MASSACHUSETTS

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Pharmacy Medical Policy
CNS Stimulants and Psychotherapeutic Agents

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Policy Number: 019

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy #621A.

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**10/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

This is a comprehensive policy covering prior authorization and quantity limit requirements for CNS Stimulants and Psychotherapeutic Agents.

Formulary status/requirements of medications affected by this policy are provided in below:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
amphetamine	Covered, PA	PA required. See criteria below
armodafinil	Covered, PA	
dextroamphetamine	Covered, PA	
dextroamphetamine ER	Covered, PA	
Desoxyn ® (methamphetamine)	Covered, PA	
Methamphetamine	Covered, PA	
modafinil	Covered, PA	
Zenzedi ® (dextroamphetamine)	Covered, PA	
Dexedrine ® (dextroamphetamine)	NFNC, PA	PA required and meet Non-formulary exception criteria
Dexedrine Spansules ® (dextroamphetamine)	NFNC, PA	
Evekeo ™ (amphetamine sulfate)	NFNC, PA	
Evekeo ODT ™ (amphetamine sulfate)	NFNC, PA	
Sunosi ® (solriamfetol)	NFNC, PA	
Wakix ® (pitolisant)	NFNC, PA, QCD	

PA – Prior Authorization; NFNF – Non-formulary, non-covered; QCD – Quality Care Dosing (refer to policy #621b)

Policy

Length of Approval	12 months
Formulary Status	All requests must meet the Prior Authorizations requirement. For non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria

Amphetamine, Dexedrine ®/Dexedrine ® Spansules, Desoxyn ®, and Zenzedi ®

Amphetamine, Dexedrine /Dexedrine Spansules, Desoxyn, Zenzedi and their generic alternatives may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. Age < 17 years, **OR**
2. Age ≥ 17 years WITH a diagnosis of attention-deficit hyperactivity disorder (ADHD) or narcolepsy, **OR**
3. Prescribed by a board certified/board eligible Psychiatrist, Neurologist, Oncologist, or Sleep Medicine specialist, **OR**
4. Prior use of amphetamine, dextroamphetamine or methamphetamine

NOTE: Amphetamine is NOT covered for Exogenous Obesity according to our subscriber certificates.

Evekeo ™and Evekeo ODT

Evekeo and Evekeo ODT tablets may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. Diagnosis of attention-deficit hyperactivity disorder (ADHD) or Narcolepsy, **AND**
2. Prescribed by a board certified/board eligible Psychiatrist, Neurologist, Oncologist, or Sleep Medicine specialist, **AND**
3. Previous use of TWO covered formulary alternatives (ex: amphetamine salt combination, dextroamphetamine, methylphenidate, Metadate ER)

NOTE: Evekeo is NOT covered for Exogenous Obesity according to our subscriber certificates

Modafinil

Modafinil may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. Age ≥18 years; **AND**
2. A diagnosis of narcolepsy, obstructive sleep apnea/hypopnea syndrome, or shift work sleep disorder, **AND**
3. Prescribed by a board certified/board eligible Psychiatrist, Neurologist, Oncologist, or Sleep Medicine specialist,

OR

4. Prior claim history of modafinil

Armodafinil

Armodafinil may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. Age ≥18 years; **AND**
2. A diagnosis of narcolepsy, obstructive sleep apnea/hypopnea syndrome, or shift work sleep disorder, **AND**
3. Prescribed by a board certified/board eligible Psychiatrist, Neurologist, Oncologist, or Sleep Medicine specialist,

OR

4. Prior claim history of armodafinil

Sunosi

Sunosi may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. Age ≥ 18 years, **AND**
2. A diagnosis of narcolepsy or obstructive sleep apnea/hypopnea syndrome, **AND**
3. Prescribed by a board certified/board eligible Psychiatrist, Neurologist, Oncologist, or Sleep Medicine specialist, **AND**
4. Prior claim history of modafinil **AND** armodafinil

Wakix

Wakix may be considered **MEDICALLY NECESSARY** and may be covered when ALL of the following criteria are met:

