



AmeriHealth.

Policy Title Armodafinil (Nuvigil®)

Policy Number FS.CLIN.31

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy	<p>Armodafinil (Nuvigil®) is a stimulant-like wakefulness-promoting agent indicated for the treatment of excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSA/HS) and shift work sleep disorder (SWSD).</p> <p>The use of armodafinil (Nuvigil®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review) to determine medical necessity.</p>
Policy description	<p>Armodafinil (Nuvigil®) is the R-enantiomer of modafinil with the longer half-life. It is a schedule-IV agent. Its precise mechanism of action(s) is unknown. Both armodafinil and modafinil have wake-promoting actions similar to sympathomimetic agents including amphetamine and methylphenidate, although their pharmacologic profile is not identical to that of the sympathomimetic amines.</p>
Policy guideline inclusion	<p><u>NARCOLEPSY</u> Armodafinil (Nuvigil®) is approved when the following inclusion criterion is met:</p> <ul style="list-style-type: none">• Documentation of a diagnosis of Narcolepsy with recommendation of armodafinil (Nuvigil®) by a neurologist or sleep specialist <p><u>OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS)</u> Armodafinil (Nuvigil®) is approved when both of the following inclusion criteria are met:</p> <ul style="list-style-type: none">• Documentation of a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS)• Documentation that armodafinil (Nuvigil®) will be used concurrently with continuous positive airway pressure (CPAP) <p><u>SHIFT WORK SLEEP DISORDER (SWSD)</u> Armodafinil (Nuvigil®) is approved when all of the following inclusion criteria are met:</p> <ul style="list-style-type: none">• Member meets one of the following:<ul style="list-style-type: none">○ Documentation of a diagnosis of Shift Work Sleep Disorder with recommendation of armodafinil (Nuvigil®) by a neurologist or sleep specialist○ Polysomnography and the multiple sleep latency test (MSLT) demonstrate loss of a normal sleep-wake pattern

- No medical or mental disorder accounts for the symptoms
- The symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness (e.g. time-zone change [jet lag] syndrome)

Policy guideline exclusion

NARCOLEPSY

Armodafinil (Nuvigil®) is denied when the following exclusion criterion is present:

- No documentation of a diagnosis of Narcolepsy with recommendation of armodafinil (Nuvigil®) by a neurologist or sleep specialist

OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS)

Armodafinil (Nuvigil®) is denied when **either** of the following exclusion criteria is present:

- No documentation of a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS)
- No documentation that armodafinil (Nuvigil®) will be used concurrently with continuous positive airway pressure (CPAP)

SHIFT WORK SLEEP DISORDER (SWSD)

Armodafinil (Nuvigil®) is denied when **either** of the following exclusion criteria is present:

- Member does not meet **one** of the following:
 - Documentation of a diagnosis of Shift Work Sleep Disorder with recommendation of armodafinil (Nuvigil®) by a neurologist or sleep specialist
 - Polysomnography and the multiple sleep latency test (MSLT) demonstrate loss of a normal sleep-wake pattern
- A medical or mental disorder accounts for the symptoms
- The symptoms meet criteria for other sleep disorder producing insomnia or excessive sleepiness (e.g. time-zone change [jet lag] syndrome).

Policy List of Applicable Drugs

Brand Name	Generic Name
Nuvigil	Armodafinil

Dosing and administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy references

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Policy link to related policies

Version effective date

October 1, 2011

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