# modafinil (Provigil®)/armodafinil (Nuvigil®)

Policy # 00361
Original Effective Date: 08/21/2013
Current Effective Date: 11/11/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

# When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand or generic modafanil (Provigil®)‡ or armodafanil (Nuvigil®)‡ products to be **eligible for coverage**** when one of the below patient selection criteria is met.

Patient Selection Criteria

Coverage eligibility will be considered for brand or generic modafanil (Provigil) or armodafanil (Nuvigil) products when one of the following patient selection criteria is met:

- Patient has narcolepsy; OR
- Patient has excessive sleepiness due to obstructive sleep apnea/hypopnea syndrome (OSAHS); AND
    - Patient has tried continuous positive airway pressure (CPAP); OR
      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has excessive sleepiness due to shift work sleep disorder (SWSD); AND
    - Patient works 5 or more overnight shifts per month; OR
      *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has fatigue associated with multiple sclerosis; OR
- Patient has excessive daytime sleepiness due to myotonic dystrophy; OR
- Patient has excessive daytime sleepiness due to Parkinson's disease; OR
- Patient has fatigue or sleepiness associated with chronic use of narcotic analgesics; AND

- Patient has tried one central nervous system (CNS) stimulant (e.g., methylphenidate, dextroamphetamine), unless use of a CNS stimulant is clinically inappropriate (e.g., patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse); OR
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Patient has fatigue associated with human immunodeficiency virus (HIV) infection; AND
  - Patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), unless use of a CNS stimulant is clinically inappropriate (e.g., patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse); OR
    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has myasthenia gravis; OR
- Adult patient with depression and Provigil or Nuvigil would be used as adjunctive/augmentation treatment (e.g., with an antidepressant such as a selective serotonin receptor inhibitor). Note: this does not include bipolar disorder or bipolar depression; OR
- Patient has idiopathic hypersomnia; OR
- Patient has cancer related fatigue; OR
- Patient has attention deficit hyperactive disorder (ADHD) or attention deficit disorder (ADD) and is younger than 18 years of age; AND
  - Patient has tried two alternative medications for ADHD or ADD. The medications used must come from two different medications/classes of medications listed below:
    - Methylphenidate products; OR
    - Amphetamines; OR
    - Straterra (atomoxetine); OR
    - Wellbutrin (bupropion); OR
    - Tricyclic antidepressants

    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

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# When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of brand or generic modafanil (Provigil) or armodafanil (Nuvigil) products when patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

# When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand or generic modafanil (Provigil) or armodafanil (Nuvigil) products when ANY of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- Excessive sleepiness due to OSAHS
  - Patient has tried CPAP
- Excessive sleepiness due to SWSD
  - Patient works 5 or more overnight shifts per month
- Fatigue or sleepiness associated with chronic use of narcotic analgesics
  - Patient has tried one CNS stimulant (e.g. methylphenidate, dextroamphetamine), unless use of a CNS stimulant is clinically inappropriate (e.g., patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse)
- Patient has fatigue or sleepiness associated with chronic use of narcotic analgesics
  - Patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), unless use of a CNS) stimulant is clinically inappropriate (e.g., patients with anxiety, glaucoma, tics, serious cardiovascular disease, seizures, underlying psychosis, or history of substance abuse)
- Patient has ADHD or ADD and is younger than 18 years of age
  - Patient has tried two alternative medications for ADHD or ADD. The medications used must come from two different medications/classes of medications listed below:
    - Methylphenidate products; OR
    - Amphetamines; OR

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- Straterra (atomoxetine); OR
- Wellbutrin (bupropion); OR
- Tricyclic antidepressants

# Background/Overview

Provigil (modafanil) and Nuvigil (armodafanil) are agents with wake promoting actions. They are similar to sympathomimetic agents and are indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, OSAHS, and SWSD. There are many other uses in the literature that have data supporting their use, however there are also other indications that don't have sufficient data to support use of these drugs. Both of these agents are Schedule IV controlled substances.

# Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Provigil (modafanil) and Nuvigil (armodafanil) have the potential to be used off label for certain conditions that do not have sufficient evidence to support usage, such as fibromyalgia, spasticity due to cerebral palsy, alcoholic organic brain syndrome, seasonal effective disorder, and many more indications not listed here. There is very little clinical evidence to support the use of Provigil (modafanil) and Nuvigil (armodafanil) in conditions not listed in the above patient selection criteria. The purpose of this policy is to limit the use of Provigil (modafanil) and Nuvigil (armodafanil) to those uses mentioned in the patient selection criteria. Patient selection criteria are based on information collected in a review of the available data.

