

Pharmacy Policy Bulletin

Title: Armodafinil /modafinil

Policy #: Rx.01.5

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, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). 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. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. 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.

▸ Intent:

The intent of this policy is to communicate the medical necessity criteria for **armodafinil** and **modafinil** as provided under the member's prescription drug benefit.

▸ Description:

Armodafinil is the R-enantiomer of modafinil with the longer half-life. Its precise mechanism of action 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.

Modafinil is a wakefulness-promoting agent. Modafinil promotes actions similar to the traditional central nervous system (CNS) stimulants amphetamine and methylphenidate, but has a pharmacologic profile different from that of sympathomimetic amines. Although the precise mechanism of action is unknown, modafinil promotes wakefulness by selectively increasing neuronal activation in discrete regions of the brain (e.g., anterior hypothalamus) that are believed to be involved in mediating normal wakefulness. Modafinil is not indicated for use in circadian rhythm sleep disorders or other sleep deprivation disorders.

Armodafinil and modafinil are indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA), narcolepsy, or shift work disorder (SWD). Neither medication is a treatment for the underlying cause of obstruction in those with OSA.

▸ Policy:

Armodafinil or **modafinil** is approved when ONE the following is met:

- A. Diagnosis of narcolepsy and recommended by a neurologist or sleep specialist; OR
- B. Diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS) by a sleep specialist and used as adjunct to standard therapy; OR
- C. Diagnosis of Shift Work Sleep Disorder (SWSD) with documentation of ALL of the following:
 - 1. Documentation of one of the following:
 - a. Recommendation of armodafinil or modafinil by a neurologist or sleep specialist
 - b. Polysomnography and the multiple sleep latency test (MSLT) demonstrate loss of a normal sleep-wake pattern
 - 2. Symptoms cannot be attributed to a medical condition
 - 3. The symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness (e.g., time-zone change [jet lag] syndrome)

▸ Black Box Warning:

N/A

▸ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▸ References:

Armodafinil. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed July 27, 2017.

Modafinil. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed July 27, 2017.

▸ Applicable Drugs:

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Generic Name
Armodafinil
Modafinil

▸ Cross References:

N/A

Policy Version Number: 10.00
 P&T Approval Date: July 12, 2018

Policy Effective Date:	October 01, 2018
Next Required Review Date:	July 12, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.