

**Antinarcotic Agents
 To Initiate a Coverage Review, call 1 800 753-2851**

Covered medication
<ul style="list-style-type: none"> ➤ Modafinil (<i>Provigil</i>[®]) ➤ Armodafinil (<i>Nuvigil</i>[®])

What it does and how it is used
<ul style="list-style-type: none"> ➤ Modafinil (<i>Provigil</i>[®]) and armodafinil (<i>Nuvigil</i>[®]) are wakefulness-promoting agents with effects similar, but not identical, to the CNS stimulants (like amphetamine and methylphenidate). At this point, the actual mechanism of action is unknown. ➤ Modafinil is a racemic mixture of R- and S-enantiomers, while armodafinil is the isolated R-enantiomer, the longer-lived enantiomer of modafinil. ➤ Both agents share the same FDA-labeled indications to treat excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift-work sleep disorder. ➤ As <i>Provigil</i>[®] has been marketed for over 10 years, it has been demonstrated to be effective in several other conditions for which it is not specifically labeled, for example, idiopathic hypersomnolence and as a short-term adjunct to antidepressant therapy. Likewise, randomized, double-blind, placebo-controlled studies in the literature describe situations in which it has <i>not</i> been shown to be effective, for example, fatigue associated with multiple sclerosis (MS). ➤ Generic versions of modafinil are expected to be available by mid-2012. ➤ Narcolepsy is a disorder that causes excessive daytime sleepiness (EDS), along with periods of cataplexy (sudden daytime muscle weakness) and sleep phenomena, such as shortened time to rapid eye movement (REM), sleep paralysis, and hallucinations. Sleep attacks occur very suddenly and intrusively, usually lasting 15 to 20 minutes, after which time the person awakes feeling refreshed, only to experience another episode just a few hours later. Cataplexy is characterized by a sudden loss of muscle tone. There may be a mild sensation of weakness affecting just a few parts of the body, or complete collapse due to a virtual state of full-body paralysis. There is no loss of consciousness or memory, and breathing is not impaired during this episode, which may last just a few minutes or as long as an hour. Narcolepsy is estimated to occur in less than 1% of the population, with peak incidence occurring around 14 years of age. Narcolepsy responds best when multiple naps are taken throughout the day, along with stimulant medication. ➤ Obstructive sleep apnea (OSA) is a chronic condition characterized by repeated episodes of complete or partial collapse of the upper airway during sleep. This constantly interrupts the patient's sleep cycle when he or she awakens in order to resume normal breathing, and leads to EDS. Continuous positive airway pressure (CPAP) is the therapy of choice for addressing nighttime symptoms of OSA, while modafinil (<i>Provigil</i>[®]) may be used to address the symptoms of EDS. ➤ Shift-work sleep disorder (SWSD) is a condition that occurs in individuals who work the night shift and is characterized by excessive sleepiness while at work. While some workers are able to adapt to night shift work, those who have SWSD are persistently tired and sleepy while at work. This is due to a mismatch between the body's regular sleep cycle and an individual's work schedule. SWSD is estimated to occur in 2% to 5% of the 6 million people who work the night shift. ➤ Idiopathic hypersomnolence is a central nervous system disorder in which the major sleep episode is normal or prolonged, but constant and recurrent EDS is still the chief complaint. In this case, cataplexy is not present and the sleep attacks are less sudden, often preceded by a long period of drowsiness and lasting an hour or more. This syndrome is estimated to account for 5% to 10% of patients who bring a complaint of sleepiness to a sleep clinic. ➤ Depression is diagnosed if a patient has persistent feelings of sadness or anxiety, a loss of interest or pleasure in his or her usual activities, and 5 or more symptoms established by the DSM-IV criteria for at least 2 consecutive weeks. These symptoms include insomnia or oversleeping and loss of energy or increased fatigue. Antidepressants such as selective serotonin reuptake inhibitors (SSRIs), tricyclics, and monoamine oxidase inhibitors (MAOIs) are often prescribed to target the imbalances causing the depressive symptoms. However, antidepressant therapy often takes up to 6 weeks to achieve its full effect. <i>Provigil</i>[®] has demonstrated effectiveness as an adjunct to antidepressants during initial therapy and in addition, antidepressant therapy may not resolve associated symptoms of fatigue and sleepiness. <i>Provigil</i>[®] may be beneficial when used as pharmacotherapy for fatigue and sleepiness in patients undergoing treatment for their depression.

Rationale for prior authorization
To reduce exposure to cost associated with uncovered uses such as use to offset sleepiness due to voluntary sleep deprivation.

Benefit design
Coverage for modafinil (<i>Provigil</i> [®]) and armodafinil (<i>Nuvigil</i> [®]) is determined through prior authorization for every claim.

Prior authorization criteria
This prescription benefit provides coverage in accord with the following criteria: 1. Coverage provided for the treatment of narcolepsy

- Prescriber must confirm that the patient does not have underlying conditions that may contribute to excessive sleepiness (e.g., nocturnal myoclonus, current drug therapy which affects sleep or contributes to daytime sedation, or chronic voluntary or involuntary sleep deprivation through shift work).
2. Coverage provided for the treatment of idiopathic hypersomnolence
 - Confirmed by polysomnography where excessive sleepiness is not due to other sleep disorders such as narcolepsy, obstructive sleep apnea, or posttraumatic hypersomnia.
 3. Coverage provided for residual daytime sleepiness due to obstructive sleep apnea/hypopnea in patients who are receiving nasal continuous positive airway pressure therapy (CPAP).
 4. Coverage is provided for treating excessive sleepiness due to SWSD (shift-work sleep disorder) in the following circumstances:
 - The patient is a night-shift worker who has complaints of persistent and frequent excessive sleepiness and/or falling asleep while at work.
 - The patient is not receiving other drugs, e.g., hypnotics or substances, or does not have any medical conditions known to cause or contribute to sleepiness.

Coverage is approved for 12 months. Coverage may be renewed.

5. Coverage provided for use in combination with antidepressant drug therapy in patients with depression associated with fatigue and/or sleepiness.

Coverage is approved for 8 weeks. Coverage may be renewed for 3 months.

6. *Provigil*[®] or *Nuvigil*[®] must not be used in combination with other CNS stimulants such as amphetamines, pemoline, methylphenidate, or atomoxetine (*Strattera*[®]).

Please Note: Coverage for *Nuvigil*[®] is provided only in circumstances where the patient is using it for one of the approved indications and where the patient is 18 years of age or older.

References

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- Stankoff B, Waubant E, Confavreux C, Edan G, Debouverie M, et al. Modafinil for fatigue in MS: A randomized placebo-controlled double-blind study. *Neurology*. 2005;64:1139-1143.
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