

## Vyvanse (lisdexamfetamine)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

Vyvanse (lisdexamfetamine)	1
Summary	1
Definitions	2
Clinical Indications	3
Medical Necessity Criteria for Initial Clinical Review	3
Initial Indication-Specific Criteria	3
Binge Eating Disorder	3
Attention Deficit Hyperactivity Disorder (ADHD)	3
Experimental or Investigational / Not Medically Necessary	4
References	4
Clinical Guideline Revision / History Information	5

### Summary

Attention-deficit/hyperactivity disorder (ADHD) is a chronic condition that is often characterized by difficulty with paying attention, hyperactivity, impulsivity, and poor self-control.. It is a neurological condition that affects an individual's development and functioning, often impacting their academic performance and social relationships. It is a neurological condition that affects an individual's development and functioning, often impacting their academic performance and social relationships.

Symptoms of ADHD can vary from person to person, and can be further divided into three primary categories: inattention, hyperactivity, and impulsivity. Inattention symptoms may include a lack of focus, not listening when spoken to, difficulty following instructions, disorganization, and easily distracted. Hyperactivity symptoms may include fidgeting, talking excessively, and a need for constant activity or motion. Impulsivity symptoms can include difficulty waiting for their turn, blurting out answers, and interrupting others. Treatment for ADHD is often a combination of counseling and medication, depending on the individual and the severity of their symptoms. Cognitive Behavioral Therapy (CBT) is often used to help those with ADHD better manage their thoughts and behaviors, while medications such as stimulants, nonstimulants, and antidepressants can help regulate dopamine levels, which often play an important role in the disorder.

Binge eating disorder (BED) is an eating disorder characterized by recurrent episodes of eating a large quantity of food (e.g., more than 1000 calories) in a finite amount of time (e.g., several hours). Additional core features include: weekly binge eating episodes (for at least three months), compensatory behaviors not being present that you may see with other eating disorders (e.g., fasting, purging), and, prior to an episode an environmental or emotional trigger or stressor is typically present. Binge eating disorders can often be chronic, and those with BED are more likely to experience other comorbidities such as arthritis, chronic pain, high blood pressure and diabetes. First line treatment for BED is cognitive-behavioral therapy (CBT) or similar psychotherapies. Pharmacotherapies are considered less effective than psychotherapies, but can be used first-line in those without access to, or who deny interest in, psychotherapy. Medication management may include antidepressants like, selective serotonin reuptake inhibitors, anti-seizure medications (e.g., topiramate, zonisamide), atomoxetine (Strattera), Vyvanse (lisdexamfetamine), and armodafinil (Nuvigil).

Vyvanse (lisdexamfetamine) is a centrally acting stimulant that is FDA approved for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and those 6 years of age and older, as well as binge-eating disorder (BED) in adults. Vyvanse (lisdexamfetamine) is considered first-line therapy in the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) and is utilized as part of a comprehensive approach including psychological, educational, and/or social interventions. Vyvanse (lisdexamfetamine) is available as oral tablets or capsules.

## Definitions

“ADHD” is a chronic psychological condition characterized by inattention, hyperactivity and impulsivity. While the exact cause of ADHD is not clear, possible factors that may be involved are genetics, the environment or problems with the central nervous system at key moments in development.

“Binge Eating Disorder (BED)” is a severe, treatable eating disorder characterized by recurrent episodes of eating large quantities of food (often very quickly and to the point of discomfort); a feeling of a loss of control during the binge; experiencing shame, distress or guilt afterwards; and often using unhealthy

compensatory measures like purging to counter the binge eating. It is the most common eating disorder in the United States.

## Clinical Indications

### Medical Necessity Criteria for Initial Clinical Review

#### Initial Indication-Specific Criteria

##### Binge Eating Disorder

The Plan considers Vyvanse (lisdexamfetamine) medically necessary when ALL of the following criteria are met for the applicable indication below:

1. The requested medication is being prescribed by or in consultation with a psychiatrist; *AND*
2. The member is at least 18 years of age; *AND*
3. The member has a diagnosis of binge-eating disorder; *AND*
4. The member has a documented prior, concurrent or planned course of therapy or counseling (such as interpersonal psychotherapy, cognitive-behavioral therapy, dialectical behavior therapy); *AND*
5. IF the request is for brand Vyvanse, the member is unable to use, or has tried and failed generic lisdexamfetamine from two or more ( $\geq 2$ ) manufacturers, when available; *AND*
6. Chart documentation must be provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met for the applicable indication, Vyvanse (lisdexamfetamine) will be approved for up to a lifetime.

##### Attention Deficit Hyperactivity Disorder (ADHD)

The Plan considers Vyvanse (lisdexamfetamine) medically necessary when ALL of the following criteria are met for the applicable indication below:

1. The member is at least 6 years of age; *AND*
2. The member has a documented diagnosis of attention-deficit/hyperactivity disorder (ADHD); *AND*
3. The member is unable to use, or has adequately tried and failed (at maximum tolerated dose for a minimum of 30 days) ONE (1) of the following:
  - a. An extended-release amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine); *or*
  - b. An extended-release methylphenidate product (e.g., dextroamphetamine, methylphenidate); *AND*
4. IF the request is for brand Vyvanse, the member is unable to use, or has tried and failed generic lisdexamfetamine from two or more ( $\geq 2$ ) manufacturers, when available; *AND*
5. Chart documentation must be provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met for the applicable indication, Vyvanse (lisdexamfetamine) will be approved for up to a lifetime.

