Oscar Clinical Guideline: armodafinil (Nuvigil) (PG036, Ver. 9)

armodafinil (Nuvigil)

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

Armodafinil (Nuvigil) was FDA approved in 2007 and is a wakefulness-promoting agent approved for use in narcolepsy, obstructive sleep apnea, and shift work sleep disorder.

Narcolepsy is a sleep disorder characterized by excessive sleepiness, daytime sleepiness, and, in some cases, cataplexy (sudden, uncontrollable muscle weakness). Treatment of narcolepsy can involve both non-pharmacologic therapy (such as practicing good sleep hygiene or psychosocial support) and medications.

Obstructive sleep apnea (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 and armodafinil.

Shift Work Sleep disorder develops in people who work during the hours typically used for sleep (such as the night shift). A night shift worker, for example, usually works during the night and has to sleep during the day but will often try to stay awake during daylight on their days off. Also, working at night and sleeping during the day disrupts one's circadian rhythm, which is an internal, biological process that responds to environmental factors. For example, the body will naturally be awake and alert during daylight and want to sleep when it's dark. Therapy for Shift Work Sleep disorder includes practicing good sleep hygiene (i.e., having a sleep schedule, blocking out light), improving daytime sleep with the use of melatonin or sleep agents, and improving wakefulness when awake (with a medication such as armodafinil).

Definitions

"Actigraphy" is a device worn on the wrist (like a watch) that measures activity and rest levels to assess sleep patterns and circadian rhythms.

"Continuous positive airway pressure (CPAP)" is a device that supplies a constant and steady flow of air pressure into the airways to maintain their openness during sleep, commonly used for the treatment of obstructive sleep apnea.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or

- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"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" is a naturally occurring chemical in the brain that plays a crucial role in regulating wakefulness and sleep.

"Mandibular advancement device" is a medical device that is placed in the mouth during sleep to reposition the lower jaw and tongue, helping to keep the airways open and reducing symptoms of obstructive sleep apnea.

"Multiple sleep latency test (MSLT)" is a diagnostic sleep study performed as 5 daytime naps, used to measure the time it takes an individual to fall asleep during the daytime. It assesses daytime sleepiness and can aid in the diagnosis of conditions such as narcolepsy. It is performed following PSG from the night before.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Polysomnography (PSG)" is a comprehensive sleep study usually performed at an attended Sleep Lab facility that monitors various physiological parameters during sleep, including brain activity, eye movements, heart rate, oxygen levels, and respiratory patterns. It is used to diagnose and evaluate several sleep disorders.

"Sleep latency" refers to the amount of time it takes an individual to fall asleep after lying down and attempting to sleep. It is commonly assessed during sleep studies and can be used as an indicator of sleep quality and sleep disorders.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. IF the request is for brand Nuvigil (armodafinil), the member is unable to use, or has tried and failed generic armodafinil from two or more (≥ 2) manufacturers, when available[s]*; AND*
2. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Narcolepsy

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member is 17 years of age or older; *AND*
2. The member has a diagnosis of narcolepsy confirmed by Multiple Sleep Latency Test (MSLT) or Cerebrospinal fluid (CSF) hypocretin-1 laboratory test; *AND*
3. The member has daily periods of excessive daytime sleepiness occurring for at least three months.

If the above prior authorization criteria are met, armodafinil will be approved for up to 36 months.[s]

Obstructive Sleep Apnea (OSA)

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member is 17 years of age or older; *AND*
2. The member has a diagnosis of obstructive sleep apnea, confirmed by polysomnography or a home sleep apnea test; *AND*
3. The member is unable to use or is currently using conventional therapy and has been adherent to such therapy, including ONE (1) of the following[s]:
    a. Positive Airway Pressure Therapy (such as CPAP); *or*
    b. Oral Appliances (such as mandibular advancement devices).

If the above prior authorization criteria are met, armodafinil will be approved for up to 36 months.[s]

Shift Work Sleep Disorder (SWSD)

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member is 17 years of age or older; *AND*
2. The member has a diagnosis of Shift Work Sleep Disorder*; AND*
3. Non-pharmacological therapies have been tried and failed, such as setting a sleep schedule and improving sleep hygiene[s].

If the above prior authorization criteria are met, armodafinil will be approved for up to 36 months.[s]

Hypersomnia secondary to dementia with Lewy bodies (DLB)

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member has a confirmed diagnosis of dementia with Lewy bodies (DLB); *AND*
3. The member experiences excessive daytime sleepiness associated with dementia with Lewy bodies.

If the above prior authorization criteria are met, armodafinil will be approved for up to 36 months.[s]

Hypersomnia secondary to traumatic brain injury (TBI)

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member has a history of traumatic brain injury (TBI); *AND*
3. The member experiences excessive daytime sleepiness following the TBI.

If the above prior authorization criteria are met, armodafinil will be approved for up to 36 months.[s]

Fatigue related to Multiple Sclerosis

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member has a confirmed diagnosis of fatigue due to multiple sclerosis; *AND*
3. The member has demonstrated excessive daytime sleepiness associated with their MS-related fatigue*; AND*
4. The member has tried and failed non-pharmacological strategies (such as exercise, cooling methods, and cognitive behavioral therapy)[s].

If the above prior authorization criteria are met, armodafinil will be approved for up to 36 months.[s]

Idiopathic Hypersomnia:

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member is 17 years of age or older; *AND*
2. The member has a confirmed diagnosis of idiopathic hypersomnia; *AND*
3. Other potential causes of hypersomnia have been ruled out through comprehensive neurological, psychiatric, and other investigations; *AND*
4. Non-pharmacological approaches, including behavioral strategies and sleep hygiene improvements, have been attempted but have not provided significant improvement in daytime function[s]; *AND*
5. The member requires treatment to improve excessive daytime sleepiness and functional impairment.

If the above prior authorization criteria are met, armodafinil will be approved for up to 36 months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Medical Necessity Criteria

The Plan considers armodafinil (Nuvigil) medically necessary when ALL the following criteria are met:

1. The member still meets the applicable initial criteria*; AND*
2. Chart documentation shows the member has experienced a clinical improvement in symptoms since starting armodafinil, as evidenced by a reduction in the symptoms of excessive daytime sleepiness.

If the above reauthorization criteria are met, the requested product will be authorized for up to 36-months.[s]

Experimental or Investigational or Unproven / Not Medically Necessary[s]

Armodafinil for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary.

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