Title: Modafinil (Provigil®)
Policy #: Rx.01.58

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 restrictions. 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. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. 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.

Intent:
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 (i.e. clinical pharmacist and/or Medical Director review).

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 (e.g., 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.

Black Box Warning:
None

Policy:
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)

Guidelines:
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION
Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

ICSD—international classification of sleep disorders: diagnostic and coding manual. 2nd ed. Weschester, IL: American Academy of Sleep Medicine, 2005

Robert L Sack, MD; Dennis Auckley, MD; R. Robert Auger, MD; Mary A. Carskadon, PhD; Kenneth P. Wright Jr, PhD; Michael V. Vitiello, PhD; Irina V. Zhdanova, MD. Circadian Rhythm Sleep Disorders: Part I, Basic Principles, Shift Work and Jet Lag Disorders An American Academy of Sleep Medicine Review. SLEEP, Vol. 30, No. 11, 2007


Applicable Drugs:
Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>Provigil</td>
<td>Modafinil</td>
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Cross References:
Policy Version Number: 3.00
P&T Approval Date: April 11, 2013
Policy Effective Date: June 01, 2013
Next Required Review Date: April 11, 2014

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