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

Effective: October 13, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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 quality 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

1. Doghramji P, Lieberman J, Gordon M. Stay Awake! Understanding, diagnosing, and successfully managing Narcolepsy. *J Fam Pract* 2007; 56 (11):S19
2. Harsh JR, Hayduk R, Rosenberg R, et al. The efficacy and safety of armodafinil as treatment for adults with excessive sleepiness associated with narcolepsy. *Curr Med Res Opin*. 2006; 22(4): 761-774.
3. McEvoy GK, editor. American Hospital Formulary Service/AHFS Drug Information 2000. Bethesda: The American Society of Health-System Pharmacists, Inc, 2000.
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.
6. Morgenthaler TI, Kapen S, Lee-Chiong T et al. Practice parameters for the medical therapy of obstructive sleep apnea. *Sleep*. 2006;29(8):1031-1035.
7. Morgenthaler TI, Lee-Chiong T, Alessi C et al. Practice parameters for the clinical evaluation and treatment of Circadian rhythm sleep disorders. *Sleep* 2007; 30(11):14445-1459.
8. Nuvigil (armodafinil) [package insert]. Parsippany, NJ: Teva Pharmaceuticals: December 2022.
9. Pack, A, Black J, Schwartz J. Modafinil as adjunct therapy for the daytime sleepiness in obstructive sleep apnea. *Am J Respir Crit Care Med.* 2001;164: 1675-1681.
10. Provigil (modafinil) [package insert]. Parsippany, NJ: Teva Pharmaceuticals; December 2022.
11. Roth T, Rippon GA, Arora S. Armodafinil improves wakefulness and long-term episodic memory in nCPAP-adherent patients with excessive sleepiness associated with obstructive sleep apnea. *Sleep Breath*. 2008; 12(1):53-62.

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.
2. October 8, 2024: Administrative update to fax number
3. October 14, 2025: No changes
4. October 13, 2026: No changes.

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.

Provider Services