

Pharmacy Medical Necessity Guidelines: Analeptic CNS Stimulants: Armodafinil and Modafinil

Effective: January 1, 2024

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|---|----|----------------------------------|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review | RXUM |
| These pharmacy medical necessity guidelines apply to the following: <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan | | | Fax Numbers: RXUM: 617.673.0988 |

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Modafinil and armodafinil are indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea (OSA) and shift work disorder (SWD).

COVERAGE GUIDELINES

The plan may authorize coverage of armodafinil or modafinil for Members when **all** the following criteria for a particular diagnosis are met and limitations do not apply:

1. Documented diagnosis of excessive daytime sleepiness associated with one of the following chronic medical conditions:
 - a. Narcolepsy
 - b. Obstructive sleep apnea (OSA)/hypoapnea syndrome
 - c. Multiple sclerosis
 - d. Chronic fatigue syndrome
 - e. Organic brain disorder
 - f. Parkinson’s disease
 - g. Idiopathic hypersomnia
 - h. Depression
 - i. Cancer-related fatigue in patients being treated with chemotherapy
 - j. Shift work disorder

LIMITATIONS

1. Requests for brand-name products, with AB-rated generics, will be reviewed according to Non-covered Medications criteria.
2. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.
3. Armodafinil and modafinil coverage will not be approved for non-medical conditions such as, but not limited to the following:
 - a) Shift work (i.e., works night shift)
 - b) Generalized fatigue
 - c) Travel (jet lag)
 - d) Sleep-deprivation (i.e. military or academic use)
4. The following quantity limitations apply:

| Medication Name | Quantity Limit |
|-----------------------------------|---------------------|
| Armodafinil 50 mg tablet | Two tablets per day |
| Armodafinil 150 mg 250 mg tablets | One tablet per day |
| Modafinil 100 mg, 200 mg tablets | One tablet per day |

CODES

None

REFERENCES

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4. McNicholas WT. Diagnosis of Obstructive Sleep Apnea on Adults. *Proc Am Thorac Soc*. 2008; 5:154-160.
5. Morgenthaler TI, Kapur VK, Brown TM. Standards of practice committee of the AASM. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. *Sleep*. 2007; 30(12):1705-1711.
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APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. October 10, 2023: Effective January 1, 2024, updated approvable diagnoses to include excessive daytime sleepiness for all chronic conditions. Removed reauthorization criteria and increased the approval duration to life of plan.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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