RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Provigil and Nuvigil are central nervous system stimulants and share the well-known potential for abuse of this class of drugs. The Drug Enforcement Administration (DEA) has rated Provigil and Nuvigil as Schedule IV drugs. Provigil and Nuvigil produce psychoactive and euphoric effects, alterations in mood, perception, thinking and feelings typical of other CNS stimulants. Physicians should follow patients closely, especially those with a history of drug and/or stimulant abuse (1-2).

In obstructive sleep apnea (OSA), Provigil and Nuvigil are indicated as an adjunct to standard treatment(s) for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Provigil. If Provigil is used adjunctively with CPAP, the encouragement of and periodic assessment of CPAP compliance is necessary (3).

A 12-week study of patients with excessive sleepiness (ES) associated with treated sleep apnea (OSA), shift work disorder (SWD), or narcolepsy evaluated the tolerability and efficacy of armodafinil for 12 months. The conclusion of the study was that armodafinil remained effective and was generally well tolerated. Armodafinil represents an option for long-term treatment of patients with ES associated with treated OSA, SWD, or narcolepsy (4).

Regulatory Status

FDA-approved indication: Provigil and Nuvigil are central nervous system stimulants that are indicated for: Improving wakefulness in adult patients with excessive sleepiness associated with narcolepsy, shift work disorder, and obstructive sleep disorder. Provigil and Nuvigil are also used as an adjunct to standard treatments for the underlying obstruction in OSA (1-2).

Off Label Uses:

Provigil has been found effective in the treatment of multiple sclerosis fatigue (3). Modafinil is a unique wake-promoting agent that is chemically distinct from traditional stimulants. Results of a placebo-controlled study showed it to significantly improve fatigue and sleepiness and to be well tolerated by patients with multiple sclerosis (MS) (5,6). For MS patients who experience significant fatigue there are several medications that have proven effective in this regard. Modafinil is among the most commonly used medications for fatigue associated with MS and according to expert...
opinion, is currently a first-line drug for MS patients (5).

Idiopathic hypersomnia, a condition similar to narcolepsy, is characterized by constant or recurrent daytime sleepiness with no other cause of sleepiness, prolonged nocturnal sleep, difficulty awakening with sleep drunkenness, and long unrefreshing naps with no history of cataplexy. Modafinil has proven effective in treating idiopathic hypersomnia in one case series and several open-label trials. The practice parameters for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007, state that modafinil may be effective for the treatment of daytime sleepiness due to idiopathic hypersomnia. As there may be underlying causes/behaviors associated with EDS, a sleep specialist physician has the training to correctly recognize and diagnose this condition. While armodafinil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition (4).

Summary
Provigil and Nuvigil are central nervous system stimulants used to increase wakefulness in adult patients with narcolepsy, shift work sleep disorder and obstructive sleep apnea. The Drug Enforcement Administration (DEA) has rated Provigil and Nuvigil as Schedule IV drugs. Provigil and Nuvigil produce psychoactive and euphoric effects, alterations in mood, perception, thinking and feelings typical of other CNS stimulants and share the potential for abuse. Provigil has been found effective in the treatment of multiple sclerosis fatigue, improving wakefulness in adult patients with excessive sleepiness associated with narcolepsy, shift work disorder, and obstructive sleep disorder (3-6).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Provigil and Nuvigil while maintaining optimal therapeutic outcomes.

References
