# Nuvigil (armodafinil)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|---|
| armodafinil<br>Nuvigil (armodafinil) | May be subject to quantity limits |

## APPROVAL CRITERIA

Requests for armodafinil 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 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-2):
a. MSLT of less than 8 minutes and evidence of two sleep-onset
b. rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
c. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight 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. Individual has a diagnosis of Obstructive Sleep Apnea-Hypopnea Syndromeobjectively 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. Individual has a diagnosis of 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 confirmed:
      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 **brand** Nuvigil 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 armodafinil agent;
   **AND**
   A. Generic armodafinil had inadequate response; **OR**
   B. Generic armodafinil 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**:


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4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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7. 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.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
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10. 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.
11. 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.
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.