Policies Repository

AmeriHealth.

Policy Title	Modafinil (Provigil®)
Policy Number	FS.CLIN.4

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Modafinil (Provigil®) is indicated to improve wakefulness in individuals with excessive daytime sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.

The use of modafinil (Provigil®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review). An urgent, temporary, 96-hour supply is available (through retail pharmacy facilitation) upon request during review for medical necessity.

Policy Description

Modafinil (Provigil®) is a wakefulness-promoting agent. Modafinil (Provigil®) is chemically unrelated to the traditional central nervous system (CNS) stimulants amphetamine and methylphenidate, and has a pharmacologic profile different from that of sympathomimetic amines. Although the precise mechanism of action is unknown, modafinil (Provigil®) promotes wakefulness by selectively increasing neuronal activation in discrete regions of the brain (eg, anterior hypothalamus) that are believed to be involved in mediating normal wakefulness. Modafinil (Provigil®) is not indicated for use in circadian rhythm sleep disorders or other sleep deprivation disorders.

Policy Guideline Inclusion

NARCOLEPSY

Modafinil (Provigil®) is approved when the following inclusion criterion is met:

- Documentation of a diagnosis of Narcolepsy with recommendation of modafinil (Provigil®) by a neurologist or sleep specialist

OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS)

Modafinil (Provigil®) is approved when **both** of the following inclusion criteria are met:

- Documentation of a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS)
- Documentation that modafinil (Provigil®) will be used concurrently with continuous positive airway pressure (CPAP)

SHIFT WORK SLEEP DISORDER (SWSD)
Modafinil (Provigil®) is approved when **all** of the following inclusion criteria are met:

- Member meets **one** of the following:
  - Documentation of a diagnosis of Shift Work Sleep Disorder with recommendation of modafinil (Provigil®) by a neurologist or sleep specialist
  - Polysomnography and the multiple sleep latency test (MSLT) demonstrate loss of a normal sleep-wake pattern
- No medical or mental disorder accounts for the symptoms
- The symptoms do not meet criteria for any other sleep disorder producing insomnia or excessive sleepiness (e.g. time-zone change [jet lag] syndrome)

Policy Guideline Exclusion

NARCOLEPSY
Modafinil (Provigil®) is denied when the following exclusion criterion is present:

- No documentation of a diagnosis of Narcolepsy with recommendation of modafinil (Provigil®) by a neurologist or sleep specialist

OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME (OSAHS)
Modafinil (Provigil®) is denied when **either** of the following exclusion criteria is present:

- No documentation of a diagnosis of obstructive sleep apnea/hypopnea syndrome (OSAHS)
- No documentation that modafinil (Provigil®) will be used concurrently with continuous positive airway pressure (CPAP)

SHIFT WORK SLEEP DISORDER (SWSD)
Modafinil (Provigil®) is denied when **either** of the following exclusion criteria is present:

- Member does not meet **one** of the following:
  - Documentation of a diagnosis of Shift Work Sleep Disorder with recommendation of modafinil (Provigil®) by a neurologist or sleep specialist
  - Polysomnography and the multiple sleep latency test (MSLT) demonstrate loss of a normal sleep-wake pattern
- A medical or mental disorder accounts for the symptoms
- The symptoms meet criteria for other sleep disorder producing insomnia or excessive sleepiness (e.g. time-zone change [jet lag] syndrome).

Policy List of Applicable Drugs

Brand Name	Generic Name
Provigil	Modafinil

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Narcolepsy. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2000:609-615.

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Markovitz PJ, Wagner S. An open-label trial of modafinil augmentation in patients with partial response to antidepressant therapy. *J Clin Psychopharmacol*. 2003;23:207-209.

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Policy Link to Related Policies

Printed 07/06/2009 10:19:54

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