Modafinil

Override(s)	Approval Duration
Prior Authorization Quantity Limit	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);

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.

*__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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. UR. Updated periodically.
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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 July 14, 2022.
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.
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 July 14, 2022.
9. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; 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 July 14, 2022.
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 July 14, 2022.
12. 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. Accessed July 14, 2022.

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.