

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Provigil (modafinil)

CLASSIFICATION

- CNS Stimulant (amphetamine related)

DESCRIPTION

- Modafinil is a central nervous system stimulant. Structurally, modafinil is a benzhydrylsulfinylacetamide compound and bears only a distant similarity to dextroamphetamine. The precise mechanism of action of modafinil in producing stimulatory effects is unclear. It appears to lack the peripheral sympathomimetic effects observed with amphetamines.
- Modafinil has been shown to reduce excessive sleepiness in patients with narcolepsy, obstructive sleep apnea/hypopnea syndrome, shift work sleep disorder, and idiopathic hypersomnia.
- Comparisons of modafinil with agents that have proven effective in narcolepsy, including methylphenidate, pemoline, and dextroamphetamine, are needed to clarify its relative safety and efficacy, and place in therapy.
- Though not FDA approved to improve fatigue in patients with Multiple Sclerosis, modafinil has been successful versus placebo in at least 2 patient blinded clinical trials
- Though not FDA approved to improve fatigue secondary to drug therapy, modafinil was moderately effective in reducing excessive daytime sleepiness in a small trial of patients with idiopathic Parkinson's Disease taking concomitant levodopa and/or other dopamine agonists.
- Additional studies will be required to determine if modafinil produces clinically significant benefits in patients with alcoholic organic brain syndrome.
- There are no studies evaluating modafinil in the treatment of attention deficit disorder

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	T2
Commercial Formulary:	T2
Medicare Part D coverage:	T3 (Preferred Brand)

COVERAGE CRITERIA

Provigil (modafinil) meets the definition of **medical necessity** for the following:

- **Narcolepsy**; to improve wakefulness in patients with excessive daytime sleepiness
- **Obstructive sleep apnea**; Improvement in excessive sleepiness, as **an adjunct to standard treatment(s) for the underlying obstruction**
- **Shift work sleep disorder**
- **Fatigue secondary to multiple sclerosis (non-FDA approved use)**
- **Fatigue secondary to drug therapy of Parkinson's Disease (non-FDA approved use)**

Provigil (modafinil) is considered **experimental** for the following:

- Attention deficit hyperactivity disorder
- Delirium
- Depression
- Fibromyalgia

- Schizophrenia; Adjunct
- Sleep deprivation
- Somnolence due to adverse reaction to a drug
- Spastic cerebral palsy
- Steinert myotonic dystrophy syndrome

Required Provider Specialty:

- Original diagnosis of the sleep disorder must be made and documented by a Neurologist or Sleep disorder specialist.
 - Subsequent requests for the medication may be made by a primary care doctor or psychiatrist, but in these cases the results of the sleep study need to be documented

DOSAGE/ADMINISTRATION:

- **Narcolepsy:** 200 mg ORALLY once daily in the morning; doses up to 400 mg have been used
- **Obstructive sleep apnea; Adjunct:** 200 mg ORALLY once daily in the morning; doses up to 400 mg have been used
- **Shift work sleep disorder:** 200 mg ORALLY once daily 1 hour before start of work shift; doses up to 400 mg have been used

PRECAUTIONS:

- Angioedema, multiorgan hypersensitivity reaction, and anaphylactoid reactions have been reported
- Steroidal contraceptives, concomitant and one month after discontinuation; effectiveness reduced, alternative contraception recommended
- Depression, mania, psychosis or suicidal ideation, history of; increased risk of psychiatric adverse effects
- Elderly patients; drug clearance may be reduced
- Hepatic impairment, severe, with or without cirrhosis; drug clearance may be reduced
- Left ventricular hypertrophy, history of; increased risk of cardiac adverse events
- Mitral valve prolapse with CNS stimulant use; increased risk of cardiac adverse events
- Rash, serious or life-threatening including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug rash with eosinophilia and systemic symptoms have been reported
- Sleepiness, abnormal or excessive; previous level of wakefulness may not return to normal

Billing/Coding information

- n/a

COST

AWP (March 2010):

- 100 mg (30): \$323.70; 200 mg (30): \$489.90

AWP (February 2012):

- 100 mg (30): \$612.00; 200 mg (30): \$924.00

COMMITTEE APPROVAL:

July 28, 2010

GUIDELINE UPDATE INFORMATION:

03/2010	Policy creation
01/2011	Added background for non-FDA approved covered uses

REFERENCES:

- DRUGDEX®, accessed 03/29/2010, 01/14/2011.
- Product Information: Provigil(R), modafinil. Cephalon, Inc., West Chester, PA, 2004.