



**MODAFINIL (Provigil)
ARMODAFINIL (Nuvigil)
UTILIZATION MANAGEMENT CRITERIA**

DRUG CLASS:	ANTINARCOLEPTIC AGENTS
BRAND (generic) NAMES:	Provigil (modafinil) 100, 200 mg tablets Nuvigil (armodafinil) 50, 150, 250 mg tablets

FDA-APPROVED INDICATIONS

Modafinil and armodafinil are indicated to improve wakefulness in patients with excessive sleepiness associated with

- narcolepsy,
- obstructive sleep apnea / hypopnea syndrome (OSAHS), and
- shift work sleep disorder.

In OSAHS, modafinil and armodafinil 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 modafinil or armodafinil. If these drugs are used adjunctively with CPAP, the encouragement of and periodic assessment of CPAP compliance is necessary.

In all cases, careful attention to the diagnosis and treatment of the underlying sleep disorder(s) is of utmost importance. Prescribers should be aware that some patients may have more than one sleep disorder contributing to their excessive sleepiness.

COVERAGE AUTHORIZATION CRITERIA for modafinil (Provigil) and armodafinil (Nuvigil) tablets:

Covered diagnoses:

- 1) Narcolepsy with symptoms of excessive sleepiness. Sleep study confirming diagnosis of narcolepsy must be submitted.
- 2) Obstructive sleep apnea/hypopnea syndrome (OSAHS) in a patient who is using concurrent continuous positive airway pressure (CPAP) therapy, or who is not a candidate for CPAP therapy. Patients using CPAP must demonstrate compliance with regular CPAP use. Patient must have symptoms of excessive daytime sleepiness. Sleep study confirming diagnosis must be submitted.
- 3) Shift work sleep disorder (SWSD) in a night shift worker with persistent and frequent excessive sleepiness or episodes of falling asleep while at work. Significant distress or impairment must be documented.

4) Idiopathic hypersomnia. Sleep study confirming diagnosis by ruling out other sleep disorders must be submitted.

5) Fatigue related to multiple sclerosis, in which fatigue causes significant distress or impairment.

Additional criteria:

1) Symptoms of excessive daytime sleepiness (or nighttime sleepiness for patients with SWSD) must consist of significant distress or impairment, preferably as documented with the Epworth Sleepiness Scale. (This does not apply to a diagnosis of fatigue related to multiple sclerosis.)

2) Other conditions which may contribute to or worsen excessive daytime sleepiness (or nighttime sleepiness for patients with SWSD) must be ruled out OR addressed and treated.

3) For narcolepsy, OSAHS, or idiopathic hypersomnia, at least one sleep study (polysomnography) that confirms the diagnosis must be submitted.

4) Patient must be age 17 years or older.

WARNINGS

- Serious rash, including Stevens-Johnson Syndrome, requiring hospitalization and discontinuation of treatment has been reported in adults and children in association with the use of modafinil.

- Modafinil is not approved for use in pediatric patients for any indication.

- Although benign rashes also occur with modafinil, it is not possible to reliably predict which rashes will prove to be serious. Accordingly, modafinil should ordinarily be discontinued at the first sign of rash, unless the rash is clearly not drug-related.

DOSAGE AND ADMINISTRATION:

Provigil: The recommended dose of Provigil is 200 mg once daily. Doses up to 400 mg/day have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200 mg dose.

Nuvigil: The recommended dose of Nuvigil is 150 mg or 250 mg given as a single dose.

REFERENCES:

Provigil (modafinil). Product Information. Cephalon, Inc. 2008.

Nuvigil (armodafinil). Product Information. Cephalon, Inc. 2010.

Modafinil. DrugDex Evaluations. Thomson-Reuters Healthcare. Accessed August 2009.

Successful treatment of idiopathic hypersomnia and narcolepsy with modafinil [abstract]. Bastuji H, Jouvet M. *Prog Neuropsychopharmacol Biol Psychiatry*. 1988;12(5):695-700.