Clinical Policy: Armodafinil (Nuvigil)
Reference Number: HIM.PA.94
Effective Date: 12/14
Last Review Date: 08/17
Line of Business: Health Insurance Marketplace

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, or shift work disorder (SWD).

Limitation 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

I. Initial Approval Criteria

A. Narcolepsy (must meet all)**:**
1. Diagnosis of narcolepsy;
2. Age ≥ 17 years;
3. Failure of a 1 month trial of a methylphenidate or amphetamine derivative at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 250 mg per day.

Approval duration: 12 months

B. Treatment of Obstructive Sleep Apnea/Hypopnea Syndrome (must meet all)**:**
1. Diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS);
2. Age ≥ 17 years;
3. Documented evidence of residual sleepiness despite compliant CPAP use as monotherapy;
4. Dose does not exceed 250 mg per day.

Approval duration: 12 months

C. Shift Work Disorder (must meet all)**:**
1. Diagnosis of shift work disorder (SWD);
2. Age ≥ 17 years;
3. Dose does not exceed 150 mg per day.

Approval duration: 12 months

D. Multiple Sclerosis (MS) Associated Fatigue (off-label) (must meet all)**:**
1. Diagnosis of MS-related fatigue;
2. Age ≥ 17 years;
3. Failure of 200 mg/day of amantadine and ≥ 10 mg/day of methylphenidate, one of which must be within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 250 mg per day.

Approval duration: 12 months

E. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy (e.g., improvement in measures, such as reported daytime improvements in wakefulness);
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. Narcolepsy, OSAHS, and MS-associated fatigue: 250 mg per day;
   b. SWD: 150 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 – HIM.PHAR.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
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

V. References

1. Nuvigil Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA Inc.; February 2017. Available at http://nuvigil.com/. Accessed April 17, 2017.
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4. Specific Monograph: Methylphenidate Monograph. Clinical Pharmacology. Accessed January 2017. http://www.clinicalpharmacology-ip.com
5. 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.
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7. 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.
8. 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.
9. Management of MS-Related Fatigue. Expert Opinion Paper. National Multiple Sclerosis Society. Available at http://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms/Fatigue. Accessed January 13, 2017.
10. Braley TJ; Chervin RD. Fatigue in multiple sclerosis: mechanisms, evaluation, and treatment. SLEEP 2010;33(8):1061-1067.
11. Management of MS-Related Fatigue. Expert Opinion Paper. National Multiple Sclerosis Society; 2006. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Opinion-Paper-Management-of-MS-Related-Fatigue.pdf.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reformatted guideline to new format. Adjusted criteria for flow. Added Workflow reference document.	12/15	12/15
Edited for flow. Removed reference to maximum mg dose: (60mg daily.) from narcolepsy section and MS associated fatigue sections. Removed Exclusions and Workflow reference document.	11/16	11/16
Converted to new template; modified age requirement from greater than 17 years to ≥ 17 years (pediatric patients defined as age < 17 years) per PI; changed initial approval duration from 6 to 12 months (to be consistent with Provigil criteria); modified duration of stimulant trial for narcolepsy to 1 month; MS-fatigue: added doses for amantadine and methylphenidate trials and specified that one of	04/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
the trials must be within the last 6 months; updated references.		

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.

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.