1. Age ≥ 6 years, **AND**
2. A diagnosis of narcolepsy or cataplexy, **AND**
3. Prescribed by a board certified/board eligible Psychiatrist, Neurologist, Oncologist, or Sleep Medicine specialist, **AND**
4. For diagnosis of narcolepsy only, prior claim history of modafinil AND armodafinil

***Note*: * Diagnosis of cataplexy diagnosis does NOT require the prior use of modafinil and armodafinil**

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
10/2024	Updated to include Wakix' s new age.
4/2024	Update criteria for armodafinil and modafinil.
1/2024	Clarified coding for Wakix and Sunosi.
11/2023	Reformatted Policy.
10/2023	Reformatted Policy and updated IC to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
4/2022	Updated armodafinil criteria to remove trial of modafanil and removed Nuvigil & Provigil as they will be handled with Formulary Exception criteria.
1/2021	Updated to add new indication for Wakix®.
1/2020	Updated to remove PA on atomoxetine and Straterra™ and make Straterra™ not covered and add Wakix® and Sunosi™ to the policy.
2/2019	Updated to add Amphetamine to the policy.
7/2018	Clarified coding for Provigil.
1/2018	Updated to include atomoxetine & criteria for Straterra™.
6/2017	Update address for Pharmacy Operations.
11/2016	Updated to include armodafinil and Evekeo.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	Updated to include Sleep Medicine specialists.
2/2014	Updated ExpressPAth language, remove Blue Value and added Zenzedi.
6/2012	Updated to include coverage criteria for new generic modafanil.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
2/2012	Reviewed – Medical Policy Group – Psychiatry and Ophthalmology. No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2011	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
5/2010	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2010	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2010	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
11/2009	Updated to include authorization requirements for Nuvigil™.
9/2009	Policy updated to change 180 day look back period to 130 days, update sample language, define coverage for new starts, and to remove Medicare Part D criteria from Medical Policy.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2009	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2009	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.

5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2008	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2008	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2007	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
11/2004	New policy, effective 11/2004, describing covered and non-covered indications.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. Clinical practice guideline: diagnosis and evaluation of the child with attention-deficit/hyperactivity disorder. American Academy of Pediatrics. Pediatrics. 2000;105:1158-1170.
2. National Institutes of Health Consensus Development Conference Statement: diagnosis and treatment of attention-deficit/hyperactivity disorder (ADHD). J Am Acad Child Adolesc Psychiatr. 2000;39:182-193.
3. Brown RT, Freeman WS, Perrin JM, et al. Prevalence and assessment of attention-deficit/hyperactivity disorder in primary care settings. Pediatrics. 2001;107:E43.
4. American Academy of Pediatrics. Subcommittee on Attention-Deficit/Hyperactivity Disorder and Committee on Quality Improvement. Clinical practice guideline: treatment of the school-aged child with attention-deficit/hyperactivity disorder. Pediatrics. 2001;108:1033-1044.
5. Jadad AR, Boyle M, Cunningham C, et al. Treatment of attention deficit/hyperactivity disorder. Evidence Report/Technology Assessment No. 11. Rockville, MD: Agency for Healthcare Research and Quality; 1999. AHRQ Pub. No. 00-E005.
6. The MTA Cooperative Group. A 14-month randomized clinical trial of treatment strategies for attention-deficit/hyperactivity disorder. The MTA Cooperative Group. Multimodal Treatment Study of Children with ADHD. Arch Gen Psychiaty. 1999;56:1073-1086.
7. Greenhill LL, Pliszka S, Dulcan MK, et al. Practice parameter for the use of stimulant medications in the treatment of children, adolescents, and adults. J Am Acad Child Adolesc Psychiatr. 2002;41(2 Suppl):26S-49S.
8. Spencer T, Biederman J, Wilens T, et al. Pharmacotherapy of attention-deficit hyperactivity disorder across the life cycle. J Am Acad Child Adolesc Psychiatry. 1996;35:409-432.
9. Spencer T, Biederman J, Wilens T, et al. Efficacy of a mixed amphetamine salts compound in adults with attention-deficit/hyperactivity disorder. Arch Gen Psychiatry. 2001:58:775-782.
10. Strattera™ [package insert]. Indianapolis, IN: Eli Lilly and Company; November 2002.
11. Michelson D, Faries D, Wernicke J, et al. Atomoxetine in the treatment of children and adolescents with attention-deficit/hyperactivity disorder: a randomized, placebo-controlled, dose-response study. Pediatrics. 2001;108(5):E83.
12. Michelson D, Allen AJ, Busner J, et al. Once-daily atomoxetine treatment for children and adolescents with attention deficit hyperactivity disorder: a randomized, placebo-controlled study. Am J Psychiatr. 2002;159:1896-1901.
13. Biederman J, Heiligenstein JH, Faries DE, et al. Efficacy of atomoxetine versus placebo in school-age girls with attention-deficit/hyperactivity disorder. Pediatrics. 2002;110:e75.
14. Michelson D, Adler L, Spencer T, et al. Atomoxetine in adults with ADHD: two randomized, placebo-

