Clinical Policy Title:	armodafinil
Policy Number:	RxA.416
Drug(s) Applied:	Nuvigil®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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 orally once a day *±	250 mg/day
	OSA	150 mg to 250 mg orally once a day *±	250 mg/day
	SWD	150 mg orally once a day as a single dose approximately 1 hour prior to the start of work shift *±	150 mg/day

* Recommendation of reduced dose in severe hepatic impairment patient due to decreased clearance and increased steady-state concentration of modafinil in this patient population.
±Consideration should be given to the use of lower doses and close monitoring in geriatric patients.

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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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

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

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Member is 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

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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
amphetamine (Evekeo®)	**Narcolepsy** 5 to 60 mg/day orally in divided doses	60 mg/day
amphetamine/ dextroamphetamine (Adderall®)		
dextroamphetamine ER (Dexedrine® Spansule®)		
dextroamphetamine IR (Zenzedi®, Procentra®)		
methylphenidate IR (Ritalin®)	**Narcolepsy** 10 to 60 mg/day orally in 2 to 3 divided doses, 30 to 45 minutes before meal **MS-associated fatigue†** Usual effective dose: 10-20 mg orally every morning and noon	60 mg/day
amantadine (Symmetrel®)	**MS-associated fatigue†** 200 mg orally once daily or 100 mg orally twice daily	200 mg/day

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

†Off-label indication

APPENDIX C: Contraindications/Boxed Warnings

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

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Serious Rash, including Stevens-Johnson Syndrome: discontinue Nuvigil® at the first sign of rash, unless the rash is clearly not drug-related.
- DRESS/Multi-organ Hypersensitivity Reactions: if suspected, discontinue Nuvigil®.
- Angioedema and Anaphylaxis Reactions: if suspected, discontinue Nuvigil®.
  Psychiatric Symptoms: use particular caution in treating patients with a history of psychosis, depression, or mania. Consider discontinuing Nuvigil® if psychiatric symptoms develop.

References

1. Nuvigil® Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2018. Available at: https://nuvigil.com/. Accessed June 28, 2021.
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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 rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Reference reviewed and updated.	07/21/2020	09/14/2020
Policy was reviewed: 1. Dosing Information was updated to include footnotes, "* Recommendation of reduced dose in severe hepatic impairment patient due to decreased clearance and increased steady-state concentration…". 2. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 3. Initial Approval Criteria and Continued Therapy Approval criteria were updated to remove HIM approval duration. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to " Member is currently receiving the medication that has been authorized by RxAdvance..." 5. Therapeutic alternative verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance..". 6. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 7. Appendix D was updated to include warnings and precautions, "Serious Rash, including Stevens-Johnson Syndrome: discontinue Nuvigil®…" 8. References were reviewed and updated.	06/28/2021	09/14/2021