UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2016 P 1071-4</th>
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<tbody>
<tr>
<td>Program</td>
<td>Prior Authorization/Notification</td>
</tr>
<tr>
<td>Medication</td>
<td>Modafinil (Provigil*) and armodafinil* (Nuvigil*)</td>
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<tr>
<td>Effective Date</td>
<td>3/1/2017; Oxford only: 3/1/2017</td>
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1. Background:
Modafinil (Provigil*) and Nuvigil* are wakefulness-promoting agents for oral administration. Both products are approved by the Food and Drug Administration (FDA) to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea and shift work disorder. Modafinil has been shown to be beneficial in the treatment of excessive sleepiness in patients with idiopathic hypersomnia, treatment of fatigue associated with multiple sclerosis, and in the augmentation therapy for the treatment of depression.

2. Coverage Criteria:

A. Initial Authorization

1. Modafinil or Nuvigil* will be approved for patients who meet one of the following criteria:

   a. Diagnosis of narcolepsy
   b. Diagnosis of idiopathic hypersomnia/
   c. Diagnosis of excessive sleepiness due to obstructive sleep apnea
   d. Diagnosis of excessive sleepiness due to shift work disorder
   e. Diagnosis of fatigue associated with multiple sclerosis
   f. For adjunctive therapy for the treatment of major depressive disorder or bipolar depression

   Authorization will be issued for 12 months.

B. Reauthorization

1. Modafinil or Nuvigil* will be approved based on the following criterion:

   a. Documentation of positive clinical response to modafinil or Nuvigil* therapy

   Authorization will be issued for 12 months.
3. **Additional Clinical Rules:**

- Supply limits may be in place.
- *Provigil (brand only) and Nuvigil (brand and generic) are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.*

4. **References:**


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<tr>
<th>Program</th>
<th>Prior Authorization/Notification – Provigil, Nuvigil</th>
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<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>10/2014</td>
<td>Added coverage for adjunctive therapy for the treatment of depression. Updated references.</td>
</tr>
<tr>
<td>10/2015</td>
<td>Updated background and references.</td>
</tr>
<tr>
<td>12/2016</td>
<td>Annual Review. Added Nuvigil to exclusion statement. Updated background statement and diagnosis terminology in override criteria. Updated references.</td>
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