

Initial Prior Authorization with Quantity Limit Nuvigil Narcolepsy Agents

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nuvigil	armodafinil

Indications

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

Narcolepsy

Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis is confirmed by sleep study.

Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis has been confirmed by polysomnography or home sleep apnea test (HSAT) with a technically adequate device.
- 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.
- The patient will continue to use CPAP or BIPAP after the requested drug is started.

Shift Work Disorder (SWD)

Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

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

Continuation of Therapy

Narcolepsy

Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when the following criteria is met:

- The patient has achieved or maintained a positive response to treatment from baseline.

Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP).

Shift Work Disorder (SWD)

Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient is still a shift-worker.

Quantity Limits Apply

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.

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

Duration of Approval (DOA)

- 534-C: DOA: 12 months

References

1. Nuvigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals; December 2022.
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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/19/2024).
4. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.

Reference number(s)
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5. 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 Clin Sleep Med. 2009;5(3):263-276.
6. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
7. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
8. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
9. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021;17(9):1895-1945.