VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

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, 2/1/22, 1/31/23, 2/13/24, 2/15/25

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Modafinil is a wakefulness promoting agent for oral administration.
The precise mechanism of action is unknown; however, is theorized that it may exert its stimulant effects by decreasing GABA- mediated neurotransmission. An intact central alpha-adrenergic system is required for modafinil's activity). 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 for Attention-deficit/hyperactivity disorder (ADHD), cancer related severe fatigue, major depressive disorder and multiple sclerosis-related fatigue 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 years for any indication.

Note: Brand Name Provigil is not a covered medication.

DOSING:

Narcolepsy:

200- mgm / once daily in AM.-

Shift Work Sleep Disorder: 200- as a single dose about 1 hour before 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 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
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2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Modified the description of Provigil to Modafinil. Updated preauthorization criteria, dosing and references. Removed other uses with supportive evidence and monitoring parameters section. Added off label and precaution sections