Oscar Clinical Guideline: armodafinil (Nuvigil) (PG036, Ver. 7)

armodafinil (Nuvigil)

Summary

Armodafinil (Nuvigil) was FDA approved in 2007 and is a wakefulness-promoting agent approved for use in narcolepsy, obstructive sleep apnea, and shift work sleep disorder.

Narcolepsy is a sleep disorder characterized by excessive sleepiness, daytime sleepiness, and, in some cases, cataplexy (sudden, uncontrollable muscle weakness). Treatment of narcolepsy can involve both non-pharmacologic therapy (such as practicing good sleep hygiene or psychosocial support) and medications.

Obstructive sleep apnea (OSA) is a condition in which breathing repeatedly starts and stops during sleep due to an obstruction in the upper airway. There are many risk factors for OSA including older age, male gender, and obesity. Treatment of OSA can be treated with non-pharmacologic therapy such as weight loss, continuous positive airway pressure (CPAP), oral appliances (such as mandibular advancement devices), and surgery. Drug therapy is also an option for treating OSA. Pharmacologic strategies include increasing respiratory drive and reducing airway collapsibility. Patients who have OSA may experience interrupted sleep during the night and, therefore, may experience excessive sleepiness during the day. Treatment for residual excessive sleepiness caused from OSA includes wakefulness-promoting agents such as modafinil and armodafinil.

Shift Work Sleep disorder develops in people who work during the hours typically used for sleep (such as the night shift). A night shift worker, for example, usually works during the night and has to sleep during the day but will often try to stay awake during daylight on their days off. Also, working at night and sleeping during the day disrupts one's circadian rhythm, which is an internal, biological process that responds to environmental factors. For example, the body will naturally be awake and alert during daylight and want to sleep when it's dark. Therapy for Shift Work Sleep disorder includes practicing good sleep hygiene (i.e., having a sleep schedule, blocking out light), improving daytime sleep with the use of melatonin or sleep agents, and improving wakefulness when awake (with a medication such as armodafinil).

Definitions

"Actigraphy" is a device worn on the wrist (like a watch) that measures activity and rest levels to assess sleep patterns and circadian rhythms.

"Continuous positive airway pressure (CPAP)" is a device that supplies a constant and steady flow of air pressure into the airways to maintain their openness during sleep, commonly used for the treatment of obstructive sleep apnea.

"Home sleep study" is a sleep study usually performed at the patient's home which monitors certain physiological parameters such as heart rate, respiratory pattern, oxygen level. It is used to diagnose sleep apnea.

"Hypocretin-1" is a naturally occurring chemical in the brain that plays a crucial role in regulating wakefulness and sleep.

"Mandibular advancement device" is a medical device that is placed in the mouth during sleep to reposition the lower jaw and tongue, helping to keep the airways open and reducing symptoms of obstructive sleep apnea.

"Multiple sleep latency test (MSLT)" is a diagnostic sleep study performed as 5 daytime naps, used to measure the time it takes an individual to fall asleep during the daytime. It assesses daytime sleepiness and can aid in the diagnosis of conditions such as narcolepsy. It is performed following PSG from the night before.

"Polysomnography (PSG)" is a comprehensive sleep study usually performed at an attended Sleep Lab facility that monitors various physiological parameters during sleep, including brain activity, eye movements, heart rate, oxygen levels, and respiratory patterns. It is used to diagnose and evaluate several sleep disorders.

"Sleep latency" refers to the amount of time it takes an individual to fall asleep after lying down and attempting to sleep. It is commonly assessed during sleep studies and can be used as an indicator of sleep quality and sleep disorders.

Medical Necessity Criteria for Initial Authorization

The Plan considers armodafinil medically necessary when prescribed to improve wakefulness in members with excessive sleepiness AND ALL the following criteria are met for the applicable indication listed below:

For the treatment of narcolepsy

1. The member is 17 years of age or older; *AND*
2. The member has a diagnosis of narcolepsy confirmed by Multiple Sleep Latency Test (MSLT) or Cerebrospinal fluid (CSF) hypocretin-1 laboratory test; *AND*
3. The member has daily periods of excessive daytime sleepiness occurring for at least three months.

For the treatment of Obstructive Sleep Apnea (OSA)

1. The member is 17 years of age or older; *AND*
2. The member has a diagnosis of obstructive sleep apnea, confirmed by polysomnography or a home sleep apnea test; *AND*
3. The member is currently using conventional therapy and has been adherent to such therapy, including ONE of the following:
    a. Positive Airway Pressure Therapy (such as CPAP); *or*
    b. Oral Appliances (such as mandibular advancement devices).

For the treatment of Shift Work Sleep Disorder (SWSD)

1. The member is 17 years of age or older; *AND*
2. The member has a diagnosis of Shift Work Sleep Disorder*; AND*
3. Non-pharmacological therapies have been tried and failed, such as setting a sleep schedule and improving sleep hygiene.

For the treatment of hypersomnia secondary to dementia with Lewy bodies (DLB)

1. The member is 18 years of age or older; *AND*
2. The member has a confirmed diagnosis of dementia with Lewy bodies (DLB); *AND*
3. The member experiences excessive daytime sleepiness associated with dementia with Lewy bodies.

