PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**NARCOLEPSY AGENTS**
BRAND NAME (generic)	**PROVIGIL (modafinil)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder.

Limitations of Use
In OSA, Provigil is indicated to treat excessive sleepiness and not as treatment 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 and during treatment with Provigil for excessive sleepiness.

Compendial Uses/ Limited Treatment Option
Fatigue related to multiple sclerosis[8,9]

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of narcolepsy AND the diagnosis is 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) AND the diagnosis is confirmed by polysomnography

AND

- The patient has been receiving treatment for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) for at least one month

OR

- The requested drug is being prescribed for multiple sclerosis-related fatigue

Quantity Limits Apply.
60 tablets/25 days* or 180 tablets/75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

REFERENCES

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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. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual*. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
6. Epstein LJ, Kristo D, Strollo PJ et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. *J Clinical Sleep Medicine* 2009:5(3):263-276.
7. Czeisler, CA et al. Modafinil for excessive sleepiness associated with shift work sleep disorder. *New England Journal of Medicine*. 2005: 353; 476-486.
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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.

