

# PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>NARCOLEPSY AGENTS</b>
<b>BRAND NAME (generic)</b>	<b>PROVIGIL (modafinil)</b>
<b>Status: CVS Caremark Criteria</b>	
<b>Type: Initial Prior Authorization</b>	

## POLICY

### FDA-APPROVED INDICATIONS

Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work disorder.

In OSA, Provigil is 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.

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.

The effectiveness of modafinil in long-term use (greater than 9 weeks in Narcolepsy clinical trials and 12 weeks in OSA and SWD clinical trials) has not been systematically evaluated in placebo-controlled trials. The physician who elects to prescribe Provigil for an extended time in patients with Narcolepsy, OSA, or SWD should periodically reevaluate long-term usefulness for the individual patient.

### COVERAGE CRITERIA

- Provigil (modafinil) will be covered with prior authorization when the following criteria are met:
  - The patient has a diagnosis of narcolepsy confirmed by sleep lab evaluation
  - OR**
  - The patient has a diagnosis of Shift Work Disorder (SWD)
  - OR**
  - The patient has a diagnosis of obstructive sleep apnea (OSA) confirmed by polysomnography

### REFERENCES

1. Provigil [package insert]. Frazer, PA: Cephalon, Inc.; October 2010.
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3. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed May 2014.
4. Morgenthaler TJ, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. *Sleep* 2007;30(12):1705-11.
5. Kushida, C, Morgenthaler, T, et al. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. *Sleep* 2006;29(2):240-243.
6. Czeisler, CA et al. Modafinil for excessive sleepiness associated with shift work sleep disorder. *New England Journal of Medicine*. 2005: 353; 476-486.