

Prior Authorization DRUG Guidelines

**Modafinil (Provigil)**

Effective Date: 1/23/2018

Date Developed: 1/22/2018 by Dr. C. Sanders

Last Approval Date: 1/23/2018, 1/22/19, 2/18/20, 2/2/21,  
8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Modafinil is a wakefulness promoting agent for oral administration. The precise mechanism of action is unknown; however, it is theorized that it may exert its stimulant effects by decreasing GABA- mediated neurotransmission). EEG 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

**Pre-Authorization Criteria:**

Modafinil may be approved for the following:

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

**Off Label:** Cancer-related fatigue, severe (in patients receiving active treatment); Hypersomnia, idiopathic; Major depressive disorder (antidepressant augmentation); Multiple sclerosis–related fatigue; Parkinson disease–related excessive daytime sleepiness

**Note:**

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

**Note:**

Off label uses of Modafinil are not covered unless documentation meets VCHCP's policy on Coverage of Prescription Medication for Off-Label Use.

**Note:** Modafinil is not approved for pediatric patients under the age of 16 for any indication.

**Note:** Brand Name Provigil is not a covered medication.

**Dosing:**

**Narcolepsy and OSA:** 200mg once daily in AM.

**Shift Work Sleep disorder (SWSD):** 200mg as a single dose about 1 hour prior to start of work shift.

**Note:** Doses up to 400mg once daily have been well tolerated, but there is no consistent evidence that this dose confers additional benefit.

**Note:** see product literature for off-label doses

**Dosage Forms:** Oral tablet 100mg, 200mg

**Adverse Reactions:** headache, nausea, decreased appetite, diarrhea, nervousness

**Precautions:** Use is not recommended in patients with a history of left ventricular hypertrophy or patients with mitral valve prolapse who have developed mitral valve prolapse syndrome with previous CNS stimulant use. Increased monitoring should be considered in patients with a recent history of myocardial infarction or unstable angina. Use may result in emergence of or exacerbation of psychiatric symptoms. Use with caution in patients with Tourette syndrome or other tic disorders.

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**Revision History:**

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	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
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated dosing, precaution and reference sections. Formatting changes
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added "EEG 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" to Modafinil background. Updated Off Label Use and dosing sections