PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **NARCOLEPSY AGENTS**

BRAND NAME*
(generic)

NUVIGIL
(armodafinil)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 534-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

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.

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Nuvigil is a Schedule IV controlled substance, and has been shown to produce psychoactive and euphoric effects consistent with other scheduled CNS stimulants. Patients should be observed for signs of misuse or abuse. Nuvigil is indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), and shift work disorder (SWD). Nuvigil should be used only in patients who have had a complete evaluation of their excessive sleepiness, and in whom a diagnosis of narcolepsy, OSA, or SWD has been made in accordance with International Classification of Sleep Disorders (ICSD) or DSM-5 diagnostic criteria. [1-3]

Nuvigil is used to improve wakefulness in adults with excessive sleepiness associated with narcolepsy. According to the American Academy of Sleep Medicine (AASM), successful treatment of hypersomnia of central origin requires an accurate diagnosis, individual tailoring of therapy to produce the fullest possible return of normal function, and regular

follow-up to monitor response to treatment. The evaluation should include a thorough evaluation of other possible contributing causes of excessive daytime sleepiness. The International Classification of Sleep Disorders, Third Edition (ICSD-3) specifies necessary diagnostic tests and criteria for each disorder of central origin. For narcolepsy, a sleep lab evaluation consisting of an overnight polysomnography (PSG) and mean sleep latency tests (MSLT) is recommended to confirm the diagnosis. Many other conditions produce such sleepiness and can mimic or coexist with a hypersomnia of central origin.[4,5]

In OSA, Nuvigil 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 Nuvigil.[1] OSA should be confirmed by polysomnography with respiratory monitoring. Oral appliances are indicated for use in patients with mild to moderate OSA who prefer them to CPAP therapy, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP.[6]

The presence or absence of obstructive sleep apnea (OSA) must be determined before initiating treatment. Diagnostic criteria for OSA are based on clinical signs and symptoms determined during a comprehensive sleep evaluation, which includes a sleep oriented history and physical examination, and findings defined by sleep testing.[6] Following the history and physical examination, patients can be stratified according to their OSA disease risk. Those patients deemed high risk should have the diagnosis confirmed and severity determined with objective testing such as polysomnography with respiratory monitoring.[6] OSA should be approached as a chronic disease requiring long-term, multidisciplinary management. The patient should be an active participant in the decision on treatment type and taught to contribute to the management of his or her own disease. Positive airway pressure (PAP) is the treatment of choice for mild, moderate, and severe OSA and should be offered as an option to all patients. Alternative therapies may be offered depending on the severity of the OSA and the patient's anatomy, risk factors, and preferences.[6] Oral appliances (OA) may improve upper airway patency during sleep by enlarging the upper airway and/or by decreasing upper airway collapsibility (e.g., improving upper airway muscle tone). Although not as efficacious as PAP, OAs are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail CPAP or other measures.[6] Patients should be established on effective treatment of the underlying airway obstruction associated with OSA before considering pharmacologic therapy for excessive sleepiness associated with OSA.[6] Patients should be continued on their treatment for the underlying airway obstruction while using pharmacologic treatment for excessive sleepiness due to OSA.[1-3,6] Therefore, patients with OSA must be established on therapy to treat the underlying obstruction for approval of Nuvigil.

The effectiveness of Nuvigil in improving wakefulness in patients with excessive sleepiness associated with SWD was demonstrated in a 12-week, multi-center, double-blind, placebo-controlled, parallel-group, clinical trial. Enrolled patients were required to work a minimum of 5 night shifts per month (each shift ≤12 hours, with ≥6 hours worked between 10pm and 8am) and have excessive sleepiness at the time of their night shifts.[7]

Nuvigil is available as tablets in the following strengths: 50 mg, 150 mg, 200 mg, and 250 mg. The recommended dosage of Nuvigil for narcolepsy and OSA is 150 mg to 250 mg taken orally once a day as a single dose in the morning, while the recommended dosage of Nuvigil for shift work disorder is 150 mg taken orally once a day approximately 1 hour prior to the start of their work shift. In patients with severe hepatic impairment, the dosage should be reduced, and for geriatric patients consideration should be given to the use of lower doses and careful monitoring.[1-3] To allow for reduced doses of 100 mg per day, the approval for Nuvigil 50 mg will be limited to 60 tablets for month. For all other strengths, approval will be limited to 30 tablets per month based on recommended dosing.

REFERENCES

1. Nuvigil [package insert]. North Wales, PA: Cephalon, Inc; July 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed March 12, 2021.
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.

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CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of narcolepsy? [If no, then skip to question 3.]	Yes	No
2	Has the diagnosis been confirmed by sleep lab evaluation? [If yes, then skip to question 7.]	Yes	No
3	Does the patient have a diagnosis of Shift Work Disorder (SWD)? [If yes, then skip to question 7.]	Yes	No
4	Does the patient have a diagnosis of obstructive sleep apnea (OSA)? [If no, then no further questions.]	Yes	No
5	Has the diagnosis been confirmed by polysomnography? [If no, then no further questions.]	Yes	No
6	Has the patient been receiving treatment for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) for at least one month? [If no, then no further questions.]	Yes	No
7	Does the patient require MORE than the plan allowance of 60 tablets per month of armofadinil (Nuvigil) 50 mg OR MORE than the plan allowance of 30 tablets per month of armodafinil (Nuvigil) 150 mg, 200 mg, 250 mg? [RPh Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Go to 3	
2.	Go to 7	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had a sleep lab test to confirm your diagnosis. Your request has been denied based on the information we have.

			[Short Description: No confirmation of diagnosis (tests, labs, etc.)]
3.	Go to 7	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet any of these conditions: - You have narcolepsy confirmed by sleep lab testing - You have shift work disorder - You have obstructive sleep apnea confirmed by testing Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
5.	Go to 6	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have had a test to confirm your diagnosis. Your request has been denied based on the information we have. [Short Description: No confirmation of diagnosis (tests, labs, etc.)]
6.	Go to 7	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have been on treatment for airway problems due to obstructive sleep apnea for at least one month. Your request has been denied based on the information we have. [Short Description: No underlying treatment for OSA]
7.	Deny RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.	Approve, 12 months, see Quantity Limit Chart	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to: - 60 tablets per month of armodafinil (Nuvigil) 50 mg - 30 tablets per month of armodafinil (Nuvigil) 150 mg, 200 mg, 250 mg Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

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.*		