PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**NARCOLEPSY AGENTS**
BRAND NAME (generic)	**PROVIGIL (modafinil)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder.

Limitations of Use
In obstructive sleep apnea (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[8,9]
Idiopathic hypersomnia[6]

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

- The patient has a diagnosis of narcolepsy
  AND
  - The request is for continuation of therapy
    AND
  - The patient had a positive response to treatment

  OR
  - 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 patient has a diagnosis of shift work disorder (SWD)
  AND
  - The request is for continuation of therapy
    AND
  - The patient had a positive response to treatment
    AND
  - The patient is still a shift-worker

  OR
  - 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 patient has a diagnosis of obstructive sleep apnea (OSA)
  AND
  - The request is for continuation of therapy
    AND
  - The patient had a positive response to treatment
    AND
  - The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP)

  OR
  - 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 requested drug is being prescribed for idiopathic hypersomnia
  AND
  - The request is for continuation of therapy
    AND
  - The patient had a positive response to treatment

  OR
  - 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
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OR

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

Quantity Limits Apply. 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.

REFERENCES

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4. American Academy of Sleep Medicine. *International Classification of Sleep Disorders: Diagnostic and Coding Manual*. 3rd edition. Westchester, IL: American Academy of Sleep Medicine; 2014.
5. Morgenthaler TJ, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. *Sleep.* 2007; 30(12):1705-1711.
6. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2021;17(9):1881-1893.
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8. Czeisler CA, Walsh JK, Roth T, et al. Modafinil for excessive sleepiness associated with shift work sleep disorder. *N Engl J Med*. 2005: 353; 476-486.
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10. Brown JN, Howard CA, Kemp DW. Modafinil for the treatment of multiple sclerosis-related fatigue. *Ann Pharmacother*. 2010 Jun; 44(6):1098-103.
11. Zifko UA, Rupp M, Schwarz S, et al. Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study. *J Neurol*. 2002; 249:983-987.