## PRIOR AUTHORIZATION CRITERIA

DRUG CLASS

NARCOLEPSY AGENTS

# BRAND NAME (generic)

PROVIGIL (modafinil)

Status: CVS Caremark Criteria Type: Initial Prior Authorization

## 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.

<u>Compendial Uses/</u> Limited Treatment Option Fatigue related to multiple sclerosis<sup>7-9</sup>

### **COVERAGE CRITERIA**

The requested drug 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.

### OR

- The patient has a diagnosis of fatigue related to multiple sclerosis AND
- The patient has experienced an inadequate treatment response, intolerance or contraindication to amantadine

#### **REFERENCES**

- 1. Provigil [package insert]. Frazer, PA: Cephalon, Inc.; December 2016.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed April 2018.
- 3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed April 2018.
- 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.

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- 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.
- 7. Pucci, E, Branas P, D'Amico R, et al. Amantadine for fatigue in multiple sclerosis. *Cochrane Database Syst Rev* 2007;:CD002818
- 8. Brown JN, Howard CA, Kemp DW. Modafinil for the treatment of multiple sclerosis-related fatigue. *Ann Pharmacother*. 2010 Jun;44(6):1098-103.

9. Zifko UA, Rupp M, Schwarz S, et al. Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study. *J Neurol.* 2002;249:983-987.

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