***AND***
4. The member is currently using and adhering to conventional therapy, such as:
   a. Positive Airway Pressure Therapy (such as CPAP); ***and/or***
   b. Oral Appliances (such as mandibular advancement devices); ***AND***
5. The member still experiences excessive daytime sleepiness associated with OSA, despite adherence to the above treatments; ***AND***
6. Other causes of excessive sleepiness have been ruled out (such as poor sleep hygiene, medication side effects, or co-existing medical conditions); ***AND***
7. The member is unable to use, or has adequately tried and failed **ONE** of the following medications, trialed for at least a 30-day duration:
   a. armodafinil; ***and/or***
   b. modafinil; ***AND***
8. Chart documentation and supporting laboratory test results are provided for review to validate the above-listed requirements.

If the above prior authorization criteria are met, Sunosi (solriamfetol) will be approved for 12-months.

Medical Necessity Criteria for Reauthorization:

Reauthorization for 12-months will be granted if **BOTH** of the following are met:

1. the member still meets the applicable initial criteria*; **AND***

2. Recent chart documentation (within the last 6 months) demonstrate that the member has experienced a significant improvement in symptoms since starting Sunosi (solriamfetol), as evidenced by a reduction in the frequency or severity of excessive daytime sleepiness.

Experimental or Investigational / Not Medically Necessary

Sunosi (solriamfetol) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Excessive Daytime Sleepiness / Impaired Cognitive Function in Obstructive Sleep Apnea (OSA) beyond the scope of approved use.
- Attention Deficit Hyperactivity Disorder (ADHD).
- Binge Eating Disorder (BED).
- Chronic Fatigue Syndrome/ Myalgic Encephalitis (CFS/ME).
- Major Depressive Disorder (MDD).
- Parkinson's Disease (PD) related somnolence.
- Shift-work related sleep disturbance / Somnolence.
- Supportive care in Glioma / High Grade Glioma: Glioblastoma (GBM).

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Clinical Guideline Revision / History Information

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