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# References


1. Provigil [package insert]. Frazer, PA: Cephalon, Inc.; April 2014.
2. Nuvigil tablets [package insert]. Frazer, PA: Cephalon, Inc.; August 2013.
3. 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.
4. Zifko UA, Rupp M, Schwarz S, et al. Modafinil in treatment of fatigue in multiple sclerosis. Results of an open-label study. J Neurol. 2002;249:983-987.
5. Rammohan KW, Rosenberg JH, Lynn DJ, et al. Efficacy and safety of modafinil (Provigil) for the treatment of fatigue in multiple sclerosis: a two center phase 2 study. J Neurol Neurosurg Psychiatry. 2002;72:179-183.
6. Stankoff B, Waubant E, Confavreux C, et al. Modafinil for fatigue in MS. Neurology. 2005;64:1139-1143.
7. Moller F, Poettgen J, Broemel F, et al. HAGIL (Hamburg vigil study): a randomized placebo-controlled double-blind study with modafinil for treatment of fatigue in patients with multiple sclerosis. Mult Scler. 2011;17:1002-1009.
8. MacAllister WS, Krupp LB. Multiple-sclerosis-related fatigue. Phys Med Rehabil Clin N Am. 2005;16:483-502.
9. Morgenthaler TI, Kapur VK, Brown T, et al, for the Standard of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. An American Academy of Sleep Medicine Report. Sleep. 2007;30(12):1705-1711.
10. Krupp LB. Fatigue in multiple sclerosis. Definition, pathophysiology and treatment. CNS Drugs. 2003;17(4):225-234.
11. Damian MS, Gerlach A, Schmidt F, et al. Modafinil for excessive daytime sleepiness in myotonic dystrophy. Neurology. 2001;56:794-796.
12. Wintzen AR, Lammers GJ, van Dijk JG. Does modafinil enhance activity of patients with myotonic dystrophy? A double-blind, placebo-controlled, crossover study. J Neurol. 2007;254:26-28.
13. MacDonald JR, Hill JD, Tarnopolsky MA. Modafinil reduces excessive somnolence and enhances mood in patients with myotonic dystrophy. Neurology. 2002;59(12):1876-1880.
14. Talbot K, Stradling J, Crosby J, Hilton-Jones D. Reduction in excess daytime sleepiness by modafinil in patients with myotonic dystrophy. Neuromuscul Disord. 2003;13(5):357-364.

15. Orlikowski D, Chevret S, Quera-Salva MA, et al. Modafinil for the treatment of hypersomnia associated with myotonic muscular dystrophy in adults: a multicenter, prospective, randomized, double-blind, placebo-controlled, 4-week trial. Clin Ther. 2009;31:1765-1773.
16. 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: http://www.psychiatryonline.com/pracGuide/pracGuideTopic_7.aspx.
17. Lam JY, Freeman MK, Cates ME. Modafinil augmentation for residual symptoms of fatigue in patients with a partial response to antidepressants. Ann Pharmacother. 2007;41:1005-1012.
18. Nasr S. Modafinil as adjunctive therapy in depressed outpatients. Ann Clin Psychiatry. 2004;16:113-138.
19. Thase ME, Fava M, DeBattista C, et al. Modafinil augmentation of SSRI therapy in patients with major depressive disorder and excessive sleepiness and fatigue: a 12-week, open-label extension study. CNS Spectr. 2006;11(2):93-102.
20. DeBattista C, Lembke A, Solvason HB, et al. A prospective trial of modafinil as an adjunctive treatment of major depression. J Clin Psychopharmacol. 2004;24(1):87-90.
21. DeBattista C, Coghramji K, Menza MA, et al for the modafinil in depression study group. Adjunct modafinil for the short-term treatment of fatigue and sleepiness in patients with major depressive disorder: a preliminary double-blind, placebo-controlled study. J Clin Psychiatry. 2003;64(9):1057-1064.
22. Fava M, Thase ME, DeBattista C. A multicenter, placebo-controlled study of modafinil augmentation in partial responders to selective serotonin reuptake inhibitors with persistent fatigue and sleepiness. J Clin Psychiatry. 2005;66(1):85-93.
23. Fava M, Thase ME, Debattista C, et al. Modafinil augmentation of selective serotonin reuptake inhibitor therapy in MDD partial responders with persistent fatigue and sleepiness. Ann Clin Psychiatry. 2007;19(3):153-159.
24. Price SC, Taylor FB. A retrospective chart review of the effects of modafinil on depression as monotherapy and as adjunctive therapy. Depress Anxiety. 2005;21:149-153.
25. Knie B, Mitra MT, Logishetty, Chaudhuri KR. Excessive daytime sleepiness in patients with Parkinson's disease. CNS Drugs. 2011;25:203-212.
26. Adler CH, Caviness JN, Hentz JG, Lind M. Randomized trial of modafinil for treating subjective daytime sleepiness in patients with Parkinson's disease. Mov Disord. 2003;18(3):287-293.

