



PHARMACY COVERAGE GUIDELINES
SECTION: MEDICATIONS

NEXT REVIEW DATE: 2ND QTR 2012

ORIGINAL EFFECTIVE DATE: 4/08/10

LAST REVIEW DATE: 9/29/11

LAST CRITERIA REVISION DATE:

ARCHIVE DATE:

NUVIGIL™ (ARMODAFINIL)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety. The guideline is not a guarantee of coverage.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available. The guideline in effect on the date of service will determine coverage.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Nuvigil is a non-amphetamine wake-promoting agent for oral administration. Nuvigil is approved by the Food and Drug Administration (FDA) to improve wakefulness in individuals with excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work sleep disorder.



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NUVIGIL (ARMODAFINIL) (cont.)

Precertification:

Precertification* for Nuvigil is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) retail and mail order prescription benefit. Medications requiring precertification are identified on the following list located on the Internet at <http://www.azblue.com/pdfs/medications/pharmacy/QIList.pdf>:

"Prescription Limitations and Precertification Requirements for Retail and Mail Order Prescriptions"

This list may also be requested by calling (602) 864-4273 or (800) 232-2345, ext. 4273.

Please refer to this list for Nuvigil maximum dosage and other drug limitations.

- * Precertification will not be required for certain individuals who are already receiving Nuvigil. Members having at least one BCBSAZ paid claim for Nuvigil within the six months preceding the current prescription will not need to obtain precertification.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Criteria:

- **Under the member's BCBSAZ retail and mail order prescription benefit**, Nuvigil is considered **medically necessary** for individuals 18 years of age* and older with documentation of **ONE** of the following:
 1. Excessive sleepiness associated with narcolepsy
 2. Excessive sleepiness due to obstructive sleep apnea in an individual on continuous positive airway pressure (CPAP) therapy
 3. Excessive sleepiness due to shift work sleep disorder
 - Individual with complaints of persistent and frequent excessive sleepiness and/or falling asleep while at work **and**
 - Individual is not receiving other drugs **or** does not have a medical condition known to cause or contribute to sleepiness
- * Nuvigil has not been studied in pediatric patients in any setting and is not FDA-approved for use in pediatric patients for any condition.



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NUVIGIL (ARMODAFINIL) (cont.)

Criteria: (cont.)

- Nuvigil for all other indications not previously listed is considered *experimental or investigational* based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Dept review	10/12/10	Updated disclaimer; removed Note section
Director Pharmacy Mgmt review	03/25/10	Adopted guideline (effective 04/08/10)
Medical Policy Panel review	03/09/10	Development
Director Pharmacy Mgmt review	03/03/10	Development

Criteria Revisions:



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NUVIGIL (ARMODAFINIL) (cont.)

Resources:

FDA Product Approval Information for Nuvigil:

- FDA-approved indication: To improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy and shift work sleep disorder. In OSAHS, NUVIGIL is indicated as an adjunct to standard treatment(s) 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. If NUVIGIL is used adjunctively with CPAP, the encouragement of and periodic assessment of CPAP compliance is necessary. In all cases, careful attention to the diagnosis and treatment of the underlying sleep disorder(s) is of utmost importance. Prescribers should be aware that some patients may have more than one sleep disorder contributing to their excessive sleepiness. The effectiveness of NUVIGIL in long-term use (greater than 12 weeks) has not been systematically evaluated in placebo-controlled trials. The physician who elects to prescribe NUVIGIL for an extended time in patients should periodically re-evaluate long term usefulness for the individual patient.
- FDA-approved dosage: The recommended dose of NUVIGIL for patients with OSAHS or narcolepsy is 150 mg or 250 mg given as a single dose in the morning. In patients with OSAHS, doses up to 250 mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 150 mg/day dose. The recommended dose of NUVIGIL for patients with SWSD is 150 mg given daily approximately 1 hour prior to the start of their work shift. Consider use of lower doses in the elderly patients and in patients with severe hepatic impairment.