Clinical Pharmacy Program Guidelines for Provigil, Nuvigil

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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<tbody>
<tr>
<td>Medication</td>
<td>Provigil (modafinil), Nuvigil (armodafinil)</td>
</tr>
<tr>
<td>Markets in Scope</td>
<td>Arizona, California, Florida- CHIP, Hawaii, Nevada, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island</td>
</tr>
<tr>
<td>Issue Date</td>
<td>2/2010</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>1/2019</td>
</tr>
<tr>
<td>Effective Date</td>
<td>3/2019</td>
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1. **Background:**

Modafinil (Provigil) and armodafinil (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.

**NOTE: This policy does not apply to Washington.**

2. **Coverage Criteria:**

A. **Narcolepsy, Obstructive Sleep Apnea, Shift Work Disorder, or Idiopathic Hypersomnia (off-label)**

1. **Authorization Criteria**

   a. **One** of the following:

   - Diagnosis of narcolepsy
   - Diagnosis of excessive sleepiness due to obstructive sleep apnea
   - Diagnosis of excessive sleepiness due to shift work disorder (circadian rhythm sleep disorder, shift work type)
   - Diagnosis of idiopathic hypersomnia

   -AND-

   b. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

   **Authorization will be issued for 12 months.**
B. **Fatigue due to MS (off-label)**

1. All of the following:
   a. Diagnosis of multiple sclerosis (MS)
      -AND-
   b. Patient is experiencing fatigue
      -AND-
   c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

C. **Adjunctive Therapy for the Treatment of Major Depressive Disorder or Bipolar Depression (off-label)**

1. Initial Authorization
   a. Treatment-resistant depression, defined as both of the following:
      1. Diagnosis of one of the following:
         - Major depressive disorder (MDD)
         - Bipolar depression
         -AND-
      2. History of failure, contraindication, or intolerance to at least two antidepressants from different classes (e.g., SSRIs, SNRIs, bupropion)
         -AND-
   b. Used as adjunctive therapy
      -AND-
   c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil
Authorization will be issued for 12 months.

2. Reauthorization

   a. Documentation of positive clinical response to therapy

   -AND-

   b. Used as adjunctive therapy

   -AND-

   c. If the request is for modafinil, the patient has a history of failure, contraindication, or intolerance to armodafinil

Authorization will be issued for 12 months.

4. References

16. Cephalon data on file (Clinical study report C10953/3022/CM/MN)

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization- Provigil, Nuvigil</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>2/2010</td>
<td>New policy</td>
</tr>
<tr>
<td>9/2010</td>
<td>Removed requirement of the trial of Provigil prior to Nuvigil approval.</td>
</tr>
<tr>
<td>6/2012</td>
<td>Annual Review. Added generic requirement for Provigil in product list table.</td>
</tr>
<tr>
<td>6/2013</td>
<td>Converted policy to new UHC enterprise wide formatting.</td>
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<tr>
<td></td>
<td>Added additional confirmation symptoms for OSA initial therapy (see sections 1.1 and 2.1 of OSA initial therapy)</td>
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<tr>
<td></td>
<td>Created reauthorization criteria for SWSD</td>
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<tr>
<td></td>
<td>Added requirement for MS fatigue that requires combination with</td>
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<tr>
<td>Date</td>
<td>Changes in Authorization Criteria</td>
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<tr>
<td>9/2013</td>
<td>For Provigil/Nuvigil, revised narcolepsy criteria from “submission of sleep study confirming diagnosis of narcolepsy” to “diagnosis of narcolepsy as confirmed by sleep study” For Provigil, revised idiopathic hypersomnia criteria from “submission of sleep study confirming diagnosis of idiopathic hypersomnia” to “diagnosis of idiopathic hypersomnia as confirmed by sleep study”</td>
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<tr>
<td>12/2014</td>
<td>Added prior authorization criteria for Provigil (modafinil) for adjunctive treatment for the treatment of major depressive disorder or bipolar depression</td>
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<tr>
<td>10/2016</td>
<td>Updated policy template. A few of the AND statements were changed to OR statements in the quantity limit section.</td>
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<tr>
<td>12/2016</td>
<td>Updated wording in quantity limit sections</td>
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<tr>
<td>3/2017</td>
<td>Changed all authorization durations to 12 months.</td>
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<tr>
<td>8/2017</td>
<td>Updated clinical criteria to only diagnosis for narcolepsy, obstructive sleep apnea, and shift work disorder and trial/failure of armodafinil if requesting modafinil. Removed quantity limit sections. Changed Provigil to modafinil throughout policy. Updated background.</td>
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<tr>
<td>3/2018</td>
<td>Modified the language around the diagnosis for shift work disorder to include circadian rhythm, shift work disorder, to match the ICD10 code. Updated off-label sections to allow for use of armodafinil.</td>
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<tr>
<td>1/2019</td>
<td>Updated criteria for idiopathic hypersomnia and multiple sclerosis since these are included in the DX2RX program.</td>
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</tbody>
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- standard educational therapies
- Created reauthorization criteria for MS fatigue
- Created quantity limit exception criteria for both Provigil and Nuvigil
- Created reauthorization criteria for Narcolepsy
- Separated Narcolepsy and Idiopathic Hypersomnia criteria
- Created reauthorization criteria for and Idiopathic Hypersomnia