controlled studies. Biol Psychiatry. 2003;53:112-120.
15. Kratochvil CJ, Heiligenstein JH, Dittmann R, et al. Atomoxetine and methylphenidate treatment in children with ADHD: a prospective, randomized, open-label trial. J Am Acad Child Adolesc Psychiatry. 2002;41:776-784.
16. Chouinard G, Annable L, Bradwejn J. An early phase II clinical trial of atomoxetine (LY139603) in the treatment of newly admitted depressed patients. Psychopharmacology (Berl). 1984;83:126-128.
17. Provigil® [package insert]. West Chester, PA; Cephalon Inc; February 2004
18. Adler CH, Caviness JN, Hentz JG et al: Randomized trial of modafinil for treating subjective daytime sleepiness in patients with Parkinson's disease. Movement Disorders 2003; 18(3):287-293.
19. Anon: US Modafinil in Narcolepsy Multicenter Study Group: Randomized trial of modafinil for the treatment of pathological somnolence in narcolepsy. Ann Neurol 1998; 43:88-97.
20. Arnulf I, Homeyer P, Garma L et al: Modafinil in obstructive sleep apnea-hypopnea syndrome: a pilot study in 6 patients. Respiration 1997; 64:159-161.
21. Bastuji H & Jouvet M: Successful treatment of idiopathic hypersomnia and narcolepsy with modafinil. Prog Neuropsychopharmacol Biol Psychiatry 1988; 12:695-700.
22. Batejat DM & Lagarde DP: Naps and modafinil as countermeasures for the effects of sleep deprivation on congnitive performance. Aviat Space Environ Med 1999; 70:493-498.
23. Besset A, Chetrit M, Carlander B et al: Use of modafinil in the treatment of narcolepsy: a long term follow-up study. Neurophysiol Clin 1996; 26:60-66.
24. Billiard M, Besset A, Montplaisir J et al: Modafinil: a double-blind multicentric study. Sleep 1994; 17:S107-S112.
25. Boivin DB, Montplaisir J, Petit D et al: Effects of modafinil on symptomatology of human narcolepsy. Clin Neuropharmacol 1993; 16:46-53.
26. Broughton RJ, Fleming JAE, George CFP et al: Randomized, double-blind, placebo-controlled crossover trial of modafinil in the treatment of excessive daytime sleepiness in narcolepsy. Neurology 1997; 49:444-451.
27. Damian MS, Gerlach A, Schmidt F et al: Modafinil for excessive daytime sleepiness in myotonic dystrophy. Neurology 2001; 56:794-796.
28. Duteil I, Rambert FA, Pessonier I et al: A possible alpha-adrenergic mechanism for drug (CRL 40028)-induced hyperactivity. Eur J Pharmacol 1979; 59:121-123.
29. Grozinger M, Hartter S, Hiemke C et al: Interaction of modafinil and clomipramine as comedication in a narcoleptic patient. Clin Neuropharmacol 1998; 21:127-129.
30. Heitmann J, Cassel W, Grote L et al: Does short-term treatment with modafinil affect blood pressure in patients with obstructive sleep apnea? Clin Pharmacol Ther 1999; 65:328-335.
31. Hellriegel E, Arora S, Nelson M et al: Steady-state pharmacokinetics and tolerability of modafinil given alone or in combination with methylphenidate in healthy volunteers. J Clin Pharmacol 2001; 41:895-904.
32. Kingshott RN, Vennelle M, Coleman EL et al: Randomized, double-blind, placebo-controlled crossover trial of modafinil in the treatment of residual excessive daytime sleepiness in the sleep apnea/hypopnea syndrome. Am J Respir Crit Care Med 2001; 163:918-923.
33. Laffont F, Mayer G & Minz M: Modafinil in diurnal sleepiness: a study of 123 patients. Sleep 1994; 17:S113-S115.
34. Lyons TJ & French J: Modafinil: the unique properties of a new stimulant. Aviat Space Environ Med 1991; 62:432-435.
35. McClellan KJ & Spencer CM: Modafinil: a review of its pharmacology and clinical efficacy in the management of narcolepsy. CNS Drugs 1998; 9(4):311-324.
36. Mitler MM & Hajdukovic R: Relative efficacy of drugs for the treatment of sleepiness in narcolepsy. Sleep 1991; 14:218-220.
37. Moachon G, Kanmacher I, Clenet M et al: Pharmacokinetic profile of modafinil. Drugs Today 1996; 32(suppl I):23-33.
38. Pack AI, Black JE, Schwartz JRL et al: Modafinil as adjunct therapy of daytime sleepiness in obstructive sleep apnea. Am J Respir Crit Care Med 2001; 164:1675-1681.
39. Reynolds JEF (Ed): Martindale: The Extra Pharmacopoeia (CD-ROM Version). Micromedex, Inc, Englewood, CO, 2000.
40. Roth T & Roehrs TA: Etiologies and sequelae of excessive daytime sleepiness. Clin Ther 1996; 18:562-576.
41. Aman MG: Stimulant drug effects in development disorders and hyperactivity: toward a resolution of disparate findings. J Autism Dev Disord 1982; 12:385-399.
42. Anon: American Academy of Pediatrics. Committee on Children with Disabilities: medication for

