

**Clinical Policy: Armodafinil (Nuvigil)**

Reference Number: CP.PMN.35

Effective Date: 08.01.09

Last Review Date: 05.18

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Armodafinil (Nuvigil<sup>®</sup>) is a wakefulness-promoting agent.

**FDA Approved Indication(s)**

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

Limitation(s) 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.

**Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Nuvigil is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Narcolepsy (must meet all):**

1. Diagnosis of narcolepsy;
2. Age  $\geq$  17 years;
3. Failure of a 1 month trial of one of the following central nervous system stimulants: amphetamine immediate release (IR), amphetamine; dextroamphetamine IR, dextroamphetamine, or methylphenidate IR, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 250 mg/day.

**Approval duration:**

**Medicaid/HIM** - 12 months

**Commercial** - Length of Benefit

**B. Obstructive Sleep Apnea/Hypopnea Syndrome (must meet all):**

1. Diagnosis of OSA;
2. Age  $\geq$  17 years;

3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy;
4. Dose does not exceed 250 mg/day.

**Approval duration:**

**Medicaid/HIM** - 12 months

**Commercial** - Length of Benefit

**C. Shift Work Disorder (SWD) (must meet all):**

1. Diagnosis of SWD;
2. Age  $\geq$  17 years;
3. Dose does not exceed 150 mg/day.

**Approval duration: 12 months**

**D. Fatigue Associated with Multiple Sclerosis (MS) (off-label) (must meet all):**

1. Diagnosis of MS-related fatigue;
2. Age  $\geq$  17 years;
3. Failure of 200 mg/day of amantadine and  $\geq$  10 mg/day of methylphenidate, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 250 mg/day.

**Approval duration:**

**Medicaid/HIM** - 12 months

**Commercial** - Length of Benefit

**E. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
  - a. Narcolepsy, OSA, and MS-associated fatigue: 250 mg per day;
  - b. SWD: 150 mg per day.

**Approval duration:**

**Medicaid/HIM** - 12 months

**Commercial** - SWD - 12 months; length of Benefit all other indications

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CPAP: continuous positive airway pressure

FDA: Food and Drug Administration

MS: multiple sclerosis

OSA: obstructive sleep apnea

SWD: shift work disorder

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
Evekeo <sup>®</sup> (amphetamine)	Narcolepsy 5 to 60 mg/day PO in divided doses	60 mg/day
amphetamine/ dextroamphetamine (Adderall <sup>®</sup> )		
dextroamphetamine ER (Dexedrine <sup>®</sup> Spansule <sup>®</sup> )		
dextroamphetamine IR (Zenzedi <sup>®</sup> , Procentra <sup>®</sup> )		
methylphenidate IR (Ritalin <sup>®</sup> , Methylin <sup>®</sup> )	Narcolepsy 10 to 60 mg/day PO in 2 to 3 divided doses	60 mg/day
	MS-related fatigue <sup>†</sup> Usual effective dose: 10-20 mg PO QAM and noon	
amantadine (Symmetrel <sup>®</sup> )	MS-related fatigue <sup>†</sup> 200 mg PO once daily or 100 mg PO twice daily	200 mg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

†Off-label indication

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Narcolepsy	150 mg to 250 mg orally once a day	250 mg/day
OSA		
SWD	150 mg orally once a day as a single dose approximately 1 hour prior to the start of work shift	150 mg/day
MS-related fatigue (off-label)	150 mg orally every morning	250 mg/day

**VI. Product Availability**

Tablets: 50 mg, 150 mg, 200 mg, and 250 mg

**VII. References**

1. Nuvigil Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; February 2017. Available at: <https://nuvigil.com/>. Accessed January 20, 2018.
2. Morgenthaler TI, Kapur VK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin An American Academy of Sleep Medicine Report: An American Academy of Sleep Medicine Report. *Sleep*. 2007;30(12):1705-1711.
3. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009 Jun 15;5(3):263-76.
4. Morgenthaler TI, Lee-Chiong T, Alessi C, et al. Practice Parameters for the Clinical Evaluation and Treatment of Circadian Rhythm Sleep Disorders: An American Academy of Sleep Medicine Report. *Sleep*. 2007;30(11):1445-1459.
5. Billiard M, Dauvilliers Y, Dolenc-Groselj L, Lammers GJ, Mayer G, Sonka K. Management of narcolepsy in adults. In: Gilhus NE, Barnes MP, Brainin M, editor(s). *European handbook of neurological management*. 2nd ed. Vol. 1. Oxford (UK): Wiley-Blackwell; 2011. p. 513-28. [118 references]
6. Management of MS-Related Fatigue. Expert Opinion Paper. National Multiple Sclerosis Society; 2006.  
<http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Opinion-Paper-Management-of-MS-Related-Fatigue.pdf>.
7. Braley TJ; Chervin RD. Fatigue in multiple sclerosis: mechanisms, evaluation, and treatment. *SLEEP* 2010;33(8):1061-1067.
8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added 200 mg dosage.	05.14	05.14

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Updated Criteria for Approval item D to address documentation of intolerance to modafinil. References updated.		
Updated approval age and references.	03.15	03.15
Converted into new policy template; Criteria: updated age to $\geq 17$ years of age ( $\geq 18$ years for MS-related fatigue); added max dose per indication, trial must be within the last 6 months (narcolepsy and MS related fatigue); re-auth: removed reported daytime improvements or use of the Epworth Sleepiness Scale requirement as they are subjective information; added member is receiving medication via Centene benefit and adherent as evidenced in claims history and max dosage per indication; added no concurrent benzodiazepine use requirement. Updated reference section to reflect current literature search.	02.16	05.16
No clinical changes to criteria: -Converted to new template -Modified duration of stimulant trial for narcolepsy from $\geq 2$ months to $\geq 1$ month so that it is consistent with Xyrem policy; -Added “armodafinil” to requirement related to hypersensitivity to modafinil per PI -Removed “Armodafinil will not be approved for concurrent use with benzodiazepines” per new template update and since this requirement cannot be enforced post-approval without an edit -Modified age requirement for MS-related fatigue from $\geq 18$ years to $\geq 17$ years of age per PI (pediatric patients defined as less than 17 years of age) -Updated references to reflect current literature search	01.17	05.17
2Q 2018 annual review: no significant changes from previously approved corporate policy; policies combined for commercial, HIM, and Medicaid lines of business; Commercial: split from CP.CPA.105 armodafinil (Nuvigil), modafinil (Provigil); Commercial: age added; Narcolepsy: added criterion related to stimulant trial; OSA: added documented evidence of residual sleepiness despite compliant CPAP use; MS-related fatigue: added requirement related to trial and failure of amantadine and methylphenidate HIM and Medicaid: removed timeframe of trial within the last 6 for months for stimulants for the relevant indications; Medicaid: removed requirement pertaining to hypersensitivity to armodafinil/modafinil; modified initial approval duration from 6 months to 12 months; references reviewed and updated.	01.20.18	05.18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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