

## Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

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| <b>Guideline Name</b> | <b>Wakefulness Agents:</b><br>Provigil (modafinil), Nuvigil (armodafinil) |
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### 1. Criteria

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| Product Name: Brand Provigil, Brand Nuvigil  |   |
| Approval Length  | 24 Month(s)   |
| Therapy Stage  | Initial Authorization                                 |
| Guideline Type   | Non-Formulary   |
| <p><b>Approval Criteria</b></p> <p><b>1 - All of the following:</b></p> <p><b>1.1 - Medication is NOT being prescribed solely for a non-medical condition such as, but not limited to, the following:</b></p> <ul style="list-style-type: none"> <li>• Shift work sleep disorder (works night shift, etc.)</li> <li>• Generalized fatigue</li> <li>• Travel induced sleep disorder (jet lag, etc.)</li> <li>• Sleep-deprivation (i.e., military or academic)</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.2 - Patient has ONE of the following conditions:</b></p> <ul style="list-style-type: none"> <li>• Excessive daytime sleepiness associated with Narcolepsy OR Idiopathic Hypersomnia</li> <li>• Obstructive Sleep Apnea/Hypopnea Syndrome</li> <li>• Attention Deficit Hyperactivity Disorder (ADHD)</li> <li>• Excessive daytime sleepiness associated with Depression</li> <li>• Excessive daytime sleepiness associated with Multiple Sclerosis</li> <li>• Cancer patient being treated with chemotherapy</li> </ul> <p style="text-align: center;"><b>AND</b></p> <p><b>1.3 - Patient has tried and failed therapy with BOTH of the preferred formulary alternatives:**</b></p> <ul style="list-style-type: none"> <li>• generic modafinil; AND</li> <li>• generic armodafinil</li> </ul> |   |
| Notes  | **Alternative agents may require prior authorization. |

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| <b>Product Name:</b> Brand Provigil, Brand Nuvigil   |   |
| Approval Length  | 24 Month(s)   |
| Therapy Stage  | Reauthorization                                       |
| Guideline Type   | Non-Formulary   |
| <p><b>Approval Criteria</b></p> <p>1 - Both of the following:</p> <p>1.1 - Provider has indicated an effective response with this medication or the need for continued therapy</p> <p style="text-align: center;"><b>AND</b></p> <p>1.2 - There is clinical rationale for NOT using the generic of the requested medication at this time**</p> |   |
| Notes  | **Alternative agents may require prior authorization. |

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|---|-----------------------|
| <b>Product Name:</b> Generic modafinil, Generic armodafinil   |                       |
| Approval Length   | 24 Month(s)           |
| Therapy Stage   | Initial Authorization |
| Guideline Type  | Prior Authorization   |
| <p><b>Approval Criteria</b></p> <p>1 - One of the following:</p> <p>1.1. - Patient lives in Rhode Island or the prescribing provider's office is located in Rhode Island*</p> <p style="text-align: center;"><b>OR</b></p> <p>1.2 - Both of the following:</p> <p>1.2.1 - Medication is NOT being prescribed solely for a non-medical condition such as, but not limited to, the following:</p> <ul style="list-style-type: none"> <li>• Shift work sleep disorder (works night shift, etc.)</li> <li>• Generalized fatigue</li> <li>• Travel induced sleep disorder (jet lag, etc.)</li> <li>• Sleep-deprivation (i.e., military or academic)</li> </ul> |                       |

**AND**

**1.2.2** - Patient has ONE of the following conditions:

- Excessive daytime sleepiness associated with Narcolepsy OR Idiopathic Hypersomnia
- Obstructive Sleep Apnea/Hypopnea Syndrome
- Attention Deficit Hyperactivity Disorder (ADHD)
- Excessive daytime sleepiness associated with Depression
- Excessive daytime sleepiness associated with Multiple Sclerosis
- Cancer patient being treated with chemotherapy

Note:

\*Note: Requests for formulary medications will be approved for 24 months without meeting any additional criteria if the patient is living in Rhode Island or the prescribing provider's office is located in Rhode Island.

**Product Name: Generic modafinil, Generic armodafinil**

Approval Length      24 Month(s)

Therapy Stage      Reauthorization

Guideline Type      Prior Authorization

**Approval Criteria**

**1** - One of the following:

**1.1** - Patient lives in Rhode Island or the prescribing provider's office is located in Rhode Island\*

**OR**

**1.2** - Provider has indicated an effective response with this medication or the need for continued therapy

Notes

\*Note: Requests for formulary medications will be approved for 24 months without meeting any additional criteria if the patient is living in Rhode Island or the prescribing provider's office is located in Rhode Island.

**2. Background**

**Benefit/Coverage/Program Information**

**RATIONALE**

To ensure that these agents are used only when medically necessary. Coverage is not provided for non-medical situation such as jet-lag, shift work sleep disorder, sleep deprivation,

or generalized fatigue. To ensure cost-effective care, Harvard Pilgrim requires that members first demonstrate trial and failure of both modafinil and armodafinil before approval of either Provigil or Nuvigil. A quantity limit is in place to encourage dose-optimization for medications available in progressive dose strengths.

**FDA APPROVED INDICATIONS**

Provigil and Nuvigil are indicated to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.

**REFERENCES**

- Nuvigil (armodafinil) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; July 2019.
- Provigil (modafinil) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; November 2018.

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