children with an attention deficit disorder. Pediatrics 1987; 80:758-760.
43. Barkley RA & Jackson TL: Hyperkinesis, autonomic nervous system activity and stimulant drug effects. J Child Psychol Psychiatry 1977; 18:347-357.
44. Burks HF: Effect of amphetamine therapy on hyperactive children. Arch Gen Psychiatry 1964; 11:604.
45. Efron D, Jarman F & Barker M: Side effects of methylphenidate and dexamphetamine in children with attention deficit hyperactivity disorder: a double-blind, crossover trial. Pediatrics 1997; 100:662-666.
46. Elia J, Borcherding BG, Potter WZ et al: Stimulant drug treatment of hyperactivity: biochemical correlates. Clin Pharmacol Ther 1990; 48:57-66.
47. Horrigan JP & Barnhill LJ: Low-dose amphetamine salts and adult attention-deficit/hyperactivity disorder. J Clin Psychiatry 2000; 61:414-417.
48. Product Information: Dexedrine(R), dextroamphetamine sulfate tablets and Spansule(R) capsules. SmithKline Beecham Pharmaceuticals, Philadelphia, PA, USA, 2003.
49. Product Information: Dextrostat(R), dextroamphetamine sulfate tablets. Richwood Pharmaceutical Company, Inc, Florence, KY, 2003.
50. Solanto MV: Neuropharmacological basis of stimulant drug action in attention deficit disorder with hyperactivity: a review and synthesis. Psychol Bull 1984; 95:387-409.
51. Sunosi™ [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc.; June 2019
52. Wakix® [package insert]. Plymouth Meeting, PA; Harmony Biosciences, LLC; August 2019