AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Provigil (modafinil)	Page:	1 of 4
Effective Date:	3/17/2023	Last Review Date:	3/2/2023

Applies to:	☐Illinois	☐Florida	☒Florida Kids
	☒New Jersey	☐Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☐Texas

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Provigil (modafinil) under the patient's prescription drug benefit.

Description:

Provigil (modafinil) 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 (modafinil) 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 (modafinil) for excessive sleepiness.

Compendial Uses/Limited Treatment Option
Fatigue related to multiple sclerosis[8,9]
Idiopathic hypersomnia[6]

Applicable Drug List:

Modafinil

Policy/Guideline:

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

AND

- The patient is unable to take armodafinil for the given diagnosis, due to a trial and inadequate treatment response, or intolerance, or a contraindication

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: 60 tablets/25 days* or 180 tablets/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.*

References:

1. Provigil [package insert]. North Wales, Pennsylvania: Teva Pharmaceuticals USA, Inc.; November 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed January 26, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 26, 2022.
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.
7. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med.* 2021;17(9):1895-1945.
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.
9. Epstein LJ, Kristo D, Strollo PJ et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. *J Clin Sleep Med.* 2009:5(3):263-276.
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.