			₩	etna •
AETNA BE	TTER HEALTH®			
Coverage	Policy/Guideline			
Name:	Provigil (modafinil)		Page:	1 of 4
Effective Date: 3/17/2023			Last Review Date:	3/2/2023
Amaliaa	⊠Illinois	□Florida	□Florida Kids	
Applies to:	☐New Jersey	\square 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.

<u>Compendial Uses/</u>Limited Treatment Option Fatigue related to multiple sclerosis^{8,9} Idiopathic hypersomnia⁶

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
- o The diagnosis is confirmed by sleep lab evaluation

OR

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

AND

AFTNA BF	TTER HEALTH®		* a	etna [™]
	Policy/Guideline			
Name:	Provigil (modafinil)		Page:	2 of 4
Effective Date: 3/17/2023			Last Review Date:	3/2/2023
Applies	⊠Illinois	□Florida	□Florida Kids	
Applies to:	☐New Jersey	\square Maryland	□Michigan	
	□Pennsylvania Kids	□Virginia	□Texas	

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

ΔND

 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

	TTER HEALTH®		*ac	etna [™]
Coverage	Policy/Guideline			
Name:	Provigil (modafinil)		Page:	3 of 4
Effective Date: 3/17/2023			Last Review Date:	3/2/2023
Amaliaa	⊠Illinois	□Florida	□Florida Kids	
Applies to:	□New Jersey	\square Maryland	□Michigan	
	□Pennsylvania Kids	□Virginia	□Texas	

- 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

0

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

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.

			* ae	etna [®]
AETNA BE	TTER HEALTH®			
Coverage	Policy/Guideline			
Name:	Provigil (modafinil)		Page:	4 of 4
Effective Date: 3/17/2023			Last Review Date:	3/2/2023
Applica	⊠Illinois	□Florida	□Florida Kids	
Applies to:	□New Jersey	\square Maryland	□Michigan	
	□Pennsylvania Kids	□Virginia	□Texas	

- 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.
- 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.
- 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.