Modafinil (Provigil)

Prior Authorization Criteria for the TRICARE Pharmacy (TPHARM) Program

Background

Modafinil (Provigil) is approved by the FDA for treatment of excessive daytime sleepiness associated with narcolepsy, excessive daytime sleepiness associated with obstructive sleep apnea/hypopnea syndrome (OSAHS) when used as an adjunct to continuous positive airway pressure (CPAP) treatment, and excessive daytime sleepiness associated with shift-worker sleep disorder (SWSD). There are numerous off-label uses. Off-label uses identified by the DoD P&T Committee as supportable based on published clinical evidence or recommendations from nationally recognized expert organizations, based on TRICARE regulations (TRICARE Policy Manual 6010.54 [August 2002] chapter 1 section 2.1) regarding coverage of unproven drugs, devices, medical treatments and procedures, are included in the criteria below. Other off-label uses are supported only by case reports, uncontrolled trials, single-blinded trials, or chart reviews, which constitute insufficient evidence to establish efficacy and safety.

The following criteria were established by the DoD Pharmacy & Therapeutics (P&T) Committee. The effective date for this prior authorization is 18 April 2007. This prior authorization approval is good for 1 year.

Prior Authorization Criteria for Modafinil (Provigil)

Coverage is provided for the use of modafinil for the treatment of:

- Excessive daytime sleepiness associated with narcolepsy; as diagnosed by polysomnogram or MSLT objective testing
- Excessive daytime sleepiness associated with obstructive sleep apnea/hypopnea syndrome (OSAHS), only after adequate titration of continuous positive airway pressure (CPAP) treatment
- Excessive sleepiness associated with shift-worker sleep disorder (SWSD), only in patients who work night shifts
- Excessive fatigue associated with multiple sclerosis, only after secondary causes of fatigue have addressed
- Excessive fatigue associated with myotonic dystrophy
- Depression, only after primary therapy has failed and if the use of other stimulant augmentation is contraindicated
- Idiopathic hypersomnia diagnosed by a sleep specialist
- Fatigue associated with mild traumatic brain injury

NOTE: this prior authorization is not intended to apply to modafinil use in active duty operational/readiness situations based on established protocols; Military Treatment Facilities should make necessary allowances such use.

Coverage is not provided for the use of modafinil (Provigil) for the treatment of other conditions, including:

- Chronic fatigue syndrome
- Stroke rehabilitation
- Appetite suppression
- Parkinson’s disease

Criteria approved through the DoD P&T Committee process Jan 2007, revised November 2009

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TRICARE Management Activity,
a component of the Military Health System
Skyline 5, Suite 810, 5111 Leesburg Pike,
Falls Church, VA 22041-3206
# US Family Health Plan Prior Authorization Request Form for Modafinil (Provigil)

To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) or the completed form may be faxed to: 1-617-562-5296

## Prior authorization criteria and a copy of this form are available at: [KWWSXVIDPLO\KHDOWKRUJIRUSURYLGHUVGRZQORDGDEOHIRUPV](#).

### Step 1
**Please complete patient and physician information** (Please Print)

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### Step 2
**Please complete the clinical assessment**

2. **Does the patient meet BOTH of the following criteria?**
   - A diagnosis of obstructive sleep apnea associated with persistent and excessive daytime sleepiness
   - Continuous positive airway pressure (CPAP) treatment has been adequately titrated and the patient is compliant with treatment

   - Yes
   - No

3. **Is the patient a nightshift worker with a diagnosis of shift-worker sleep disorder (SWSD) associated with excessive sleepiness?**

   - Yes
   - No

4. **Does the patient meet BOTH of the following criteria?**
   - A diagnosis of multiple sclerosis associated with excessive fatigue
   - Secondary causes of fatigue have been addressed

   - Yes
   - No

5. **Does the patient have a diagnosis of myotonic dystrophy associated with excessive fatigue?**

   - Yes
   - No

6. **Does the patient meet ALL of the following criteria?**
   - A diagnosis of depression
   - Primary antidepressant therapy (defined as a 4-6 week trial of at least one antidepressant agent) has failed.
   - The use of other stimulant augmentation (such as methylphenidate products) is contraindicated due to adverse effects, previous failure, or hypersensitivity.

   - Yes
   - No

7. **Does the patient have a documented diagnosis of idiopathic hypersomnia diagnosed by a sleep specialist?**

   - Yes
   - No

8. **Does the patient have a diagnosis of fatigue associated with mild traumatic brain injury?**

   - Yes
   - No

### Step 3
**I certify the above is true to the best of my knowledge.**

Please sign and date: 

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**Prescriber Signature**

**Date**

Latest revision: December 2009