27. Hogl B, Saletu M, Brandauer E, et al. Modafinil for the treatment of daytime sleepiness in Parkinson's disease: a double-blind, randomized, crossover, placebo-controlled polygraphic trial. Sleep. 2002;25(8):905-909.
28. Ondo WG, Fayle R, Atassi F, Jankovic J. Modafinil for daytime somnolence in Parkinson's disease: double-blind, placebo-controlled parallel trial. J Neurol Neurosurg Psychiatry. 2005;76:1636-1639.
29. Nieves AV, Lang AE. Treatment of excessive daytime sleepiness in patients with Parkinson's disease with modafinil. Clin Neuropharmacol. 2002;25(2):111-114.
30. Happe S, Pirker W, Sauter C, et al. Successful treatment of excessive daytime sleepiness in Parkinson's disease with modafinil. J Neurol. 2001;248:632-634.
31. Rye DB. Excessive daytime sleepiness and unintended sleep in Parkinson's disease. Curr Neurol and Neurosci Rep. 2006;6:169-176.
32. Zesiewicz TA, Sullivan KL, Arnulf I, et al. Practice parameter: treatment of nonmotor symptoms of Parkinson disease: Report of the quality standards subcommittee of the American Academy of Neurology. Neurology. 2010;74:924-931.
33. Bassetti C, Aldrich MS. Idiopathic hypersomnia. A series of 42 patients. Brain. 1997;120:1423-1435.
34. Billiard M, Merle C, Barlander B, et al. Idiopathic hypersomnia. Psychiatry Clin Neurosci. 1998;52(2):125-129.
35. Bastuji H, Jouvet M. Successful treatment of idiopathic hypersomnia and narcolepsy with modafinil. Prog Neuropsychopharmacol Biol Psychiatry. 1988;12(5):695-700.
36. Laffont F, Mayer G, Minz M. Modafinil in diurnal sleepiness. A study of 123 patients. Sleep. 1994;17:S113-S115.
37. Rabkin JG, McElhiney MC, Fabkin R, Ferrando SJ. Modafinil treatment for fatigue in HIV+ patients: a pilot study. J Clin Psychiatry. 2004;65:1688-1695.
38. Rabkin J, McElhiney MC, Rabkin R, McGrath PJ. Modafinil treatment for fatigue in HIV/AIDS: a randomized placebo-controlled study. J Clin Psychiatry. 2010;71:707-715.
39. Rabkin JG, McElhiney MC, Rabkin R. Treatment of HIV-related fatigue with armodafinil: a placebo-controlled randomized trial. Psychosomatics. 2011;52:328-336.
40. Breitbart W, Rosenfeld B, Kaim M, Funesti-Esch J. A randomized, double-blind, placebo-controlled trial of psychostimulants for the treatment of fatigue in ambulatory patients with human immunodeficiency virus disease. Arch Intern Med. 2001;161(3):411-20.
41. Wagner GJ, Rabkin R. Effects of dextroamphetamine on depression and fatigue in men with HIV: a double-blind, placebo-controlled trial. J Clin Psychiatry. 2000;61(6):436-440.

