Pharmacy Medical Necessity Guidelines: Nuvigil® (armodafinil) & Provigil® (modafinil)

Effective: December 17, 2018

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Not Covered</th>
<th>Type of Review – Clinical Review</th>
<th>√</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RX Department to Review</td>
<td>RXUM</td>
<td></td>
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</tr>
</tbody>
</table>

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
- CareLinkSM – 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
- MM: 888.415.9055
- PRECERT: 617.972.9409

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

**OVERVIEW**

Nuvigil (armodafinil) and modafinil are oral wakefulness-promoting medications, Food and Drug Administration-approved to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder. The precise mechanism of action is not fully known, but the resultant stimulation is similar in effect to amphetamine and methylphenidate, yet the pharmacological profile is not identical to these products.

**COVERAGE GUIDELINES**

**Note:** Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan using the Universal Pharmacy Medical Review Request Form for members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Tufts Health Plan Large Groups</th>
<th>Tufts Health Plan Small Groups and Individual Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step-1</td>
<td>Covered for members age 25 and under</td>
<td>Covered for members age 25 and under</td>
</tr>
<tr>
<td>amphetamine mixed salts (Adderall)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>amphetamine/dextroamphetamine extended-release (Adderall XR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dextroamphetamine (Dexedrine)</td>
<td>PA required for members age 25 and under</td>
<td>PA required for members age 25 and older</td>
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<tr>
<td>dextroamphetamine extended-release (Dexedrine Spansule)</td>
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</tr>
<tr>
<td>methylphenidate (Ritalin)</td>
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<td></td>
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<tr>
<td>methylphenidate extended-release (Metadate ER, Ritalin-SR)</td>
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</tbody>
</table>

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).
Automated Step Therapy Coverage Criteria
The following stepped approach applies to coverage of the Step-2 medications by the plan:

**Step 1:** Generic medications on Step-1 are covered without prior authorization for members under the age of 25.

**Step 2:** The plan may cover armodafinil or modafinil, if the following criteria are met:
- The Member has had a trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Service
The following stepped approach applies to armodafinil and modafinil:

**Step 2:** The plan may cover Step-2 medications if the following criteria are met:
- The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples.

**Note:** The plan may authorize coverage of armodafinil or modafinil for Members when the following criteria are met:
1. The Member has had a treatment failure, inability to tolerate or other medical contraindication to one or more Step-1 formulary alternative medications.

    AND

2. One of the following:
   a. The Member has documented excessive daytime sleepiness associated with a documented diagnosis of narcolepsy
      OR
   b. The Member has documented excessive daytime sleepiness associated with a documented diagnosis of one of the following chronic medical conditions:
      i. Depression
      ii. Chronic fatigue syndrome
      iii. Multiple sclerosis
      iv. Organic brain disorder
      v. Obstructive sleep apnea/hypopnea syndrome
      vi. Parkinson’s disease

**Note:** The plan does not consider generalized anxiety disorder (GAD) as a contraindication for treatment with a stimulant formulary alternative.

**Note:** The plan may cover medications on Step-2 if a Member has received non-covered brand name Provigil (modafinil) or Nuvigil (armodafinil) as evidenced by physician documented use, excluding the use of samples.

**LIMITATIONS**
- Brand-name Provigil (modafinil) and Nuvigil (armodafinil) is not covered for all Commercial formularies. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- Nuvigil (armodafinil) and Provigil (modafinil) will not be authorized for non-medical conditions such as, but not limited to the following:
  o Shift work sleep disorder
  o Generalized fatigue
  o Travel (Jet lag)
  o Sleep-deprivation (i.e., military or academic use)
Pharmacy Medical Necessity Guidelines:

Nuvigil® (armodafinil) & Provigil® (modafinil)

The following quantity limitations apply to coverage. Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Quantity Limitations and submit a formulary exception request for those Members requiring higher quantities.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nuvigil (armodafinil)</td>
<td>90 tablets per 90 days</td>
</tr>
<tr>
<td>Provigil (modafinil)</td>
<td>180 tablets per 90 days</td>
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</tbody>
</table>

CODES
None

REFERENCES

APPROVAL HISTORY
April 2000: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- February 8, 2005: Add to criteria #2 the diagnoses of “Parkinson’s Disease,” “Attention Deficit Disorder” and “Chronic Fatigue Syndrome.” Change criteria #3 from “the requesting physician has documented that the Member has had a treatment failure of or is unable to tolerate one or more formulary alternative medications* (see attachment)” to “the Member has had a treatment failure, inability to tolerate or other medical contraindication to one or more formulary alternative medications* (see attachment).”
- February 14, 2006: No changes
- January 9, 2007: No changes
- January 15, 2008: No changes
- November 11, 2008: Added automated step therapy coverage criteria to medical necessity guidelines. Added note that The plan does not consider generalized anxiety disorder (GAD) as a contraindication for treatment with a stimulant formulary alternative. Removed "Attention Deficit Disorder (ADD)" and "Attention Deficit Hyperactivity Disorder (ADHD)" from criteria #2.
- November 10, 2009: Added Nuvigil (armodafinil) to Pharmacy Medical Necessity Guidelines. Added dispensing limitations for Nuvigil (armodafinil) and Provigil (modafinil). Effective 01/01/2010, Tufts Medicare Preferred formularies will be included in the automated step therapy program (previously non-automated prior authorization).
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- November 9, 2010: Removed Concerta (methyphenidate ext-rel) from the list of formulary alternatives. Removed "Dispensing" from, “The following quantity limitations apply to coverage. Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Dispensing Limitations..."
and submit a formulary exception request for those Members requiring higher quantities. Replaced with “Quantity”.

- **September 13, 2011:** For effective date October 1, 2011: removed Provigil from Step Therapy criteria; as it is no longer covered on the Commercial Formularies.
- **September 13, 2011:** Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
- **May 8, 2012:** Added modafinil to Step-2 of the Medical Necessity guidelines
- **June 12, 2012:** Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
- **August 14, 2012:** Removed non-covered brand product Provigil from step therapy grid and added this product to the limitations section. Added note that non-covered Provigil may qualify as a prerequisite for Step-2 medications. Added use of samples or vouchers/coupons for brand name medications limitation.
- **June 11, 2013:** No changes
- **October 8, 2013:** Administrative change: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
- **April 1, 2014:** Administrative update: Removed language pertaining to the Generic Focused Formulary and added EHB MA/RI Formulary.
- **June 10, 2014:** No changes
- **June 9, 2015:** No changes
- **January 1, 2016:** Administrative change to rebranded template applicable to Tufts Health Direct
- **May 10, 2016:** No changes
- **July 12, 2016:** Added armodafinil to Step-2 for all Commercial Formularies. Moved Nuvigil to not covered for MA/RI/NH EHB Formularies.
- **April 11, 2017:** Administrative update, Adding Tufts Health RITogether to the template.
- **July 11, 2017:** Updated Medical Necessity Guideline to note Nuvigil is not covered for all Commercial formularies.
- **November 14, 2017:** Reversed the order of criteria in step 2, to ask for treatment failure to one or more Step-1 formulary alternative medications prior to asking for an appropriate diagnosis. Also, listed the age restriction and PA requirements for step 1 medications.
- **December 11, 2018:** Administrative update to the template.

### 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.