PRIOR AUTHORIZATION WITH STEP THERAPY POLICY

POLICY: Wakefulness-Promoting Agents – Armodafinil, Modafinil Prior Authorization with Step Therapy Policy
- Nuvigil® (armodafinil tablets – Cephalon, generic)
- Provigil® (modafinil tablets – Cephalon, generic)

REVIEW DATE: 10/02/2024

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Armodafinil and modafinil, agents with wake-promoting actions that are similar to sympathomimetic agents (e.g., amphetamine and methylphenidate), are indicated to improve wakefulness in adults with **excessive sleepiness** associated with the following conditions:[1,2]
- **Narcolepsy**.
- **Obstructive sleep apnea/hypoapnea syndrome** (approved as adjunctive therapy).
- **Shift work sleep disorder**.

Armodafinil and modafinil are Schedule IV controlled substances.[1,2] Review of the medical literature notes many other uses of modafinil that are considered off-label or investigational. While armodafinil has not been studied off-label to the same extent as modafinil, it is expected that armodafinil will have similar clinical efficacy for these uses. Additionally, in the pivotal trials for shift work sleep disorder, enrolled patients were required to work a minimum of five night shifts per month.

Two specialized tests, which can be performed in a sleep disorders clinic, are required to establish a diagnosis of narcolepsy.[3] Polysomnogram (PSG) is an overnight recording of brain and muscle activity, breathing, and eye movements. The multiple sleep latency test assesses daytime sleepiness by measuring how quickly a person falls asleep and whether they enter rapid eye movement (REM) sleep. On the day after PSG, the patient is asked to take five short naps separated by two hours over the course of a day. If an individual falls asleep in < 8 minutes on average over the five naps, this indicates excessive daytime sleepiness. However, patients with narcolepsy also have an abnormally quick start to REM sleep. If REM sleep happens within 15 minutes at least two times out of the five naps and the sleep study the night before, this is likely an abnormality caused by narcolepsy.

Guidelines

Pertinent medical guidelines related to modafinil and armodafinil are summarized below.

Narcolepsy and Cataplexy

The American Academy of Sleep Medicine (AASM) practice parameters for the treatment of central disorders of hypersomnolence were updated in 2021.[4,5]

- Modafinil, Wakix® (pitolisant tablets), Xyrem® (sodium oxybate oral solution), and Sunosi™ (solriamfetol tablets) are recommended as effective treatments for daytime sleepiness due to narcolepsy and reducing disease severity in adults (Strong Recommendation for each).
- Wakix and Xyrem have also demonstrated efficacy for the treatment of cataplexy in patients with narcolepsy (Strong Recommendation for each).
- Xyrem and armodafinil have Conditional Recommendations for the treatment of narcolepsy, showing efficacy for daytime sleepiness due to narcolepsy and reducing disease severity.
- Dextroamphetamine has a Conditional Recommendation for the treatment of narcolepsy, showing efficacy for excessive daytime sleepiness and cataplexy.
- Methylphenidate has a Conditional Recommendation for the treatment of narcolepsy, showing efficacy in reducing disease severity.
- There was insufficient and inconclusive evidence to make recommendations for l-carnitine, scheduled naps, selegiline, triazolam, selective serotonin reuptake inhibitors (SSRIs), and serotonin-norepinephrine reuptake inhibitors (SNRIs).
- Modafinil and Xyrem have Conditional Recommendations for the treatment of narcolepsy in pediatric patients.
- A Strong Recommendation should be followed by clinicians under most circumstances. A Conditional Recommendation requires that the clinician use clinical knowledge and experience and strongly consider the individual patient's values and preferences to determine the best course of action.

Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea/Hypoapnea Syndrome

- According to the AASM guideline on medical therapy for obstructive sleep apnea (OSA) [2006], continuous positive airway pressure (CPAP) is the most uniformly effective therapy, and, to date, this is the only intervention for OSA shown to have favorable impacts on both cardiovascular and neurobehavioral morbidities.[6]

- Modafinil, in patients compliant with nasal CPAP, consistently improved subjective and objective sleepiness, quality of life, and vigilance compared with placebo.