42. Peuckmann V, Elsner F, Krumm N, et al. Pharmacological treatments for fatigue associated with palliative care. Cochrane Database Syst Rev. 2010;11:CD006788.
43. Lechin F, van der Dijs B, Pardey-Maldonado B, et al. Enhancement of noradrenergic neural transmission: an effective therapy of myasthenia gravis: a report on 52 consecutive patients. J Med. 2000;31(5-6):333-61.
44. Webster L, Andrews M, Stoddard G. Modafinil treatment of opioid-induced sedation. Pain Med. 2003;4(2):135-140.
45. Corey PJ, Heck AM, Weathermon RA. Amphetamines to counteract opioid-induced sedation. Ann Pharmacother. 1999;33:1362-1366.
46. Reissig JE, Rybarczyk AM. Pharmacologic treatment of opioid-induced sedation in chronic pain. Ann Pharmacother. 2005;39:727-731.
47. Bourdeanu L, Loseth DB, Funk M. Management of opioid-induced sedation in patients with cancer. Clin J Oncol Nurs. 2005;9(6):705-711.
48. American Pain Society. Principles of analgesic use in the treatment of acute pain and cancer pain. 6th ed. Glenview, IL: American Pain Society; 2008.
49. The NCCN Adult Cancer Pain Clinical Practice Guidelines in Oncology (Version 1.2012). © 2012 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org.
50. Carroll JK, Kohli S, Mustian KM, et al. Pharmacologic treatment of cancer-related fatigue. The Oncologist. 2007;12(Suppl 1):43-51.
51. Jean-Pierre P, Morrow GR, Roscoe JA, et al. A phase 3 randomized, placebo-controlled, double-blind, clinical trial of the effect of modafinil on cancer-related fatigue among 631 patients receiving chemotherapy: a University of Rochester Cancer Center Community Clinical Oncology Program Research base study. Cancer. 2010;116:3513-3520.
52. The NCCN Cancer-Related Fatigue Clinical Practice Guidelines in Oncology (Version 1.2012). © 2012 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org.
53. Saletu B, Salteu M, Grunberger J, et al. Treatment of alcoholic organic brain syndrome: double-blind, placebo-controlled clinical, psychometric and electroencephalographic mapping studies with modafinil. Neuropsychobiology. 1993;27:26-39.
54. 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.

55. 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.
56. 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.
57. Caldwell JA, Caldwell JL. Fatigue in military aviation: an overview of US military-approved pharmacological countermeasures. Avait Space Environ Med. 2005;76(7):C39-C51.
58. Schaller JL, Behar D. Modafinil in fibromyalgia treatment. J Neuropsychiatry Clin Neurosci. 2001;13(4):530-531.
59. Schwartz TL, Rayancha S, Rashid A, et al. Modafinil treatment for fatigue associated with fibromyalgia. J Clin Rheumatol. 2007;13(1):52.
60. Pachas WN. Modafinil for the treatment of fatigue of fibromyalgia. J Clin Rheumatol. 2003;9(4):282-285.
61. Turkington D, Hedwat D, Rider I, Young AH. Recovery from chronic fatigue syndrome with modafinil. Hum Psychopharmacol. 2004:19(1):63-64.
62. 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.
63. 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):715-25.
64. Turner DC, Clark L, Pomarol-Clotet E, McKenna P, Robbins TW, Sahakian BJ. Modafinil improves cognition and attentional set shifting in patients with chronic schizophrenia. Neuropsychopharmacology. 2004;29:1363-1373.
65. Rosenthal MH, Bryant SL. Benefits of adjunct modafinil in an open-label, pilot study in patients with schizophrenia. Clin Neuropharmacol. 2004;27(1):38-42.
66. Sevy S, Rosenthal MH, Alvir J, et al. Double-blind, placebo-controlled study of modafinil for fatigue and cognition in schizophrenia patients treated with psychotropic medications. J Clin Psychiatry. 2005;66:839-843.
67. Pierre JM, Peloian JH, Wirshing DA, et al. A randomized, double-blind, placebo-controlled trial of modafinil for negative symptoms in schizophrenia. J Clin Psychiatry. 2007;68(5):705-710.
68. Morein-Zamir S, Turner DC, Sahakian BJ. A review of the effects of modafinil on cognition in schizophrenia. Schizophr Bull. 2007;33(6):1298-1306.

