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

Effective: August 17, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ 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 and shift work sleep disorder (SWSD), and for adjunctive therapy for obstructive sleep apnea/hypopnea syndrome (OSAHS).

Armodafinil and modafinil are oral wakefulness-promoting medications, approved for use in patients with excessive daytime sleepiness associated with narcolepsy. The stimulation is similar in effect to amphetamine and methylphenidate, yet the pharmacological profile is not identical to these products. A possible mechanism of action involves brain peptides called orexins, also known as hypocretins. Activation of orexin neurons increases dopamine and norepinephrine and excites histaminergic tuberomammilary neurons, thereby increasing histamine levels. Thus increasing histamine release in the brain may be a possible mechanism of action in humans.

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: obstructive sleep apnea (OSA)/hypoapnea syndrome, narcolepsy, multiple sclerosis, chronic fatigue syndrome, organic brain disorder, Parkinson's disease, idiopathic hypersomnia

OR

2. Documented diagnosis of excessive daytime sleepiness associated with depression

AND

Documentation the Member has had a treatment failure with at least a 4-week course of therapy with an antidepressant

AND

Documentation the Member will be using armodafinil or modafinil concurrently with an antidepressant agent

Upon renewal

1. Documentation the Member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is considered medically necessary

LIMITATIONS

1. Approval duration will be limited to two years.
2. Requests for brand-name products, with AB-rated generics, will be reviewed according to Non-covered Medications criteria.

3. 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.
4. Armodafinil and modafinil coverage will not be approved for non-medical conditions such as, but not limited to the following:
    a) Shift work sleep disorder
    b) Generalized fatigue
    c) Travel (jet lag)
    d) Sleep-deprivation (i.e. military or academic use)
5. The following quantity limitations apply:

Nuvigil (armodafinil)	50 mg: Two tablets per day
Nuvigil (armodafinil)	150 mg, 250 mg: One tablet per day
Provigil (modafinil)	100 mg, 200 mg: One tablet per day

CODES

None

REFERENCES

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12. Ishizuka T, Sakamoto Y, Sakurai T, Tamatodani A (March 2003). Modafinil increases histamine release in the anterior hypothalamus of rats. Neurosci. Lett. 339 (2): 143-6.

APPROVAL HISTORY

February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2016: Administrative change to rebranded template.
- February 9, 2016: Approval duration extended to 2 years.
- July12, 2016: No changes
- May 9, 2017, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- August 8, 2017: No changes.
- August 7, 2018: Updated criteria to remove prerequisite trial with a stimulant for the diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea/hypopnea.
- August 13, 2019: Added the following diagnoses to the criteria: chronic fatigue syndrome, organic brain disorder, Parkinson's disease, and idiopathic hypersomnia. Removed stimulant trial requirements from the criteria. Administrative changes made to template.
- August 11, 2020: Updated samples language in the limitations section of the MNG.

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.