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 characterized by an excessive sleepiness, with some individuals experiencing sudden and uncontrollable muscle weakness (cataplexy). Management of narcolepsy typically involves both non-pharmacological interventions (such as good sleep hygiene or psychosocial support) and medications.

On the other hand, OSA is a condition in which breathing repeatedly starts and stops during sleep due to an obstruction in the upper airway. There are many risk factors for OSA including older age, male gender, and obesity. Treatment of OSA can be treated with non-pharmacologic therapy such as weight loss, continuous positive airway pressure (CPAP), oral appliances (such as mandibular advancement devices), and surgery. Drug therapy is also an option for treating OSA. Pharmacologic strategies include increasing respiratory drive and reducing airway collapsibility. Patients who have OSA may experience interrupted sleep during the night and, therefore, may experience excessive sleepiness during the day. Treatment for residual excessive sleepiness caused from OSA includes wakefulness-promoting agents such as modafinil (Provigil), armodafinil (Nuvigil), and Sunosi (solriamfetol).

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. Sunosi (solriamfetol) does not impact serotonin reuptake.

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.

"Cataplexy" refers to a sudden, transient episode of muscle weakness accompanied by full conscious awareness, typically triggered by emotions such as laughing, crying, or terror.

"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.

"Home sleep study" is a sleep study usually performed at the patient's home which monitors certain physiological parameters such as heart rate, respiratory pattern, oxygen level. It is used to diagnose 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.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria
Narcolepsy
The Plan considers Sunosi (solriamfetol) medically necessary when when the ALL the following criteria are met for the applicable indication listed below:

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 cerebrospinal fluid (CSF) hypocretin-1 laboratory test; *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, defined as ALL of the following:
    a. ONE (1) of the following stimulant medications:
        i. Amphetamine-dextroamphetamine (Adderall); *and/or*
        ii. Dextroamphetamine (Dexedrine); *and/or*
        iii. Methylphenidate (Concerta); *and*
    b. ONE (1) of the following wakefulness-promoting agents:
        i. Armodafinil (Nuvigil); *and/or*
        ii. Modafinil (Provigil); *AND*
6. Chart documentation and supporting laboratory test results are provided for review to validate the above-listed requirements.

Obstructive Sleep Apnea (OSA)

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

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 unable to use or 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 (1) of the following medications, trialed for at least a 30-day duration:
    a. Armodafinil (Nuvigil); *and/or*
    b. Modafinil (Provigil); *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 up to 12-months.

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent General Medical Necessity Criteria

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

1. The member still meets the applicable initial criteria*; AND*
2. Recent chart documentation (within the last 6 months) demonstrates 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.

If the above reauthorization criteria are met, Sunosi (solriamfetol) will be approved for up to 12-months.

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. There is only one published cross-over study which showed improvement in objective and subjective measures of cognitive function. However, the study was short in nature (about 5 weeks in total), small (n=59), and no other studies have corroborated these results. There is not yet enough data to support the safety and efficacy of Sunosi (solriamfetol) for the management of cognitive impairment associated with OSA.
- Attention Deficit Hyperactivity Disorder (ADHD). Sunosi (solriamfetol) is not approved for ADHD, and there is only one small (n=60) published study which showed improvement in the ADHD Investigator Symptom Rating Scale and the Clinical Global Impressions scale, compared to placebo. There is not yet enough data to support the safety and efficacy of Sunosi (solriamfetol) for the management of ADHD.
- Binge Eating Disorder (BED). There is not enough data to support the safety and efficacy of Sunosi (solriamfetol) for the management of BED.
- Chronic Fatigue Syndrome/ Myalgic Encephalitis (CFS/ME). There is not enough data to support the safety and efficacy of Sunosi (solriamfetol) for the management of CFS/ME.
- Major Depressive Disorder (MDD). There is not enough data to support the safety and efficacy of Sunosi (solriamfetol) for the management of MDD.
- Parkinson's Disease (PD) related somnolence. In one published proof-of-concept study (n=66), there was no benefit, compared to placebo, of Sunosi (solriamfetol) for the management of PD-related somnolence.
- Shift-work related sleep disturbance / Somnolence. There is not enough data to support the safety and efficacy of Sunosi (solriamfetol) for the management of shift-work related sleep disturbances/somnolence.

- Supportive care in Glioma / High Grade Glioma: Glioblastoma (GBM). There is not enough data to support the safety and efficacy of Sunosi (solriamfetol) for the management of GBM or supportive care in glioma.

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