Antinareoleptic Agents

Coverage Medications

- Modafinil (Provigil®)
- Armodafinil (Nuvigil®)

What they do and how they are used

- Modafinil (Provigil®) and armodafinil (Nuvigil®) 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 still 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 Provigil® has been marketed for over ten 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 literature is available regarding situations in which it has not 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 REM (rapid eye movement), sleep paralysis, and hallucinations. Sleep attacks occur very suddenly and intrusively, usually lasting 15-20 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 short 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 they awaken 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 (Provigil®) may be used to address the symptoms of EDS.
- Shift-work sleep disorder 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 2-5% 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 5-10% 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 their 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 the 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 six weeks to achieve its full effect. Provigil® 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. Provigil® 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

Two coverage options exist

Coverage for modafinil (Provigil®) and Armodafinil (Nuvigil®) is determined through prior authorization for every claim. AND

Coverage is provided immediately (without generating a coverage review process) for doses up to 200 mg per day for Provigil® or 250 mg per day for Nuvigil®. Coverage for higher dose therapy, up to 400 mg per day for Provigil® is provided through a coverage review process. Coverage for higher dose therapy of Nuvigil® is NOT provided.

Prior authorization criteria

Antinareoleptics
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This prescription benefit provides coverage for Nuvigil® and Provigil® and in accord with the following criteria:

1. Combination therapy with other CNS stimulants such as amphetamines, pemoline, methylphenidate or atomoxetine (Strattera®) is not provided

2. Treatment of:
   a) 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)
   
   b) Excessive daytime sleepiness due to obstructive sleep apnea in patients who are receiving nasal continuous positive airway pressure therapy (CPAP) or is not a candidate for receiving nasal continuous positive airway pressure therapy (CPAP)
   
   c) 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
      • The patient does not have any medical conditions known to cause or contribute to sleepiness
   
   d) Idiopathic hypersomnolence
      • Confirmed by polysomnography where excessive sleepiness is not due to other sleep disorders such as narcolepsy, obstructive sleep apnea or posttraumatic hypersomnia.
   
   e) Depression associated with fatigue and/or sleepiness in combination with antidepressant drug therapy

Coverage duration and quantity:
Coverage is approved for 12 months and may be renewed

Coverage for doses of Provigil®, up to 400 mg per day is provided for patients who do not respond adequately to the initial doses.

References