I. Description

Modafinil (Provigil) and armodafinil (Nuvigil) are indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea /hypopnea syndrome (OSAHS) and shift work sleep disorder (SWSD).

II. Criteria/Guidelines

Modafinil or armodafinil is covered (subject to Limitations/Exclusions and Administrative Guidelines) to reduce excessive sleepiness associated with any of the following disorders:

A. Narcolepsy: The patient meets the following criteria for narcolepsy established by the International Classification of Sleep Disorders:

1. The patient has a complaint of excessive daytime sleepiness occurring almost daily for at least three months.
2. Nocturnal polysomnography followed by a Multiple Sleep Latency Test (MSLT) that demonstrates a mean sleep latency of less than or equal to eight minutes and two or more sleep onset REM periods are observed following sufficient nocturnal sleep (minimum of six hours) during the night prior to the test.
3. The hypersomnia is not better explained by another sleep disorder or neurological disorder, mental disorder, medication use, or substance use disorder.

B. OSAHS: When used as an adjunct to standard treatment(s) for the underlying obstruction for patients meeting the following criteria:

1. Diagnosis must be confirmed by a polysomnogram.
2. The patient must be compliant using a CPAP or BIPAP at optimal pressure for at least two months for a minimum of four hours per night.
C. Shift work sleep disorder (SWSD): (Federal 87 plan members only)

1. The patient must be symptomatic for at least three months; and
2. The diagnosis must be confirmed by a MSLT that demonstrates excessive sleepiness at the
time of night shifts (MSLT score < 6 minutes) or daytime insomnia must be documented by
a daytime polysomnogram.

D. These criteria will continue to apply when modafinil and armodafinil become available in a
generic form.

III. Limitations/Exclusions

A. Modafinil and armodafinil are not covered for the following conditions:

1. Attention deficit hyperactivity disorder (ADHD)
2. Medication induced fatigue
3. Idiopathic hypersomnia

B. Lifestyle uses of modafinil and armodafinil are not a plan benefit. Examples of lifestyle uses
include but are not limited to:

1. Fatigue not associated with a medical condition;
2. Excessive sleepiness associated with SWSD (except for Federal 87 plan members only).

C. Modafinil and armodafinil are controlled substances and are not eligible for a drug tier
exception.

IV. Administrative Guidelines

A. Precertification is required for patients with narcolepsy. Submit the following documentation:

1. Clinical notes documenting the patient's symptoms
2. The polysomnogram and MSLT test results

B. Precertification is required and may be given for up to 12 months for patients with OSAHS.
Submit the following documentation:

1. Polysomnogram results
2. Medical notes documenting patient compliance with CPAP or BIPAP for at least two
   months, four or more hours per night
3. For continuation of therapy after the initial 12 months, submit current medical notes
documenting the patient's continued compliance with CPAP or BIPAP

C. Precertification is required and may be given for up to 12 months for patients with a diagnosis
of SWSD: Submit the following documentation:

1. Results from the MSLT or daytime polysomnogram
2. A current work schedule
3. For continuation of therapy after the initial 12 months, submit an updated work schedule
D. Complete HMSA’s Drug Review Request with the required documentation and mail or fax the form as indicated

V. Important Reminder
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA consider the application of this Medical Policy to the case at issue.

VI. References

8. The Medical Letter. New indications for modafinil (Provigil). April 26, 2004