### Overview

**Modafinil** is a central nervous system stimulant that has been shown to significantly increase dopamine in the brain by blocking dopamine transporters. Studies have shown modafinil increases high-frequency alpha waves while decreasing both delta and theta wave activity, effects consistent with generalized increases in mental alertness.

Armodafinil is the R-enantiomer of modafinil. Armodafinil binds to the dopamine transporter and inhibits dopamine reuptake, which may result in increased extracellular dopamine levels in the brain. However, it does not appear to be a dopamine receptor agonist and does not appear to bind to or inhibit the most common receptors or enzymes that are relevant for sleep/wake regulation.

### Coverage Guidelines

Authorization may be granted for members who are currently receiving treatment with modafinil or armodafinil, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

Or

Approval may be granted when the following drug specific criteria are met for excessive day time sleepiness (EDS) associated with the following conditions:

**Modafinil**

1. Patient has a diagnosis of narcolepsy
2. Patient has a diagnosis of excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome that has been confirmed by a sleep study AND is currently using CPAP
3. Patient has a diagnosis of ADD or ADHD

### Table

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
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</thead>
<tbody>
<tr>
<td>MassHealth</td>
<td>☒ Prior Authorization</td>
</tr>
<tr>
<td>Commercial/Exchange</td>
<td>☐ Quantity Limit</td>
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<tr>
<td>☐ Step Therapy</td>
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<table>
<thead>
<tr>
<th>Benefit</th>
<th>Specialty Medications</th>
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</thead>
<tbody>
<tr>
<td>☒ Pharmacy Benefit</td>
<td>All Plans</td>
</tr>
<tr>
<td>☐ Medical Benefit (NLX)</td>
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<tr>
<th>Benefit</th>
<th>Non-Specialty Medications</th>
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<tr>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
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<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
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<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
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<thead>
<tr>
<th>Benefit</th>
<th>Medical Specialty Medications (NLX)</th>
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</thead>
<tbody>
<tr>
<td>All Plans</td>
<td>Phone: 844-345-2803</td>
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| Exceptions | N/A |
4. Patient has a diagnosis of fatigue associated with Multiple Sclerosis (MS)
5. Patient has a diagnosis of fatigue associated with chemotherapy
6. Patient has a diagnosis of excessive sleepiness associated with Parkinson’s disease
7. Patient has a diagnosis of shift work sleep disorder and all of the following:
   - Patient is ≥ 17 years of age
   - Patient has had an inadequate response, adverse reaction, or contraindication to one hypnotic agent and melatonin

**Armodafinil**

1. Patient has a diagnosis of narcolepsy OR
2. Patient has a diagnosis of excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome that has been confirmed by a sleep study AND is currently using CPAP.
3. Patient has a diagnosis of shift work sleep disorder and all of the following:
   - Patient is ≥ 17 years of age
   - Patient has had an inadequate response, adverse reaction, or contraindication to one hypnotic agent and melatonin

**Continuation of Therapy**

Reauthorization requires physician documentation of improvement of member’s condition.

**Limitations**

1. Approvals will be granted for the following:
   - Fatigue associated with chemotherapy – 12 months
   - Excessive sleepiness associated with Parkinson’s disease – 12 months
   - All other indications – 36 months
2. The following diagnoses are excluded from coverage:
   - Fatigue or sleepiness associated with traumatic brain injuries
   - Idiopathic hypersomnolence
   - Fatigue or sleepiness associated with use of narcotic analgesics
   - Cerebral palsy (spastic)
   - Adjunctive treatment of depression
3. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity Limit</th>
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<tbody>
<tr>
<td>modafinil 100mg and 200mg</td>
<td>30 tablets per 30 days</td>
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<tr>
<td>armodafinil 50mg</td>
<td>60 tablets per 30 days</td>
</tr>
<tr>
<td>armodafinil 100mg, 150mg and 200mg</td>
<td>30 tablets per 30 days</td>
</tr>
</tbody>
</table>

**References**

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

Review History
06/27/2005 - Reviewed and Revised
04/24/2006 - Reviewed
04/23/2007 - Reviewed
04/28/2008 - Reviewed and Revised
04/27/2009 - Reviewed and Revised
04/26/2010 - Reviewed and Revised
07/15/2010 - Updated per MM/plan direction (stimulant trial for OSA/narcolepsy)
12/15/2010 - Updated (disclaimer)
04/25/2011 - Reviewed
05/17/2011 - Updated (generic Concerta)
04/11/2012 - Updated (modafanil generic; BART request ahead of drug file); removed long-acting stimulant trial
04/23/2012 - Reviewed and Revised (modafinil trial for Nuvigil)
04/22/2013 - Reviewed and Revised
04/28/2014 - Reviewed
06/26/2017 - Reviewed and Revised
04/17/2019 - Reviewed
05/20/2020 - Reviewed and Updated May P&T Mtg; overview written, updated references; added indication of shift work sleep disorder. Effective 8/1/20.
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