Policy Applies to: Commercial plans only

Background:
Modafinil (Provigil®) and armodafinil (Nuvigil®) are schedule IV controlled substances that are FDA approved for the use in the treatment of excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSAHS) who are compliant with continuous positive airway pressure (CPAP) therapy, and in shift work sleep disorder. Modafinil and armodafinil are not indicated for the reduction of daytime sleepiness associated with multiple sclerosis, Parkinson's disease, Alzheimer’s disease, depression, or idiopathic hypersomnia. Additionally, modafinil and armodafinil are not approved to counteract the sedating properties of other medications.

The FDA advisory panel has recommended that modafinil only be used for OSAHS in patients who are compliant with continuous positive airway pressure (CPAP) therapy and that modafinil be used as an adjunctive, not replacement therapy. The committee has also urged that modafinil only be used in patients who truly suffer from shift work sleep disorder (SWSD), and not be used in those patients who are just sleepy.

Several studies have been conducted in the treatment of OSAHS. Study participants had undergone multiple sleep latency testing (MSLT) or maintenance of wakefulness test (MWT) and were CPAP compliant but remained drowsy throughout much of the day. Patients with severe OSA were excluded from these studies. The trials indicated that modafinil helped maintain wakefulness but did not effect CPAP use, the primary pathology of sleep-disordered breathing, or nighttime sleep (sleep duration, sleep efficiency, and the percentage of time in REM and non-Rem stages).

Many of the studies evaluating modafinil in the treatment of SWSD have only been published in abstract form. Modafinil has been shown to improve measures associated with excessive sleepiness (activity level, vigilance, general productivity) in patients with SWSD. However, there is little evidence of consistent results of modafinil improving physical functioning, general health, mental health, or social functioning of patients with SWSD. Modafinil has not been shown to affect sleep efficiency, sleep latency, number of
health, or social functioning of patients with SWSD. Modafinil has not been shown to affect sleep efficiency, sleep latency, number of awakenings, sleep duration, or sleep stages. Another study did show a statistical difference in increasing sleep latency when compared to placebo, although the difference in time (1.7 minutes) is not likely to be clinically significant.

There is limited and conflicting data evaluating the use of modafinil in the treatment of fatigue associated with multiple sclerosis. There is even less data evaluating the use of modafinil for the treatment of depression or Parkinson's disease. These later studies are limited to mostly uncontrolled trials and several case reports. All of these studies are small in sample size and have a short duration, which make the results difficult to extrapolate.

Approval Criteria: When a benefit, modafinil/armodafinil may be approved when all of the following are met:

1. Modafinil/armodafinil are recommended to be prescribed under the supervision of a neurologist or sleep specialist AND
2. Modafinil/armodafinil are to be used in the treatment of documented narcolepsy by a MSLT or other appropriate testing OR
3. Modafinil/armodafinil are to be used in the treatment of fatigue associated with multiple sclerosis OR
4. Modafinil/armodafinil are to be used as an adjunctive treatment of obstructive sleep apnea / hypopnea syndrome (OSAHS) with obstructive apneas documented by objective polysomnographic testing in patients who must be currently receiving and compliant with continuous positive airway pressure (CPAP) therapy.

Coverage for armodafinil will be granted only after the documented trial and failure of modafinil, when prescribed for an approved indication.

Modafinil and armodafinil will not be covered for the use in SWSD or any other diagnosis not listed above. Coverage for modafinil and armodafinil will not be approved when the main purpose is to counteract the sedating effects of another medication.

Duration of Authorization:

If approved, authorization should be granted for a period of up to one year for the diagnosis of sleep apnea. Up to a lifetime authorization may be granted for all other approvable diagnoses.

References:


View Previous Versions

[Version 009 of J-7]
[Version 008 of J-7]
[Version 007 of J-7]
[Version 006 of J-7]
[Version 005 of J-7]
[Version 004 of J-7]
[Version 003 of J-7]
[Version 002 of J-7]
[Version 001 of J-7]