Adjunctive/Augmentation Treatment for Major Depressive Disorder

- According to the American Psychiatric Association (APA) practice guideline for the treatment of patients with major depressive disorder (2010), modafinil (or methylphenidate) are potential treatments for sedation associated with antidepressant medications.[7]
- The APA guidelines state that modafinil has shown benefit when combined with an SSRI, related to specific effects on residual symptoms such as fatigue and hypersomnolence.
- The guidelines note that there is no clear guidance regarding the length of time modafinil should be co-administered.
- While armodafinil has not been studied for this use, it is considered to be interchangeable with modafinil for this condition.

Excessive Daytime Sleepiness Associated with Myotonic Dystrophy

- Practice parameters from the AASM, last updated in 2021, suggest that clinicians use modafinil for the treatment of hypersomnia secondary to myotonic dystrophy in adults (Conditional Recommendation).[4,5]
- While armodafinil has not been studied for this use, it is considered to be interchangeable with modafinil for this condition.

Excessive Daytime Sleepiness Associated with Parkinson's Disease

- Practice parameters from the AASM (2021) suggest that clinicians use modafinil for the treatment of hypersomnia secondary to Parkinson's disease in adults (Conditional Recommendation).[4,5]
- While armodafinil has not been studied for this use, it is considered to be interchangeable with modafinil for this condition.

Fatigue Associated with Multiple Sclerosis

- Practice parameters from the AASM (2021) suggest that clinicians use modafinil for the treatment of hypersomnia secondary to multiple sclerosis in adults (Conditional Recommendation).[4,5]
- While armodafinil has not been studied for this use, expert opinion considers it to be interchangeable with modafinil for this condition.

Idiopathic Hypersomnia

Idiopathic hypersomnia, a condition similar to narcolepsy, is characterized by constant or recurrent daytime sleepiness with no other cause of sleepiness, prolonged nocturnal sleep, difficulty awakening with sleep drunkenness, and long unrefreshing naps with no history of cataplexy.[8-10] The AASM practice parameters for the treatment of central disorders of hypersomnolence (2021) include recommendations for the treatment of idiopathic hypersomnia.[4,5]

- Only modafinil has a Strong Recommendation for use.
- Clarithromycin, methylphenidate, Wakix, and Xyrem have Conditional Recommendations for the treatment of idiopathic hypersomnia in adults.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of modafinil (brand and generic) and armodafinil (brand and generic). This Prior Authorization Policy also contains a Step Therapy component. When clinically appropriate, the patient is directed to try one Step 1 Product (generic modafinil or generic armodafinil) prior to brand Nuvigil or brand Provigil (Step 2). All approvals are provided for the duration noted below.

- **Nuvigil® (armodafinil tablets – Cephalon, generic)**
- **Provigil® (modafinil tablets (Cephalon, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Excessive Daytime Sleepiness Associated with Narcolepsy.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been evaluated using polysomnography and a multiple sleep latency test; AND
   - **C)** Diagnosis of narcolepsy has been confirmed, according to the prescriber; AND
   - **D)** The medication is prescribed by or in consultation with a sleep specialist physician or a neurologist; AND
   - **E)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

2. **Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea/Hypoapnea Syndrome.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Armodafinil/modafinil will be used in conjunction with continuous positive airway pressure therapy; OR
     - **ii.** Patient is unable to initiate or tolerate continuous positive airway pressure therapy; AND
   - **C)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers,

preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

3. **Excessive Sleepiness Associated with Shift Work Sleep Disorder.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient works at least five overnight shifts per month; AND
   - **C)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

Other Uses with Supportive Evidence

4. **Adjunctive/Augmentation Treatment for Depression in Adults.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is concurrently receiving other medication therapy for depression; AND
     Note: Examples of other medications for the treatment of depression include selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs).
   - **C)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

5. **Excessive Daytime Sleepiness Associated with Myotonic Dystrophy.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

6. **Excessive Daytime Sleepiness Associated with Parkinson's Disease.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

7. **Fatigue Associated with Multiple Sclerosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

8. **Idiopathic Hypersomnia.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center); AND
   - **C)** If brand Provigil or Nuvigil is being requested, the patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried generic modafinil or generic armodafinil; AND
     - **ii.** Brand product (Nuvigil or Provigil) is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

CONDITIONS NOT COVERED

- **Nuvigil® (armodafinil tablets – Cephalon, generic)**
- **Provigil® (modafinil tablets (Cephalon, generic)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Attention Deficit Hyperactivity Disorder (ADHD).** The American Academy of Pediatrics clinical practice guidelines for the treatment of ADHD in children and adolescents (2011 and 2019) do not address the use of modafinil/armodafinil.[11,12] These guidelines note that with the greater availability of approved medications for children/adolescents with ADHD, it has become increasingly unlikely that clinicians need to consider the off-label use of other medications. Many options exist for the treatment of ADHD in adults (e.g., methylphenidate, dextroamphetamine) and further large scale trials that demonstrate benefit for modafinil in adults with ADHD are needed.

