VENTURA COUNTY
HEALTH CARE PLAN

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

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. An intact central alpha-adrenergic system is required for modafinil's activity.

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)

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 for any indication.
Note: Brand Name Provigil is not a covered medication.

Dosing:

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

REFERENCES

1) *Fava M, Thase ME, DeBattista C. A multicenter, placebo-controlled study of modafinil augmentation in partial responders to selective serotonin reuptake inhibitors with persistent fatigue and sleepiness. J Clin Psychiatry. 2005;66(1):85-93. doi:10.4088/jcp.v66n0112*
2) *Ghaffari N, Robertson PA. Caution in prescribing modafinil and armodafinil to individuals who could become pregnant. JAMA Intern Med. 2021;181(2):277-278. doi:10.1001/jamainternmed.2020.4206*
3) *Kumar R, "Approved and Investigational Uses of Modafinil: An Evidence-Based Review," Drugs, 2008, 68(13):1803-39.*
4) *Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30(12):1705-1711. doi:10.1093/sleep/30.12.1705*
5) *Provigil (modafinil) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; July 2019*
6) *Volkow ND, Fowler JS, Logan J, et al. Effects of modafinil on dopamine and dopamine transporters in the male human brain: clinical implications. JAMA. 2009;301(11):1148-1154. doi: 10.1001/jama.2009.351.*

Revision History:
Date Developed: 1/22/18 by Catherine Sanders, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19
Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/18/20
Date Reviewed/No Updates: 2/2/21 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/2/21
Date Reviewed/ Updated: 8/3/21 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 8/3/21
Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/1/22
Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/31/23

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
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review