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 request is for continuation of therapy
    AND
  - The patient had a positive response to treatment

  OR
  - The requested drug is being prescribed by, or in consultation with, a sleep specialist
    AND
  - The diagnosis is confirmed by sleep lab evaluation

OR

- The patient has a diagnosis of shift work disorder (SWD)
  AND
  - The request is for continuation of therapy
    AND
  - The patient had a positive response to treatment
    AND
  - The patient is still a shift-worker

  OR
  - The requested drug is being prescribed by, or in consultation with, a sleep specialist
    AND
  - A sleep log and actigraphy monitoring have been completed for at least 14 days and shows a disrupted sleep and wake pattern
    AND
  - Symptoms have been present for 3 or more months

OR

- The patient has a diagnosis of obstructive sleep apnea (OSA)
  AND
  - The request is for continuation of therapy
    AND
  - The patient had a positive response to treatment
    AND
  - The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)

  OR
  - The requested drug is being prescribed by, or in consultation with, a sleep specialist
    AND
  - The diagnosis has been confirmed by polysomnography
    AND
  - The patient has been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month
    AND
  - Treatment with continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP) will continue

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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5. 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):1705-1711.
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8. 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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