For the treatment of hypersomnia secondary to traumatic brain injury (TBI)

1. The member is 18 years of age or older; *AND*
2. The member has a history of traumatic brain injury (TBI); *AND*

3. The member experiences excessive daytime sleepiness following the TBI.

If the above prior authorization criteria are met, armodafinil will be approved for up to 12 months.

Medical Necessity Criteria for Reauthorization:

Reauthorization for up to 12 months will be granted if BOTH of the following are met:

1. The member still meets the applicable initial criteria*; AND*
2. Chart documentation shows the member has experienced a clinical improvement in symptoms since starting armodafinil, as evidenced by a reduction in the symptoms of excessive daytime sleepiness.

Experimental or Investigational / Not Medically Necessary

Armodafinil for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
2. Black JE, Hull SG, Tiller J, Yang R, Harsh JR. The long-term tolerability and efficacy of armodafinil in patients with excessive sleepiness associated with treated obstructive sleep apnea, shift work disorder, or narcolepsy: an open-label extension study. J Clin Sleep Med. 2010 Oct 15;6(5):458-66.
3. Caples SM, Anderson WM, Calero K, Howell M, Hashmi SD. Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American Academy of Sleep Medicine clinical guidance statement. J Clin Sleep Med. 2021 Jun 1;17(6):1287-1293. doi: 10.5664/jcsm.9240.
4. Czeisler CA, Walsh JK, Wesnes KA, Arora S, Roth T. Armodafinil for treatment of excessive sleepiness associated with shift work disorder: a randomized controlled study. Mayo Clin Proc. 2009 Nov;84(11):958-72. doi: 10.1016/S0025-6196(11)60666-6.
5. Drake C, Gumenyuk V, Roth T, Howard R. Effects of armodafinil on simulated driving and alertness in shift work disorder. Sleep. 2014 Dec 1;37(12):1987-94. doi: 10.5665/sleep.4256.
6. Epstein LJ, Kristo D, Strollo PJ Jr, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med. 2009;5(3):263-76.
7. Howard R, Roth T, Drake CL. The effects of armodafinil on objective sleepiness and performance in a shift work disorder sample unselected for objective sleepiness. J Clin Psychopharmacol. 2014 Jun;34(3):369-73. doi: 10.1097/JCP.0000000000000136.
8. Julienne E. Bower et al., Management of Fatigue in Adult Survivors of Cancer: ASCO–Society for Integrative Oncology Guideline Update. JCO 0, JCO.24.00541 DOI:10.1200/JCO.24.00541
9. Krahn LE, Arand DL, Avidan AY, Davila DG, DeBassio WA, Ruoff CM, Harrod CG. Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in adults: guidance from the American Academy of Sleep Medicine. J Clin Sleep Med. 2021 Dec 1;17(12):2489-2498. doi: 10.5664/jcsm.9620. Erratum in: J Clin Sleep Med. 2022 Aug 1;18(8):2089. doi: 10.5664/jcsm.10100.
10. Kryger MH, Malhotra A. Management of obstructive sleep apnea in adults. UpToDate.com. https://www.uptodate.com/contents/management-of-obstructive-sleep-apnea-in-adults?search=osa&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2 Updated April 01, 2020. Accessed July 07, 2020.

11. Lapid, Maria I., Karen M. Kuntz, Sara S. Mason, Jeremiah A. Aakre, Emily S. Lundt, Walter Kremers, Laura A. Allen, Daniel A. Drubach, and Bradley F. Boeve. "Efficacy, safety, and tolerability of armodafinil therapy for hypersomnia associated with dementia with Lewy bodies: a pilot study." Dementia and geriatric cognitive disorders 43, no. 5-6 (2017): 269-280.
12. Maski K, Trotti LM, Kotagal S, Robert Auger R, Rowley JA, Hashmi SD, Watson NF. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021 Sep 1;17(9):1881-1893. doi: 10.5664/jcsm.9328. PMID: 34743789; PMCID: PMC8636351.
13. Menn, Stuart J., Ronghua Yang, and Alan Lankford. "Armodafinil for the treatment of excessive sleepiness associated with mild or moderate closed traumatic brain injury: a 12-week, randomized, double-blind study followed by a 12-month open-label extension." Journal of Clinical Sleep Medicine 10, no. 11 (2014): 1181-1191.
14. Morgenthaler TI, Kapur VK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. Sleep. 2007;30(12):1705-11.
15. Morgenthaler TI, Lee-Chiong T, Alessi C, et al. Practice Parameters for the Clinical Evaluation and Treatment of Circadian Rhythm Sleep Disorders. Sleep. 2007;30(11):1445-59.
16. Nuvigil (armodafinil) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals; December 2022.
17. Schwartz JR, Khan A, McCall WV, Weintraub J, Tiller J. Tolerability and efficacy of armodafinil in naïve patients with excessive sleepiness associated with obstructive sleep apnea, shift work disorder, or narcolepsy: a 12-month, open-label, flexible-dose study with an extension period. J Clin Sleep Med. 2010 Oct 15;6(5):450-7.

Clinical Guideline Revision / History Information

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