Pharmacy Policy Bulletin

Category:	Prior Authorization
Number:	J-122
Subject:	Provigil (modafinil) & Nuvigil (armodafinil)- Medicare Only
Effective Date Begin:	May 20, 2009
Effective Date End:	
Original Date:	December 3, 2008
Review Date(s):	May 19, 2010 May 20, 2009 December 3, 2008

Policy Applies to: *Medicare* 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 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 MSLT demonstrating sleep latency less than 10 minutes or other appropriate testing ***OR***
3. Modafinil/armodafinil are to be used in the treatment of documented narcolepsy for those patients meeting the ICD-9 and American Sleep Disorders Association criteria for narcolepsy (also consistent with DSM IV criteria) These criteria include either a) recurrent daytime naps or lapsed into sleep that occur almost daily for at least 3 months, plus sudden bilateral loss of postural muscle tone in association with intense emotion (cataplexy) or b) a complaint of excessive sleepiness or sudden muscle weakness with associated features such as sleep paralysis, hypnagogic hallucinations, automatic behaviors, or disrupted major sleep episode. ***OR***
4. Modafinil/armodafinil are to be used in the treatment of fatigue associated with multiple sclerosis ***OR***
5. Modafinil/armodafinil are to be used as an adjunctive treatment of obstructive sleep apnea / hypopnea syndrome (OSAHS) for those patients currently receiving and compliant with continuous positive airway pressure (CPAP). Patients must meet ICSD criteria (consistent with DSM IV criteria) including a) excessive sleepiness or insomnia, plus frequent episodes of impaired breathing during sleep, and associated features such as loud snoring, morning headaches and dry mouth upon awakening; or b) excessive sleepiness or insomnia and polysomnography demonstrating more than 5 obstructive apneas, each greater than 10 seconds in duration per hour of sleep and one or more of the following: frequent arousals from sleep associated with apneas, bradytachycardia, and arterial oxygen desaturation in association with apneas.
6. Modafinil/armodafinil are to be use in the treatment of SWSD. In clinical studies SWSD is defined as a minimum of 5 night shifts per month with at least 3 of the nights being consecutive night shifts. Also, night shifts are defined by at least 6 hours occurring between 2200h and 0800h, and which were no more than 12 hours in duration.

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:

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