Mass General Brigham
Health Plan

Modafinil (Provigil®)
Armodafinil (Nuvigil®)
Effective 01/01/2024

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 that has been shown to significantly increase dopamine in the brain by blocking dopamine transporters. Studies have shown modafinil increases high-frequency alpha waves while decreasing both delta and theta wave activity, effects consistent with generalized increases in mental alertness.

Armodafinil is the R-enantiomer of modafinil. Armodafinil binds to the dopamine transporter and inhibits dopamine reuptake, which may result in increased extracellular dopamine levels in the brain. However, it does not appear to be a dopamine receptor agonist and does not appear to bind to or inhibit the most common receptors or enzymes that are relevant for sleep/wake regulation.

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with modafinil or armodafinil, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
Or
Approval may be granted when the following drug specific criteria are met for excessive daytime sleepiness (EDS) associated with the following conditions:

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

Armodafinil

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

Continuation of Therapy

Reauthorization requires physician documentation of 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:

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. Provigil (modafinil) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; November 2018.
2. Nuvigil (armodafinil) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2018.
3. 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.*
4. 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.
5. *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.*

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7. Katon W, and Ciechanowski, P. Treatment of resistant depression in adults. In: Schwank TL and Sokol HN, editors. UpToDate. Waltham (MA): UpToDate; 2009.
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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. 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.
11. Morgenthaler TI, Kapur VK, Brown TM, Swick TJ, Alessi C, Aurora RN, et al.Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007;30:1705-11.
12. Sonka K, Susta M. Diagnosis and management of central hypersomnias. Ther Adv Neurol Disord. 2012;5(5):297-305.
13. Drake C, Gumenyuk V, Roth T, Howard R. Effects of armodafinil on simulated driving and alertness in shift work disorder. Sleep 2014; 37:1987
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15. Tarsy D. Management of comorbid problems associated with Parkinson disease. In: Basow DS (Ed). UpToDate. Waltham (MA): UpToDate; 2015. Available at: http://www.utdol.com/index.do.
16. 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.

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