

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

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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.
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Document History

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External Review: 02/2001; 02/2003; 04/2004; 11/2005, 06/2006, 08/2007, 10/2008, 05/2009, 12/2010, 10/2011, 10/2011, 10/2012, 08/2013, 08/2014, 08/2015, 08/2016, 08/2017, 08/2018, 08/2019, 08/2020, 08/2021, 08/2022, 08/2023, 04/2024, 04/2025

CRITERIA FOR APPROVAL

- | | | | |
|---|--|-----|----|
| 1 | Does the patient have a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA)?
[If Yes, then go to 2. If No, then go to 9.] | Yes | No |
|---|--|-----|----|

2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then go to 5.]	Yes	No
3	Has the patient achieved or maintained a positive response to treatment from baseline? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Is the patient compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)? [If Yes, then go to 21. If No, then no further questions.]	Yes	No
5	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Is the diagnosis confirmed by polysomnography or home sleep apnea test (HSAT) with a technically adequate device? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Has the patient been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Will the patient continue to use continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP) after the requested drug is started? [If Yes, then go to 21. If No, then no further questions.]	Yes	No
9	Does the patient have a diagnosis of excessive sleepiness associated with narcolepsy? [If Yes, then go to 10. If No, then go to 14.]	Yes	No
10	Is this request for continuation of therapy? [If Yes, then go to 11. If No, then go to 12.]	Yes	No
11	Has the patient achieved or maintained a positive response to treatment from baseline? [If Yes, then go to 21. If No, then no further questions.]	Yes	No
12	Is the requested drug being prescribed by, or in consultation with, a sleep specialist?	Yes	No

[If Yes, then go to 13. If No, then no further questions.]		
13	Is the diagnosis confirmed by a sleep study? [If Yes, then go to 21. If No, then no further questions.]	Yes No
14	Does the patient have a diagnosis of excessive sleepiness associated with Shift Work Disorder (SWD)? [If Yes, then go to 15. If No, then no further questions.]	Yes No
15	Is this request for continuation of therapy? [If Yes, then go to 16. If No, then go to 18.]	Yes No
16	Has the patient achieved or maintained a positive response to treatment from baseline? [If Yes, then go to 17. If No, then no further questions.]	Yes No
17	Is the patient still a shift-worker? [If Yes, then go to 21. If No, then no further questions.]	Yes No
18	Is the requested drug being prescribed by, or in consultation with, a sleep specialist? [If Yes, then go to 19. If No, then no further questions.]	Yes No
19	Has a sleep log and actigraphy monitoring been completed for at least 14 days and shows a disrupted sleep and wake pattern? [If Yes, then go to 20. If No, then no further questions.]	Yes No
20	Have the patient's symptoms been present for 3 or more months? [If Yes, then go to 21. If No, then no further questions.]	Yes No
21	Does the patient require MORE than the plan allowance per month of any of the following: A) 60 tablets of armodafinil (Nuvigil) 50 mg, B) 30 tablets of armodafinil (Nuvigil) 150 mg, 200 mg, 250 mg? [No further questions]	Yes No
RPh Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.		

Mapping Instructions			
	Yes	No	DENIAL REASONS

1.	Go to 2	Go to 9	
2.	Go to 3	Go to 5	
3.	Go to 4	Deny	<p>Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Continuation: Efficacy]</p>
4.	Go to 21	Deny	<p>Your plan only covers this drug if you are using it with treatment for airway problems due to obstructive sleep apnea. We have denied your request because you are not using it with treatment for airway problems due to obstructive sleep apnea. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Continuation: Not on required concurrent therapy with PAP]</p>
5.	Go to 6	Deny	<p>Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Prescriber specialty]</p>
6.	Go to 7	Deny	<p>Your plan only covers this drug when you have a sleep test that shows obstructive sleep apnea (OSA). We denied your request</p>

			<p>because we did not receive your results, or your test result did not show obstructive sleep apnea (OSA). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Lab/test for OSA]</p>
7.	Go to 8	Deny	<p>Your plan only covers this drug if you have been using treatment for airway problems due to obstructive sleep apnea for at least one month. We have denied your request because you have not been using treatment for airway problems due to obstructive sleep apnea for one month. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Not on required concurrent therapy with PAP for 1 month]</p>
8.	Go to 21	Deny	<p>Your plan only covers this drug if you will be using it with treatment for airway problems due to obstructive sleep apnea. We have denied your request because you will not be using it with treatment for airway problems due to obstructive sleep apnea. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Not on required concurrent therapy with PAP]</p>
9.	Go to 10	Go to 14	

10.	Go to 11	Go to 12	
11.	Go to 21	Deny	<p>Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Continuation: Efficacy]</p>
12.	Go to 13	Deny	<p>Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Prescriber specialty]</p>
13.	Go to 21	Deny	<p>Your plan only covers this drug when you have a sleep lab test that shows narcolepsy. We denied your request because we did not receive your results, or your test result did not show narcolepsy. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Lab/test for narcolepsy]</p>
14.	Go to 15	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are: A) Obstructive sleep apnea (OSA), B) Narcolepsy, and C) Shift work disorder (SWD). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing</p>

			<p>information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
15.	Go to 16	Go to 18	
16.	Go to 17	Deny	<p>Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Continuation: Efficacy]</p>
17.	Go to 21	Deny	<p>We have denied your request because your plan does not cover this drug if you are no longer a shift worker. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Exclusion, No longer shift worker]</p>
18.	Go to 19	Deny	<p>Your plan only covers this drug if your doctor is a sleep specialist or has talked about your care plan with a sleep specialist. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Prescriber specialty]</p>

19.	Go to 20	Deny	<p>Your plan only covers this drug when you have a sleep test that shows shift work disorder (SWD). We denied your request because we did not receive your results, or your test result did not show shift work disorder (SWD). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Lab/test for SWD]</p>
20.	Go to 21	Deny	<p>Your plan only covers this drug if you have had symptoms for 3 or more months. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Disease duration]</p>
21.	Deny	[PA approved for 12 months. See Quantity Limit Chart.]. Approve, 12 Months	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers [A) 60 tablets per 30 days of Nuvigil 50 mg; B) 30 tablets per 30 days of Nuvigil 150 mg, 200 mg, 250 mg]. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Exceeds max limit, Partial denial]</p>