OVERVIEW

FDA-APPROVED INDICATIONS

Modafinil (Provigil) and armodafinil (Nuvigil) 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 tuberomammillary neurons, thereby increasing histamine levels. Thus increasing histamine release in the brain may be a possible mechanism of action in humans.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of armodafinil or modafinil for members when the following criteria for a particular diagnosis are met and limitations do not apply:

- The member has documented excessive daytime sleepiness associated with one of the following chronic medical conditions:
  - Narcolepsy
  - Multiple Sclerosis
  - Obstructive Sleep Apnea/Hypopnea Syndrome
- The member has had a treatment failure, or the provider indicates clinical inappropriateness of therapy with at least one preferred alternative stimulant medication, such as an amphetamine or methylphenidate product. OR
- The member has documented excessive daytime sleepiness associated with depression, and
- The member has had a treatment failure with at least a 4-week course of therapy with an antidepressant, and
- The member will be using modafinil or armodafinil concurrently with an antidepressant agent, and
- The member has had a treatment failure, or the provider indicates clinical inappropriateness of therapy with at least one preferred alternative stimulant medication, such as an amphetamine or methylphenidate product.

Upon renewal,

- The member has had an office visit and has been reassessed for this condition within the past year, and continued therapy with this medication is considered medically necessary.

Note: Tufts Health Plan – Network Health does not consider generalized anxiety disorder as a contraindication for treatment with a stimulant alternative. A history of bipolar disorder or cyclothymic disorder is considered as a contraindication for treatment with a stimulant formulary alternative.

LIMITATIONS

- Approval will be limited to one year.
- Requests for brand-name products, with AB-rated generics, will be reviewed according to Brand Name criteria.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- Armodafinil and modafinil coverage will not be approved for non-medical conditions such as, but not limited to the following:
  - Shift work sleep disorder
Pharmacy Medical Necessity Guidelines: Analeptic Stimulants

- Generalized fatigue
- Travel (jet lag)
- Sleep-deprivation (i.e. military or academic use)

The following quantity limitations apply. Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armodafinil 50 mg</td>
<td>Two tablets per day</td>
</tr>
<tr>
<td>Armodafinil 150 mg, 250 mg</td>
<td>One tablet per day</td>
</tr>
<tr>
<td>Modafinil 100 mg, 200 mg</td>
<td>One tablet per day</td>
</tr>
</tbody>
</table>

CODES
None

REFERENCES

APPROVAL HISTORY
- 2/10/15: Reviewed by the Pharmacy and Therapeutics Committee

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.
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.