Mass General Brigham
Health Plan

Modafinil (Provigil®)
Armodafinil (Nuvigil®)
Effective 03/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Modafinil is a central nervous system stimulant indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD).
Armodafinil is the R-enantiomer of modafinil indicated to improve wakefulness in adult patients with excessive sleepiness associated with OSA, narcolepsy, or SWD.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted all of the following criteria are met:

Armodafinil and Modafinil
Member has ONE of the following diagnoses:
1. Narcolepsy
2. Excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome that has been confirmed by a sleep study AND is currently using CPAP
3. Attention deficit disorder (ADD) or Attention deficient hyperactivity disorder (ADHD)
4. Fatigue associated with Multiple Sclerosis (MS)
5. Fatigue associated with chemotherapy
6. Excessive sleepiness associated with Parkinson's disease
7. Adjunct treatment of depression and the following:
    a. The member has had previous use with at least TWO antidepressant medications (e.g., citalopram, bupropion, fluoxetine, escitalopram, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, nortriptyline)

8. Shift work sleep disorder and ALL of the following:
    a. Patient is ≥ 17 years of age
    b. Patient has had an inadequate response, adverse reaction, or contraindication to one hypnotic agent **and** melatonin

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation is submitted demonstrating improvement of member's condition.

Limitations

1. Approvals will be granted for the following:
    a. Fatigue associated with chemotherapy – 12 months
    b. Excessive sleepiness associated with Parkinson's disease – 12 months
    c. All other indications – 36 months
2. The following diagnoses are excluded from coverage:
    a. Fatigue or sleepiness associated with traumatic brain injuries
    b. Idiopathic hypersomnolence
    c. Fatigue or sleepiness associated with use of narcotic analgesics
    d. Cerebral palsy (spastic)
3. The following quantity limits apply:

Drug Name and Strength	Quantity Limits
modafinil 100mg and 200mg	30 tablets per 30 days
armodafinil 50mg	60 tablets per 30 days
armodafinil 150mg, 200mg and 250mg	30 tablets per 30 days

References

1. Biederman J, Swanson JM, Wigal SB, Boellner SW, Earl CQ, Lopez FA, et al. A comparison of once-daily and divided doses of modafinil in children with attention-deficit/hyperactivity disorder: a randomized, double-blind, and placebo-controlled study. J Clin Psychiatry. 2006;67(1):137-47.
2. Billiard M, Dauvilliers Y, Dolenc-Groselj L, Lammers GJ, Mayer G, Sonka K. Management of narcolepsy in adults. In: Gilhus NE, Barnes MP, Brainin M, editors. European Handbook of neurological management. 2nd edition. Vol 1. Oxford (UK): Wiley-Blackwell; 201:513-28.
3. Drake C, Gumenyuk V, Roth T, Howard R. Effects of armodafinil on simulated driving and alertness in shift work disorder. Sleep 2014; 37:1987
4. Greenhill LL, Biederman J, Boellner SW, Rugino TA, Sangal RB, Earl CQ et al. A randomized, double-blind, placebo-controlled study of modafinil film-coated tablets in children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2006;45(5):503-11.
5. Harsh JR, Hayduk R, Rosenberg R, Wesnes K, Walsh J, Arora S, et al. The efficacy and safety of armodafinil as treatment for adults with excessive sleepiness associated with narcolepsy. Curr Med Res Opin. 2006;22(4):761-74.
6. Hirshkowitz M, Black JE, Wesnes K, Niebler G, Arora S, Roth T. Adjunct armodafinil improves wakefulness and memory in obstructive sleep apnea/hypopnea syndrome. Respir Med. 2007;101(3):616-27.
7. Nuvigil (armodafinil) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2022.
8. Provigil (modafinil) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; December 2022.
9. Roth T, White D, Schmidt-Nowara W, Wesnes K, Niebler G, Arora A, Black J. Effects of armodafinil in the treatment of residual excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome: a 12-week, multicenter, double-blind, randomized, placebo-controlled study in CPAP-adherent adults. Clin Ther. 2006;28(5):689-706.

10. Sonka K, Susta M. Diagnosis and management of central hypersomnias. Ther Adv Neurol Disord. 2012;5(5):297-305.
11. Spathis A, Fife K, Blackhall F, Dutton S, Bahadori R, Whrton R, et al. Modafinil for the treatment of fatigue in lung cancer: results of a placebo-controlled, double-blind, randomized trial. J Clin Oncol. 2014. Doi: 10.1200/JCO.2013.54.4346.
12. Stankoff B, Waubant E, Confavreux C, Edan G, Debouverie M, Rumbach L, et al. Modafinil for fatigue in MS: a randomized placebo-controlled double-blind study**.** *Neurology. 2005;64(7):1139-43.*

Review History

06/27/2005 - Reviewed and Revised
04/24/2006 - Reviewed
04/23/2007 - Reviewed
04/28/2008 - Reviewed and Revised
04/27/2009 - Reviewed and Revised
04/26/2010 - Reviewed and Revised
07/15/2010 - Updated per MM/plan direction (stimulant trial for OSA/narcolepsy)
12/15/2010 - Updated (disclaimer)
04/25/2011 - Reviewed
05/17/2011 - Updated (generic Concerta)
04/11/2012 - Updated (modafanil generic; BART request ahead of drug file); removed long-acting stimulant trial
04/23/2012 - Reviewed and Revised (modafinil trial for Nuvigil)
04/22/2013 - Reviewed and Revised
04/28/2014 - Reviewed
06/26/2017 - Reviewed and Revised
04/17/2019 – Reviewed
05/20/2020 – Reviewed and Updated May P&T Mtg; overview written, updated references; added indication of shift work sleep disorder. Effective 8/1/20.
03/17/2021 – Reviewed and Updated; Updated QL to current commercially available products. Removed Armodafinil 100mg (not available) and added armodafinil 250mg QL. Effective 06/01/2021.
09/21/2022 – Reviewed and Updated Sept P&T; Administrative update to reword diagnoses section for modafinil and armodafinil. No Clinical Changes. Separated out Comm/Exch vs MH policies.
01/11/2023 – Reviewed and Updated for Jan P&T; added indication of major depressive disorder for Modafinil. Effective 4/1/23
10/11/2023 – Reviewed and Updated for Oct P&T; added examples of antidepressants for diagnosis of adjunct treatment of depression. Effective 1.1.24
12/11/2024 – Reviewed and updated for December P&T. Updated policy to align modafinil and armodafinil criteria. As a result, armodafinil can be approved for the following diagnoses: ADD/ADHD, multiple sclerosis, fatigue associated with chemotherapy, excessive sleepiness associated with Parkinson's disease, and adjunct treatment to depression. Effective 03/01/2025.