2. **Bipolar Disorder, including Bipolar Depression.** Limited data (one small study [n = 85] and case reports [n = 2]) are available that describe the use of modafinil for bipolar disorder and bipolar depression.[13-15] In one study (n = 257), armodafinil was not more effective than placebo in treating bipolar depression.[16] Only limited data support modafinil for this condition and more data are needed.

3. **Cancer-Related Fatigue.** The National Comprehensive Cancer Network guidelines on cancer-related fatigue (version 2.2024 – October 30, 2023) no longer consider modafinil or armodafinil to be effective for the treatment of cancer-related fatigue and recommend against its use.[17]

4. **Chronic Fatigue Syndrome.** Limited data characterize modafinil therapy in those with chronic fatigue syndrome.[18] In a randomized, double-blind, crossover study in 14 patients with chronic fatigue syndrome, use of modafinil for 20 days had minimal effects on cognitive function and no significant effects on fatigue, health-related quality of life, or mood.[19] More data are required to assess efficacy in this patient population.

5. **Excessive Daytime Sleepiness Associated with Primary Insomnia.** One randomized, placebo-controlled study found that neither combination therapy with modafinil and cognitive behavioral therapy nor modafinil as monotherapy significantly decreased daytime sleepiness associated with primary insomnia.[20]

6. **Enhancement of Performance in Situations of Induced Sleep Deprivation.** Studies are needed to define the role**/**appropriateness of modafinil in these situations for the general population (as opposed to military personnel, etc.). Studies have shown that modafinil may enhance performance and sustain alertness in individuals subjected to situations that deprive sleep (e.g., military aviation, emergency physicians).[21-24] Further studies are needed before its use in the general population in these types of situations can be promoted.

7. **Fibromyalgia.** Limited data are available regarding the use of modafinil in fibromyalgia with most of the data being observational.[25-27] Larger-sized, randomized, placebo-controlled trials are required to better assess and validate the efficacy of modafinil in patients with fibromyalgia before it can be recommended as a therapeutic modality.

8. **Hypersomnia, Fatigue or Sleepiness Due to Other Conditions (<u>not</u> Idiopathic Hypersomnia, see Other Uses with Supportive Evidence).** More data are needed in specific conditions to define the role of modafinil and armodafinil.

9. **Post-Stroke Sleep-Wake Disorders or Sleep Disorders.** Sleep-wake disorders occur in approximately 20% to 40% of patients who have experienced a stroke, which includes hypersomnia and excessive daytime sleepiness. Very limited data (i.e., case reports and one small study) have explored the use of modafinil in these patients to improve alertness.[28,29] More data are needed to determine effectiveness in this condition.

