

PROVIGIL (modafinil tablets)

Effective Date: 4/28/08

Date Developed: 1/15/08 by Sheldon Haas, MD

Last Approval Date: 1/26/16, 1/24/17, 1/22/19, 2/18/20, 2/2/21

(Archive Date: 1/1/18)

Unarchived Date: 1/22/19 (Formulary Exclusion – For Exception Review Use)

Provigil (modafinil) is a wakefulness promoting agent for oral administration. The precise mechanism of action is unknown, however, it has wake producing action similar to sympathomimetic agents.

Pre-Authorization Criteria:

The below FDA Approved Indications must be established by a Psychiatrist, Endocrinologist, Internist or Sleep Specialist.

Following established diagnosis by any one of the above specialists, the Primary Care Physician (PCP) may prescribe.

FDA-Approved Indications:

1. Narcolepsy
2. Excessive sleepiness due to Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)
3. Excessive sleepiness due to Shift Work Sleep Disorder (SWSD)

Other Uses with Supportive Evidence

4. **Fatigue associated with MS.** *Approve when initially recommended and prescribed by a Neurologist*
5. **EDS due to myotonic dystrophy.** *Approve when initially recommended and prescribed by a Neurologist*
6. **Attention-Deficit/Hyperactivity Disorder (ADHD) and Attention-Deficit Disorder (ADD):** *Approve when initially recommended and prescribed by a Psychiatrist.*

7. **Adjunctive/augmentation treatment for depression in adults.** *Approve when initially recommended and prescribed by a Psychiatrist.*
8. **EDS in Parkinson's disease (PD).** *Approve when initially recommended and prescribed by a Neurologist*
9. **Idiopathic hypersomnia.** *Approve when initially recommended and prescribed by a sleep specialist.*
10. **Fatigue associated with HIV infection.** *Approve when initially recommended and prescribed by a specialist in treatment of HIV.*
11. **Myasthenia gravis.** *Approve when initially recommended and prescribed by a Neurologist.*
12. **Cancer-related fatigue.** *Approve when initially recommended and prescribed by an Oncologist.*

Note: Provigil is NOT approved for pediatric patients (under the age of 16 years) for any indication.

DOSING:

Narcolepsy:

200-400 mgm /day, to be taken in the morning.

OSAHS;

200-400 mgm /day ,to be used as an adjunct to treatment with a C-Pap apparatus, and weight control therapy.

Shift Work Sleep Disorder:

200-400 mgm /day, to be taken 1 hour before start of work.

This medication may be taken with/without food, but if med causes upset stomach, then take with food only.

MONITORING PARAMETERS: Patients should be evaluated prior to each refill of this medication.

Diagnosis must be established by Psychiatrist, Endocrinologist, Internist or Sleep Specialist, however, once the diagnosis has been established the PCP may monitor the treatment and prescribe refills, as necessary.

Possible Complications include psychiatric symptoms, Stevens-Johnson Syndrome or other lesser dermatologic conditions, chest pain or rapid heartbeat, severe dizziness or syncope, very nervous and excitable conditions, severe headache or skin rash, all of which should be immediately reported to prescribing physician.

References:

1. 2008 PDR, page 3466-3471. ©2013 UpToDate® - www.uptodate.com
Epocrates 2013 - www.epocrates.com

Revision History:

Date Revised: 10/17/11 by A. Reeves MD
 Date Reviewed/No Updates: 4/2/12; 1/16/13 by A. Reeves, MD
 Date Approved by P&T Committee: 4/28/8; 10/25/11; 4/24/12; 1/29/13
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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/1/18	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – excluded from the Formulary effective 1/1/18
1/22/19	Yes	Catherine Sanders, MD; Robert Sterling, MD	Unarchived – Formulary Exclusion – For Exception Review Use Only Annual Review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review