

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	NARCOLEPSY AGENTS
BRAND NAME (generic)	NUVIGIL (armodafinil)
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization with Quantity Limit	

POLICY

FDA-APPROVED INDICATIONS

Nuvigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA), narcolepsy, or shift work disorder (SWD).

Limitations of Use

In OSA, Nuvigil 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 Nuvigil for excessive sleepiness.

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

Quantity Limits Apply.

QUANTITY LIMIT		
Drug	1 Month Limit*	3 Month Limit*
Nuvigil (armodafinil) 50 mg	60 tablets / 25 days	180 tablets / 75 days
Nuvigil (armodafinil) 150 mg, 200 mg, 250 mg	30 tablets / 25 days	90 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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3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed March 12, 2021.
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, Walsh JK, Wesnes KA, Arora S, Roth T. Armodafinil for Treatment of Excessive Sleepiness Associated with Shift Work Disorder: A Randomized Controlled Study. *Mayo Clin Proc.* 2009; 84(11):958-972.