

# Provigil (modafinil)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial and Continuation: 1 year

Medications	Quantity Limit
modafinil Provigil (modafinil)	May be subject to Dose Optimization or Quantity Limit

## **APPROVAL CRITERIA**

Requests for modafinil may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
  - II. Individual is using to treat excessive daytime sleepiness associated with one of the following diagnoses:
    - A. Narcolepsy type 1 (narcolepsy with cataplexy) confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least **ONE** ([1 **and** 2], **OR** 3) of the following (ICSD-3):
      1. Clear cataplexy (defined as “more than one episode of generally brief [ $<2$  min] usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness”); **AND**
      2. Multiple Sleep Latency Test (MSLT) showing **ONE** of the following:
        - a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
        - b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);

**OR**

    - 3. Cerebrospinal fluid hypocretin-1 deficiency (less than [ $<$ ] 100 pg/mL or less than one-third of the normative values with the same standardized assay);

**OR**

  - B. Narcolepsy type 2 confirmed by the following:
    1. MSLT with **ONE** of the following (ICSD-3):
      - a. MSLT of less than 8 minutes and evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
      - b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);

**AND**

  - 2. The absence of cataplexy; **AND**
  - 3. Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and PSG.
- OR**
- C. Obstructive Sleep Apnea-Hypopnea Syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing **ONE** of the following (ASM 2017, ICSD-3):
  1. Greater than or equal to 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep; **OR**

2. Greater than 5 obstructive events per hour of sleep and individual reports any of the following:
  - a. Unintentional sleep episodes during wakefulness
  - b. Daytime sleepiness; **OR**
  - c. Unrefreshing sleep; **OR**
  - d. Fatigue; **OR**
  - e. Insomnia; **OR**
  - f. Waking up breath holding, gasping, or choking; **OR**
  - g. Bed partner describing loud snoring, breathing interruptions or both; **OR**
  - h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus;

**AND**

3. Individual has an Epworth Sleepiness Scale score greater than or equal to 10, despite treatment with continuous positive airway pressure (CPAP) for at least 4 hours per night for  $\geq 70\%$  of nights during a consecutive 30-day period (i.e., 4 to 5 nights per week);

**OR**

- D. Shift-Work Sleep Disorder (SWSD) confirmed by the following:
  1. No other medical or mental disorder accounts for the symptoms; **AND**
  2. Symptoms do not meet criteria for any other sleep disorder (such as, jet lag)
  3. Symptoms have occurred for at least 3 months; **AND**
  4. Individual has one of the following:
    - a. Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase; **OR**
    - b. Polysomnography demonstrate loss of a normal sleep-wake pattern (such as disturbed chronobiological rhythmicity).

Requests for modafinil may also be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of idiopathic hypersomnia (IH) confirmed by the following (ICSD-3, Kahn 2015, AASM 2021):
  - A. Daily periods of irresistible need to sleep or daytime lapses into sleep for more than 3 months; **AND**
  - B. Absence of cataplexy; **AND**
  - C. Insufficient sleep syndrome ruled out (if deemed necessary, by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least 1 week of wrist actigraphy); **AND**
  - D. Multiple Sleep Latency Test (MSLT) shows the following:
    1. Fewer than ( $<$ ) 2 sleep-onset rapid eye movement periods (SOREMPs); **OR**
    2. No SOREMPs if the REM sleep latency period on the preceding overnight polysomnogram is 15 minutes or less; **AND**
  - E. The presence of at least one of the following:
    1. MSLT showing a mean sleep latency of 8 minutes or less; **OR**
    2. Total 24-hour sleep time of 660 minutes or longer (typically 12-14 hours) on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over at least 7 days with unrestricted sleep); **AND**

- F. Hypersomnolence or MSLT findings are not better explained by another sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse.

Renewal requests for modafinil may be approved if the following criteria are met:

- I. Individual has met initial diagnostic criteria noted above;

**AND**

- II. Modafinil use has resulted in a reduction in frequency of cataplexy attacks compared to baseline; **OR**
- III. Modafinil use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT) compared to baseline.

**\*NOTE:** The quantity limit for modafinil 200mg tablets can be increased from 200mg (30 tablets/30 days) to 400mg (60 tablets/30 days) after a trial of 200mg (30 tablets/30 days) per day with no success. According to the package insert, doses of 400mg per day given as a single dose have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200mg dose.

**Key References:**

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