

# PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>NARCOLEPSY AGENTS</b>
<b>BRAND NAME (generic)</b>	<b>PROVIGIL (modafinil)</b>
<b>Status: CVS Caremark® Criteria</b> <b>Type: Initial Prior Authorization with Quantity Limit</b>	

## POLICY

### FDA-APPROVED INDICATIONS

Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD).

### Limitations of Use

In OSA, Provigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with Provigil for excessive sleepiness.

### Compendial Uses/Limited Treatment Option

Fatigue related to multiple sclerosis<sup>8,9</sup>  
Idiopathic hypersomnia<sup>6</sup>

### COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of obstructive sleep apnea (OSA)

**AND**

- The request is NOT for continuation of therapy

**AND**

- The requested drug is being prescribed by, or in consultation with, a sleep specialist

**AND**

- The diagnosis has been confirmed by polysomnography

**AND**

- The patient has been receiving treatment for the underlying airway obstruction (continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BIPAP]) for at least one month

**AND**

- Treatment with continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP) will continue

**OR**

- The request is for continuation of therapy

**AND**

- The patient has achieved or maintained a positive response to treatment from baseline

**AND**

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- The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)

**OR**

- The patient has a diagnosis of narcolepsy

**AND**

- The request is NOT for continuation of therapy

**AND**

- The requested drug is being prescribed by, or in consultation with, a sleep specialist

**AND**

- The diagnosis is confirmed by sleep lab evaluation

**OR**

- The request is for continuation of therapy

**AND**

- The patient has achieved or maintained a positive response to treatment from baseline

**OR**

- The patient has a diagnosis of shift work disorder (SWD)

**AND**

- The request is NOT for continuation of therapy

**AND**

- The requested drug is being prescribed by, or in consultation with, a sleep specialist

**AND**

- A sleep log and actigraphy monitoring have been completed for at least 14 days and show a disrupted sleep and wake pattern

**AND**

- Symptoms have been present for 3 or more months

**OR**

- The request is for continuation of therapy

**AND**

- The patient has achieved or maintained a positive response to treatment from baseline

**AND**

- The patient is still a shift-worker

**OR**

- The requested drug is being prescribed for idiopathic hypersomnia

**AND**

- The request is NOT for continuation of therapy

**AND**

- The requested drug is being prescribed by, or in consultation with, a sleep specialist

**AND**

- The patient has experienced the presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months

**AND**

- Insufficient sleep syndrome has been ruled out such as by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least a week of sleep log with wrist actigraphy

**AND**

- A multiple sleep latency test (MSLT) documented fewer than two sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs if the REM latency on the preceding polysomnogram was less than or equal to 15 minutes

**AND**

- Sleep lab evaluation showed at least ONE of the following: A) mean sleep latency on multiple sleep latency test (MLST) of less than or equal to 8 minutes, B) total 24-hour sleep time of greater than or equal to 660 minutes on 24-hour polysomnographic monitoring after correcting any chronic sleep deprivation or by wrist actigraphy in association with a sleep log and averaged over at least 7 days of unrestricted sleep

**AND**

- The patient does not have cataplexy

**AND**

- Hypersomnolence or multiple sleep latency test (MSLT) results are not better explained by ANY of the following: A) another sleep disorder, B) other medical or psychiatric disorder, C) use of drugs or medications

**OR**

- The request is for continuation of therapy

**AND**

- The patient has achieved or maintained a positive response to treatment from baseline

**OR**

- The requested drug is being prescribed for multiple sclerosis-related fatigue

**AND**

- The request is NOT for continuation of therapy

**OR**

- The request is for continuation of therapy

**AND**

- The patient has achieved or maintained a positive response to treatment from baseline

Quantity Limits Apply.

60 tablets per 25 days\* or 180 tablets per 75 days\*

\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA):

- 178-C: Initial therapy DOA: 12 months; Continuation of therapy DOA: 12 months
- 2814-C: Initial therapy DOA: 12 months; Continuation of therapy DOA: 12 months

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