69. Freudenreich O, Henderson DC, Macklin EA, et al. Modafinil for clozapine-treated schizophrenia patients: a double-blind, placebo-controlled pilot trial. J Clin Psychiatry. 2009;70:1674-1680.
70. Kane JM, D'Souza DC, Patkar AA, et al. Armodafinil as adjunctive therapy in adults with cognitive deficits associated with schizophrenia: a 4-week, double-blind, placebo-controlled study. J Clin Psychiatry. 2010;71:1475-1481.
71. Bobo WV, Woodward ND, Sim MY, et al. The effect of adjunctive armodafinil on cognitive performance and psychopathology in antipsychotic-treated patients with schizophrenia/schizoaffective disorder: a randomized, double-blind, placebo-controlled trial. Schizophr Res. 2011;130:106-113.
72. Lundt L. Modafinil treatment in patients with seasonal affective disorder/winter depression: an open-label pilot study. J Affect Disord. 2004;81(2):173-8.
73. Lam RW, Levitt AJ, Levitan RD, et al. The Can-SAD study: a randomized controlled trial of the effectiveness of light therapy and fluoxetine in patients with winter seasonal affective disorder. Am J Psychiatry. 2006;163(5):805-812.
74. Pjrek E, Winkler D, Kasper S. Pharmacotherapy of seasonal affective disorder. CNS Spectr. 2005;10(8):664-649.
75. Bassetti CL. Sleep and stroke. Semin Neurol. 2005;25(1):19-32.
76. 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 [epub ahead of print].
77. American Academy of Pediatrics. Supplemental Information. Implementing the key action statements: an algorithm and explanation for process of care for the evaluation, diagnosis, treatment, and monitoring of ADHD in children and adolescents. Pediatrics. 2011 [epub ahead of print]. Available at: http://pediatrics.aappublications.org/content/suppl/2011/10/11/peds.2011-2654.DC1.full.
78. Taylor FB, Russo J. Efficacy of modafinil compared to dextroamphetamine for the treatment of attention deficit hyperactivity disorder in adults. J Child Adolesc Psychopharmacol. 2000;10(4):311-320.
79. Turner DC, Clark L, Dowson J, et al. Modafinil improves cognition and response inhibition in adults attention-deficit/hyperactivity disorder. Biol Psychiatry. 2004;55(10):1031-1040.
80. Doctor's guide to medical and other news. No benefit noted from Provigil (modafinil) in adult attention deficit hyperactivity disorder. July 31, 2000.

81. 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.
82. 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.
83. Fernandes PP, Petty F. Modafinil for remitted bipolar depression with hypersomnia. Ann Pharmacother. 2003;37(12):1807-1809.
84. 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.
85. Jha A, Weintraub A, Allshouse A, et al. A randomized trial of modafinil for the treatment of fatigue and excessive daytime sleepiness in individuals with chronic traumatic brain injury. J Head Trauma Rehabil. 2008;23(1):52-63.
86. Kaiser PR, Valko PO, Werth E, et al. Modafinil ameliorates excessive daytime sleepiness after traumatic brain injury. Neurology. 2010;75:1780-1785.
87. Chan KM, Strohschein FJ, Fydz D, et al. Randomized controlled trial of modafinil for the treatment of fatigue in postpolio patients. Muscle Nerve. 2006;33(1):138-141.
88. Vasconcelos OM, Prikhorenko OA, Salajegheh MK, et al. Modafinil for the treatment of fatigue in post-polio syndrome. A randomized controlled trial. Neurology. 2007;68(20):1680-1686.
89. Hurst DL, Lajara-Nanson W. Use of modafinil in spastic cerebral palsy. J Child Neurol. 2002;17:169-172.
90. Hurst DL, Lajara-Nanson WA, Dinakar P, Schiffer RB. Retrospective review of modafinil use for cerebral palsy. J Child Neurol. 2004;19(12):948-951.
91. Hurst DL, Lajara-Nanson WA, Lance-Fish ME. Walking with modafinil and its use in diplegic cerebral palsy: retrospective review. J Child Neurol. 2006;21:294-297.
92. Murphy AM, Milo-Manson G, Best A, et al. Impact of modafinil on spasticity reduction and quality of life in children with CP. Dev Med Child Neurol. 2008;50:510-514.
93. Verrotti A, Greco R, Spalica A, et al. Pharmacotherapy of spasticity in children with cerebral palsy. Pediatr Neurol. 2006;34(1):1-6.

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| 08/01/2013 | Medical Policy Committee review |
| 08/21/2013 | Medical Policy Implementation Committee approval. New policy. |
| 08/07/2014 | Medical Policy Committee review |
| 08/20/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/06/2015 | Medical Policy Committee review |
| 08/19/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/04/2016 | Medical Policy Committee review |
| 08/17/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/03/2017 | Medical Policy Committee review |
| 08/23/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 08/09/2018 | Medical Policy Committee review |
| 08/15/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/03/2019 | Medical Policy Committee review |
| 10/09/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/01/2020 | Medical Policy Committee review |
| 10/07/2020 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/07/2021 | Medical Policy Committee review |
| 10/13/2021 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/06/2022 | Medical Policy Committee review |
| 10/11/2022 | Medical Policy Implementation Committee approval. No change to coverage. |

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| 10/05/2023 | Medical Policy Committee review |
| 10/11/2023 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/03/2024 | Medical Policy Committee review |
| 10/08/2024 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |

Next Scheduled Review Date: 10/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.