REFERENCES

1. Provigil® tablets [prescribing information]. Parsippany, NJ: Teva; December 2022.
2. Nuvigil® tablets [prescribing information]. Parsippany, NJ: Teva; December 2022.
3. National Institutes of Health. Narcolepsy. National Institute of Neurological Disorders and Stroke. Last reviewed on July 19,2024. Available at: Narcolepsy | National Institute of Neurological Disorders and Stroke (nih.gov). Accessed on September 26, 2024.
4. 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*. 2021;17(9):1881–1893.
5. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med*. 2021;17(9):1895-1945.
6. Veasey SC, Guilleminault C, Strohl KP, et al. Medical therapy for obstructive sleep apnea: a review by the medical therapy for obstructive sleep apnea task force of the standards of practice committee of the American Academy of Sleep Medicine. *Sleep*. 2006;29(8):1036-1044.
7. Gelenberg A, Freeman MP, Markowitz JC, et al. Practice guideline for the treatment of patients with major depressive disorder, Third edition. American Psychiatric Association, November 2010. Available at: American Psychiatric Association Practice Guidelines (psychiatryonline.org). Accessed on September 26, 2024.
8. Mayer G, BenesH, Young P, et al. Modafinil in the treatment of idiopathic hypersomnia without long sleep time—a randomized, double-blind, placebo-controlled study. *J Sleep Res*. 2015;24(1):74-81.
9. Arnulf I, Thomas R, Roy A, et al. Update on the treatment of idiopathic hypersomnia: progress, challenges, and expert opinion. *Sleep Med Rev*. 2023;69:101766. .
10. Inoue Y, Tabata T, Tsukimori N. Efficacy and safety of modafinil in patients with idiopathic hypersomnia without long sleep time: a multicenter, randomized, double-blind, placebo-controlled, parallel-group comparison study. *Sleep Med*. 2021;80:315-321.
11. American Academy of Pediatrics. ADHD: Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. *Pediatrics.* 2011;128(5):1007-1022.
12. Wolraich ML, Hagan JF, Allan C, et al. AAP Subcommittee on children and adolescents with attention-deficit/hyperactivity disorder. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528.
13. Frye MA, Frunze H, Suppes T, et al. A placebo-controlled evaluation of adjunctive modafinil in the treatment of bipolar depression. *Am J Psychiatry*. 2007;164:1242-1249.
14. Post RM, Altshuler LL, Frye MA, et al. New findings from the bipolar collaborative network: clinical implications for therapeutics. *Curr Psychiatry Rep*. 2006;8:489-497.
15. Fernandes PP, Petty F. Modafinil for remitted bipolar depression with hypersomnia. *Ann Pharmacother*. 2003;37(12):1807-1809.
16. Calabrese JR, Ketter RA, Youakim JM, et al. Adjunctive armodafinil for major depressive episodes associated with bipolar I disorder: a randomized, multicenter, double-blind, placebo-controlled, proof-of-concept study. *J Clin Psychiatry.* 2010;71:1363-1370.

17. The NCCN Cancer-Related Fatigue Clinical Practice Guidelines in Oncology (Version 2.2024 – October 30, 2023). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 26, 2024.
18. Turkington D, Hedwat D, Rider I, Young AH. Recovery from chronic fatigue syndrome with modafinil. *Hum Psychopharmacol*. 2004:19(1):63-64.
19. Randall DC, Cafferty FH, Shneerson JM, et al. Chronic treatment with modafinil may not be beneficial in patients with chronic fatigue syndrome. *J Psychopharmacol*. 2005;19(6):647-660.
20. Perlis ML, Smith MT, Orff H, et al. The effects of modafinil and cognitive behavior therapy on sleep continuity in patients with primary insomnia. *Sleep*. 2004;27(4):715-725.
21. Gill M, Haerich P, Westcott K, et al. Cognitive performance following modafinil versus placebo in sleep-deprived emergency physicians: a double-blind, randomized crossover study. *Acad Emerg Med*. 2006;13:158-165.
22. Caldwell JA, Caldwell JL, Smythe NK, Hall KK. A double-blind, placebo-controlled investigation of the efficacy of modafinil for sustaining the alertness and performance of aviators: a helicopter simulator study. *Psychopharmacol*. 2000;150:272-282.
23. Bonnet MH, Balkin TJ, Dinges DF, et al. The use of stimulants to modify performance during sleep loss: a review by the sleep deprivation and stimulant talk force of the American Academy of Sleep Medicine. *Sleep*. 2005;28(9):1163-1187.
24. Caldwell JA, Caldwell JL. Fatigue in military aviation: an overview of US military-approved pharmacological countermeasures. *Avait Space Environ Med*. 2005;76(7):39-C51.
25. Schaller JL, Behar D. Modafinil in fibromyalgia treatment. *J Neuropsychiatry Clin Neurosci*. 2001;13(4):530-531.
26. Schwartz TL, Rayancha S, Rashid A, et al. Modafinil treatment for fatigue associated with fibromyalgia. *J Clin Rheumatol*. 2007;13(1):52.
27. Pachas WN. Modafinil for the treatment of fatigue of fibromyalgia. *J Clin Rheumatol*. 2003;9(4):282-285.
28. Bassetti CL. Sleep and stroke. *Semin Neurol*. 2005;25(1):19-32.
29. Bivard A, Lillicrap T, Krishnamurthy V, et al. MIDAS (modafinil in debilitating fatigue after stroke): a randomized, double-blind, placebo-controlled, cross-over trial. *Stroke*. 2017;48(5):1293-1298.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/20/2023
Annual Revision	No criteria changes.	10/02/2024