



Prior Authorization Approval Criteria

Nuvigil (armodafinil)

Generic name:	armodafinil
Brand name:	Nuvigil
Medication class:	antinarcoleptic
FDA-approved uses:	Narcolepsy Shift Work Sleep Disorders (SWSD) Adjunct to standard treatments for Obstructive Sleep Apnea (OSA)
Available dosage forms:	50 mg, 150 mg, 250 mg tablet
Usual dose:	Narcolepsy: 150-250 mg orally once daily SWSD: 150-250 mg given as a single dose one hour prior to the start of work OSA: 150-250 mg once daily
Approximate monthly cost: (based on AWP 2009)	\$336.60 for 150mg and 250mg.
Duration of therapy:	Indefinite

Criteria for Use for all indications:

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be prescribed by or recommended by a neurologist. (For sleep apnea, must be prescribed by or recommended by a neurologist or a pulmonary specialist.) Clinical notes of the specialist consult is required.

Criteria for Use: Narcolepsy: *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed narcolepsy
- Failed/intolerant to at least one formulary/preferred treatment, such as methylphenidate or dextroamphetamine, or a compelling rationale as to why these agents cannot be used.
- If approved, only 30 pills per month will be allowed.

Criteria for Use: SWSD *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed shift work sleep disorder.
- Documentation of the patient work shift since the amount of doses will be based on the patients work shift.

Criteria for use: OSA *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed obstructive sleep apnea
- Documentation that the patient has been compliant with continuous positive airway pressure (CPAP) for at least 2 months for at least 4 hours per night.

Contraindication:

- In patients with known hypersensitivity to modafinil and armodafinil or its inactive ingredients.

Not approved if:

- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of Nuvigil.

- Being used in pediatric patients.
- Being used for an off label use for any other indication than specified in the above criteria for approval and shall be considered investigational.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/09/09