

# WELLCHOICE™

## PRIOR AUTHORIZATION CRITERIA

Generic/Brand: **Modafinil (Provigil)**

Therapeutic Class: psychostimulant

### DESCRIPTION:

Modafinil is a racemic compound with unique properties in promoting wakefulness; modafinil's mechanism of action appears to be distinct from that of other CNS stimulants. In clinical trials for narcolepsy, modafinil improved daytime vigilance, as assessed by decreases in the number and duration of daytime sleep episodes. Modafinil appears to selectively decrease somnolence and does not affect activities of memory, concentration, or learning, or sleep latency/sleep structure in narcoleptic patients; the drug has no appreciable effects on the incidence of cataplectic attacks associated with narcolepsy. Due to its unique pharmacologic profile, modafinil has shown promise in clinical trials as a treatment for fatigue or excessive sleepiness associated with sleep apnea and multiple sclerosis.

### Indications:

Modafinil is FDA approved for the following uses:

1. treatment of narcolepsy
2. adjunctive treatment of excessive daytime sleepiness associated with obstructive sleep apnea (despite the use of CPAP)
3. sleep problems resulting from circadian rhythm disruption (i.e., shift-work sleep disorder).
4. It is also recognized for off-label treatment to alleviate severe persistent fatigue in persons diagnosed with multiple sclerosis or major depression.

### CRITERIA FOR APPROVAL:

1. Provigil may be approved based solely on the following diagnoses:

- Narcolepsy
- excessive daytime sleepiness associated with obstructive sleep apnea (despite the use of CPAP)
- sleep problems resulting from circadian rhythm disruption (i.e., shift-work sleep disorder).

2. Provigil may be approved to alleviate severe persistent fatigue related to multiple sclerosis if the member has failed therapy with or has a medical contraindication to CNS stimulants (amphetamine, dextroamphetamine, methylphenidate)

3. Provigil may be approved to treat severe persistent **fatigue related to depression** if the member:

- has failed therapy with or has a medical contraindication to CNS stimulants (amphetamine, dextroamphetamine, methylphenidate) has failed or is not a candidate for augmentation therapy.

### FORMULARY ALTERNATIVES INCLUDE:

Methylphenidate immediate and sustained release, dextroamphetamine immediate and sustained release, amphetamine salt combo (immediate release).

### LENGTH OF APPROVAL:

The length of time requested by the prescriber, but no longer than 6 months. A new request for review would need to be made when approval expires and should include patient's clinical response to the drug.

### REFERENCES:

Clinical Pharmacology, Version 2.14, Copyright 2004, Gold Standard Multimedia

Lippincott's Drug Facts and Comparisons, October 2004, © 2004 Wolters Kluwer Health, Inc.

Practice guideline for the treatment of major depressive disorder (Revision). Am J. Psychiatry 2000;157 (Supplement): 1-45.