BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.60.061

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	February 2, 2024
Subject:	Modafinil powder	**Page:**	1 of 4

Last Review Date: March 8, 2024

Modafinil powder

Description

Modafinil powder

Background
Modafinil is a central nervous system stimulant with potential for abuse. The Drug Enforcement Administration (DEA) has listed Modafinil as a Schedule IV drug. The mechanism through which Modafinil promotes wakefulness is unknown. It has wake-promoting actions similar to sympathomimetic agents including amphetamine and methamphetamine, but the pharmacologic profile is not identical to that of the sympathomimetic amines (1).

Regulatory Status
FDA-approved indications: Modafinil is a central nervous system stimulant that is indicated for improving wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (1).

Limitations of Use: (1)
In OSA, Modafinil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction.

Off-Label Uses:

- Modafinil is used as an adjunct to standard treatments for OSA (2-3).
- Modafinil has been found effective in the treatment of multiple sclerosis fatigue. Modafinil is a unique wake-promoting agent that is chemically distinct from traditional stimulants. Results of a placebo-controlled study showed it to significantly improve fatigue and sleepiness and to be well tolerated by patients with multiple sclerosis (MS). For MS

patients who experience significant fatigue there are several medications that have proven effective in this regard. Modafinil is among the most commonly used medications for fatigue associated with MS and according to expert opinion, is currently a first-line drug for MS patients (4-5).

Idiopathic hypersomnia, a condition similar to narcolepsy, is characterized by constant or recurrent daytime sleepiness with no other cause of sleepiness, prolonged nocturnal sleep, difficulty awakening with sleep drunkenness, and long unrefreshing naps with no history of cataplexy. Modafinil has proven effective in treating idiopathic hypersomnia in one case series and several open-label trials. The practice parameters for the treatment of narcolepsy and other hypersomnias of central origin state that Modafinil may be effective for the treatment of daytime sleepiness due to idiopathic hypersomnia. As there may be underlying causes/behaviors associated with EDS, a sleep specialist physician has the training to correctly recognize and diagnose this condition (3).

Related Policies
Provigil Nuvigil, Sunosi, Wakix

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Modafinil powder may be considered **medically necessary** if the conditions indicated below are met.

Modafinil powder may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 16 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Narcolepsy
2. Idiopathic or Primary Hypersomnia

3. Multiple Sclerosis (MS) Fatigue
4. Shift Work Sleep Disorder (SWSD) - Irregular sleep/wake rhythm
5. Excessive sleepiness due to obstructive sleep apnea (OSA) **AND ONE** of the following:
    a. Compliant with other standard OSA treatments (such as CPAP and oral appliances)
    b. CPAP therapy is contraindicated
    c. Standard OSA treatments found to be ineffective after history of compliant use

AND ALL of the following:
1. The requested dosage form is for oral use only
2. The requested strength is **NOT** commercially available

Prior – Approval *Renewal* Requirements
Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 600 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Modafinil is a central nervous system stimulant used to increase wakefulness in adult patients with narcolepsy, shift work sleep disorder and obstructive sleep apnea. The Drug Enforcement Administration (DEA) has listed modafinil as a Schedule IV drug. Modafinil is indicated for

improving wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder. Modafinil is also used off-label to treat MS fatigue (1-5).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Modafinil powder while maintaining optimal therapeutic outcomes.

References

1. Provigil [package insert]. North Wales, PA: Cephalon, Inc; December 2022.
2. Black JE, Hull SG, Tiller J, et al. The long-term tolerability and efficacy of armodafinil in patients with excessive sleepiness associated with treated obstructive sleep apnea, shift work disorder, or narcolepsy: an open-label extension study. *J Clin Sleep Med*. 2010 Oct 15;6(5):458-66.
3. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine Report. *Sleep*. 2007;30(12):1705-1711.
4. Zifko UA, Rupp M, Schwarz S, et al. Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study. *J Neurol*. 2002;249:983-987.
5. Brown JN, Howard CA, Kemp DW. Modafinil for the treatment of multiple sclerosis-related fa*tigue. Ann Pharmacother*. 2010 Jun;44(6):1098-103.

Policy History

Date	Action
February 2024	Addition to PA
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.