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 [<] 110 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 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 ≥ 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 (including 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.

Requests for **brand** Provigil must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic modafinil agent; **AND**
   A. Generic modafinil had inadequate response; **OR**
   B. Generic modafinil caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Key References:

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). NCD #240.4. Updated effective date: March 13, 2008. Available at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=226&ncdver=3&DocID=240.4&bc=gAAAABAAAAAA&. Accessed on April 15, 2024.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 10, 2024.
3. Dauvilliers Y, Bassetti C, Lammers GJ, Arnulf I, et al. Pitolisant vs placebo or modafanil in patients with narcolepsy: a double-blind, randomized trial. *Lancet Neurol*. 2013; 12: 1068-75.
4. Dauvilliers Y, Sonka K, Bogan RK, et.al. Changes in cataplexy frequency by prior therapy in a phase 3, double-blind, placebo-controlled, randomized withdrawal study of JZP-258 in adults with narcolepsy with cataplexy. Poster Session, World Sleep Congress 2019. Available from: https://worldsleepcongress.com/wp-content/uploads/2019/09/WS19-Poster-abstracts-by-author.pdf. NCT03030599.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults: Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2009; 5(3):263-276. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173/pdf/jcsm.5.3.263.pdf. Accessed April 3, 2024.
7. Kahn Z, Trotti LM. Central disorders of hypersomnolence: Focus on the narcolepsies and idiopathic hypersomnia. *Chest*. 2015 July;148(1):262-273. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4694150/#r10. Accessed April 10, 2023.

8. Kapur VK, Auckley DH, Chowdhri 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. Available from: https://aasm.org/resources/clinicalguidelines/diagnostic-testing-osa.pdf. Accessed April 10, 2023.
9. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.
10. 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.* Published online Sept. 1, 2021. Available at https://jcsm.aasm.org/doi/10.5664/jcsm.9328. Accessed on April 3, 2024.
11. Sateia MJ. International classification of sleep disorders – third edition: Highlights and modifications. *Chest.* 2014 Nov; 146(5): 1387-1394. Available from: https://medicinainternaelsalvador.com/wp-content/uploads/2017/03/internation-classification-ICSD-III-beta.pdf. Accessed April 3, 2024.
12. Strollo PJ, Hedner J, Collop N. et.al. Solriamfetol for the treatment of excessive sleepiness in OSA: A placebo-controlled randomized withdrawal study. *Chest.* 2019;155(2):364-374.
13. Szakacs Z, Dauvilliers Y, Mikhaylov V et al. Safety and efficacy of pitolisant on cataplexy in patients with narcolepsy: a randomized, double-blind, placebo-controlled trial. *Lancet*. 2017; 16: 200-7.
14. Thorpy MJ, Shapiro C, Mayer G, et.al. A randomized study of soriamfetol for excessive sleepiness in narcolepsy. *Ann Neurol.* 2019; 85:359-370.
15. Wise MS, Arand DL, Auger RR, Brooks SN, Watson NF; American Academy of Sleep Medicine. Treatment of Narcolepsy and other Hypersomnias of Central Origin. Sleep. 2007 Dec 1;30(12):1712-27. Available from: http://www.aasmnet.org/Resources/PracticeParameters/Review_Narcolepsy.pdf.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.