

# Initial Prior Authorization with Quantity Limit Provigil Narcolepsy Agents

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Provigil	modafinil

## Indications

### 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

- Fatigue related to multiple sclerosis<sup>8,9</sup>

- Idiopathic hypersomnia<sup>6</sup>

## Coverage Criteria

### Idiopathic Hypersomnia

Authorization may be granted when the requested drug is being prescribed for idiopathic hypersomnia when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The patient has experienced the presence of daytime lapses into sleep or daily irrepressible periods of need to sleep for at least 3 months.
- 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.
- A multiple sleep latency test (MSLT) documented fewer than two sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs if the rapid eye movement (REM) latency on the preceding polysomnogram was less than or equal to 15 minutes.
- Sleep lab evaluation showed at least ONE of the following: mean sleep latency on MLST of less than or equal to 8 minutes, 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.
- The patient does NOT have cataplexy.
- Hypersomnolence or MSLT results are not better explained by ANY of the following: another sleep disorder, other medical or psychiatric disorder, use of drugs or medications.

### Multiple Sclerosis-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for multiple sclerosis-related fatigue.

### Narcolepsy

Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when ALL of the following criteria are met:

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

## Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis has been confirmed by polysomnography or home sleep apnea test (HSAT) with a technically adequate device.
- 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.
- The patient will continue to use CPAP or BIPAP after the requested drug is started.

## Shift Work Disorder (SWD)

Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- A sleep log and actigraphy monitoring have been completed for at least 14 days AND show a disrupted sleep and wake pattern.
- Symptoms have been present for 3 or more months.

# Continuation of Therapy

## Idiopathic Hypersomnia

Authorization may be granted when the requested drug is being prescribed for idiopathic hypersomnia when the following criteria is met:

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

## Multiple Sclerosis-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for multiple sclerosis-related fatigue when the following criteria is met:

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

## Narcolepsy

Authorization may be granted for a diagnosis of excessive sleepiness associated with narcolepsy when the following criteria is met:

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

## Obstructive Sleep Apnea (OSA)

Authorization may be granted for a diagnosis of excessive sleepiness associated with obstructive sleep apnea (OSA) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient is compliant with using continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BIPAP).

## Shift Work Disorder (SWD)

Authorization may be granted for a diagnosis of excessive sleepiness associated with shift work disorder (SWD) when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient is still a shift-worker.

## 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: DOA: 12 months
- 2814-C: DOA: 12 months

## References

1. Provigil [package insert]. Parsippany, NJ: Teva Pharmaceuticals; December 2022.
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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/19/2024).
4. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504.
5. 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.

Reference number(s)
178-C, 2814-C

6. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
7. Sateia MJ. International Classification of Sleep Disorders- Third Edition: Highlights and Modifications. CHEST. 2014;146(5):1387-1394.
8. 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.
9. 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.
10. National Multiple Sclerosis Society. Fatigue. Available at: <https://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms/Fatigue>. Accessed November 19, 2024.
11. Shangyan H, Kuiqing L, Yumin X, et al. Meta-analysis of the efficiency of modafinil versus placebo in the treatment of multiple sclerosis fatigue. Mult Scler Relat Disord. 2018;19:85-89.
12. Trotti LM, Becker LA, Friederich Murray C, et al. Medications for daytime sleepiness in individuals with idiopathic hypersomnia. Cochrane Database Syst Rev. 2021;5(5):CD012714.