Clinical Policy: Armodafinil (Nuvigil)
Reference Number: ERX.NPA.21
Effective Date: 09.01.17
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] 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)

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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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;
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 within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 250 mg/day.

Approval duration: 12 months

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

Approval duration: 12 months

C. Shift Work Disorder (must meet all)**:**
1. Diagnosis of SWD;
2. Age ≥ 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 ≥ 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/day.

Approval duration: 12 months

E. Other diagnoses/indications
1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively 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. Narcolepsy, OSAHS, and MS-related fatigue: 250 mg/day;
   b. SWD: 150 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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**

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Evekeo® (amphetamine)	Narcolepsy 5 to 60 mg/day PO in divided doses	60 mg/day
Amphetamine/ dextroamphetamine (Adderall®)		
Dextroamphetamine ER (Dexedrine® Spansule®)		
Dextroamphetamine IR (Zenzedi®, Procentra®)		

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Methylphenidate IR (Ritalin®, Methylin®)	Narcolepsy 10 to 60 mg/day PO in 2 to 3 divided doses MS-related fatigue† Usual effective dose: 10-20 mg PO QAM and noon	60 mg/day
Amantadine (Symmetrel®)	MS-related fatigue† 200 mg PO once daily or 100 mg PO twice daily	200 mg/day

**May require a PA*
†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
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 (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.; April 2015. Available at: https://nuvigil.com/. Accessed June 19, 2017.
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.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from ERX.NSMN.08 Armodafinil and modafinil (retired) and converted to new template.	06/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Narcolepsy: added that stimulant trial should have occurred within the last 6 months. OSA: added requirement of residual sleepiness despite compliant CPAP use as monotherapy. Added off-label criteria for MS-related fatigue. Modified generalized max dose/health plan approved QL requirement to specific max dose. 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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.