Clinical Policy: Armodafinil (Nuvigil)
Reference Number: CP.PMN.35
Effective Date: 08/09
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Armodafinil (Nuvigil®) is a wakefulness-promoting agent.

FDA approved indication
Nuvigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with:
- Obstructive sleep apnea (OSA)
- Narcolepsy
- 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.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® 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 ≥ 17 years;~~
2. ~~Documented failure of 2 month course of methylphenidate or amphetamine derivatives at the maximum recommended dose of 60mg daily within the last 6 months, unless contraindicated;~~
4. ~~No documentation of hypersensitivity to modafinil (armodafinil will not be approved when there is documentation of hypersensitivity to modafinil);~~
5. ~~Armodafinil will not be approved for concurrent use with benzodiazepines;~~
3. Failure of a 1 month trial of one of the following central nervous system (CNS) stimulants: amphetamine immediate release (IR), amphetamine; dextroamphetamine IR, dextroamphetamine, or methylphenidate IR, at up to maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced;

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4. No documentation of hypersensitivity to armodafinil or modafinil;
6.5. ~~Requested d~~Dose does not exceed 250 mg/day.

Approval duration: 6 months

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

1. Diagnosis of obstructive sleep apnea;
2. Age ≥ 17 years;
3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy;
4. No documentation of hypersensitivity to armodafinil or modafinil;
~~5. Armodafinil will not be approved for concurrent use with benzodiazepines;~~
6.5. ~~Requested d~~Dose does not exceed 250 mg/day.

Approval duration: 6 months

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

1. Diagnosis of shift work disorder;
2. Age ≥ 17 years;
3. No documentation of hypersensitivity to armodafinil or modafinil;
~~4. Armodafinil will not be approved for concurrent use with benzodiazepines;~~
5.4. ~~Requested d~~Dose does not exceed 150 mg/day.

Approval duration: 6 months

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

1. Diagnosis of MS-related fatigue;
2. Age ≥ 17~~8~~ years;
3. ~~Trial and f~~Failure of 200 mg/day of amantadine and ≥ 10 mg/day of methylphenidate, ~~the following (a and b),~~ one of which must be within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced;~~:~~
~~a. Amantadine 100mg bid, unless contraindicated;~~
~~b. Methylphenidate 10 to 60mg per day, in two to three divided doses, unless contraindicated.~~
4. No documentation of hypersensitivity to armodafinil or modafinil;
~~5. Armodafinil will not be approved for concurrent use with benzodiazepines;~~
6.5. ~~Requested d~~Dose does not exceed 250 mg/day.

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria; ~~Claims history shows member is currently receiving this medication via Centene benefit and adherent to treatment regimen;~~
2. Documentation of positive response to therapy;

~~2.~~3. If request is for a dose increase, new dose does not exceed ~~request must not exceed FDA approved limit per indication~~the FDA approved maximum recommended dose for the relevant indication. For MS-related fatigue, ~~requested d~~dose does not exceed 250 mg/day. ~~;~~

~~3. Armodafinil will not be approved for concurrent use with benzodiazepines.~~

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 ~~(~~months~~)~~

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 policy – CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CNS: central nervous system

CPAP: continuous positive airway pressure
FDA: Food and Drug Administration
MS: multiple sclerosis
OSA: obstructive sleep apnea
OSAHS: obstructive sleep apnea/hypopnea syndrome
SWD: shift work disorder

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V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Narcolepsy	150 mg to 250 mg orally once a day	250 mg/day
Obstructive sleep apnea		
Shift work disorder	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†	150 mg every morning	250 mg/day

†*Off-label indication*

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VI. Product Availability

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

VII. Workflow Document

CP.PMN.35.armodafinil (Nuvigil)workflo

Field Code Changed

VIII. References

1. Nuvigil® prescribing information. Accessed Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2015. Available at: -https://nuvigil.com/. Accessed January 9, 2017.
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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.
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2. February 2016. Available at: http://www.nuvigil.com/PDF/Full_Prescribing_Information.pdf.
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9. Olek MJ. Symptom management of multiple sclerosis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed February 4, 2016.

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
References updated to reflect current literature search.	04/10	04/10
Added the following language to the Description section: 1. Armodafinil is a psychostimulant and the R-enantiomer of the racemic compound modafinil (Provigil®). 2. Armodafinil is a schedule C-IV controlled substance. Criteria for Approval section revised to exclude concomitant use with benzodiazepines. Special Instructions section updated for warnings on abuse potential. References updated to reflect current literature search.	05/11	05/11
Added the following language to the diagnosis requirement: "consistent with DSM-IV criteria and evidenced in the progress notes". Added dosing qualifiers to prior trials and failures. References updated.	05/12	05/12
Updated the Special Instructions section with geriatric dosing caution. Update the Specials Instructions section with impaired hepatic function dosing. References updated.	05/13	05/13
Added 200mg dosage. Updated Criteria for Approval item D to address documentation of intolerance to modafinil. References updated.	05/14	05/14
Updated approval age and references.	03/15	03/15
Converted into new policy template; Criteria: updated age to ≥17 years of age (≥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 ≥ 2 months to ≥ 1 month so that it is consistent with Xyrem policy;	01/17	05/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
-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 ≥18 years to ≥17 years of age per PI (pediatric patients defined as less than 17 years of age) -Updated references to reflect current literature search		

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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.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.