RXADVANCE
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Clinical Policy Title:	armodafinil
Policy Number:	RxA.416
Drug(s) Applied:	Nuvigil®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

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

Dosage Forms

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

Clinical Policy

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

I. Initial Approval Criteria

A. Narcolepsy (must meet all):
1. Diagnosis of narcolepsy;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 17 years;
4. Failure of a 1-month trial of one of the following central nervous system stimulants at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: amphetamine immediate-release (IR), amphetamine; dextroamphetamine IR, dextroamphetamine, or methylphenidate IR;
   **Prior authorization may be required for CNS stimulants*
5. Dose does not exceed 250 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months
HIM: 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 per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

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

Approval Duration
Commercial: 12 months
Medicaid: 12 months

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

Approval Duration
Commercial: 12 months
Medicaid: 12 months
HIM: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed:
   a. Narcolepsy, OSA, and MS-associated fatigue: 250 mg per day;
   b. SWD: 150 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months
HIM: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CPAP: continuous positive airway pressure
FDA: Food and Drug Administration
IR: immediate-release
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.

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

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†Off-label indication

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to modafinil or armodafinil

- Boxed Warning(s):
  - None reported

References

1. Nuvigil Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2018. Available at: https://nuvigil.com/. Accessed July 21, 2020.
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/Op inion-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.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 21, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed 1. Clinical Policy title was updated. 2. Lines of business 'Policy Applies to' was updated to 'All lines of business'. 3. Approval duration updated for both Initial and Continued Approval criteria. 4. Continued therapy criteria II.A.1 was	07/21/2020	09/14/2020

rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Reference reviewed and updated.		