### Experimental or Investigational / Not Medically Necessary

Vyvanse (lisdexamfetamine) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

### References

1. Aigner M, Treasure J, Kaye W, Kasper S. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the pharmacological treatment of eating disorders. *World J Biol Psychiatry* 2011;12:400-43.
2. American Academy of Child and Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with AttentionDeficit/Hyperactivity Disorder. *J Am Acad Child Adolesc Psychiatry*. 2007;46(7):894-921.
3. American Academy of Pediatrics subcommittee on attention-deficit/hyperactivity disorder, steering committee on quality improvement and management. 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.
4. Amianto F, Ottone L, Daga A, et al. Binge-eating disorder diagnosis and treatment: a recap in front of DSM-5. *BMC Psychiatry*. 2015 Apr 3;15:70. doi: 10.1186/s12888-015-0445-6.
5. Coghill D, Banaschewski T, Cortese S, et al. The management of ADHD in children and adolescents: bringing evidence to the clinic: perspective from the European ADHD Guidelines Group (EAGG). *Eur Child Adolesc Psychiatry*. 2023 Aug;32(8):1337-1361. doi: 10.1007/s00787-021-01871-x. Epub 2021 Oct 22.
6. Cortese S, Adamo N, Del Giovane C, et al. Comparative efficacy and tolerability of medications for attention-deficit hyperactivity disorder in children, adolescents, and adults: a systematic review and network meta-analysis. *Lancet Psychiatry*. 2018 Sep;5(9):727-738. doi: 10.1016/S2215-0366(18)30269-4. Epub 2018 Aug 7.
7. Crone C, Fochtmann LJ, Attia E, Boland R, Escobar J, Fornari V, Golden N, Guarda A, Jackson-Triche M, Manzo L, Mascolo M, Pierce K, Riddle M, Seritan A, Uniacke B, Zucker N, Yager J, Craig TJ, Hong SH, Medicus J. The American Psychiatric Association Practice Guideline for the Treatment of Patients With Eating Disorders. *Am J Psychiatry*. 2023 Feb 1;180(2):167-171. doi: 10.1176/appi.ajp.23180001. PMID: 36722117.
8. Elliott J, Johnston A, Husereau D, et al. Pharmacologic treatment of attention deficit hyperactivity disorder in adults: A systematic review and network meta-analysis. *PLoS One*. 2020 Oct 21;15(10):e0240584. doi: 10.1371/journal.pone.0240584.
9. Gasior M, Hudson J, Quintero J, Ferreira-Cornwell MC, Radewonuk J, McElroy SL. A Phase 3, Multicenter, Open-Label, 12-Month Extension Safety and Tolerability Trial of Lisdexamfetamine Dimesylate in Adults With Binge Eating Disorder. *J Clin Psychopharmacol*. 2017 Jun;37(3):315-322. doi: 10.1097/JCP.0000000000000702.
10. Grilo CM, Ivezaj V, Tek C, Yurkow S, Wiedemann AA, Gueorguieva R. Cognitive Behavioral Therapy and Lisdexamfetamine, Alone and Combined, for Binge-Eating Disorder With Obesity: A Randomized Controlled Trial. *Am J Psychiatry*. 2025 Feb 1;182(2):209-218. doi: 10.1176/appi.ajp.20230982. Epub 2024 Dec 11.
11. Guerdjikova AI, Mori N, Blom TJ, et al. Lisdexamfetamine dimesylate in binge eating disorder: a placebo controlled trial. *Hum Psychopharmacol*. 2016 Sep;31(5):382-91. doi: 10.1002/hup.2547.
12. Himmerich H, Lewis YD, Conti C, et al. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines update 2023 on the pharmacological treatment of eating disorders. *World J Biol Psychiatry*. 2023 Apr 24:1-64. doi: 10.1080/15622975.2023.2179663. Epub ahead of print.

13. Hudson JI, McElroy SL, Ferreira-Cornwell MC, Radewonuk J, Gasior M. Efficacy of Lisdexamfetamine in Adults With Moderate to Severe Binge-Eating Disorder: A Randomized Clinical Trial. *JAMA Psychiatry*. 2017 Sep 1;74(9):903-910. doi: 10.1001/jamapsychiatry.2017.1889.
14. MayoClinic.org - ADHD. Posted June 2019. Updated Jan 2021. Available at: <https://www.mayoclinic.org/diseases-conditions/adhd/symptoms-causes/syc-20350889>.
15. McElroy SL, Hudson JI, Mitchell JE, et al. Efficacy and safety of lisdexamfetamine for treatment of adults with moderate to severe binge-eating disorder: a randomized clinical trial. *JAMA Psychiatry*. 2015 Mar;72(3):235-46. doi: 10.1001/jamapsychiatry.2014.2162.
16. National Eating Disorder Association - BED. Updated Jan 2021. Available at: <https://www.nationaleatingdisorders.org/learn/by-eating-disorder/bed>
17. National Institute for Health and Care Excellence (NICE). Attention deficit hyperactivity disorder: diagnosis and management. NG87. Published 14 March 2018, updated 13 September 2019. Available at: <https://www.nice.org.uk/guidance/ng87/chapter/Recommendations>. Accessed 26 August 2025.
18. National Institute for Health and Care Excellence (NICE). Eating disorders: recognition and treatment. NG69. Published 23 May 2017, updated 16 December 2020. Available at: <https://www.nice.org.uk/guidance/ng69/chapter/Recommendations>. Accessed 26 August 2025.
19. Padilha SCOS, Virtuoso S, Tonin FS, Borba HHL, Pontarolo R. Efficacy and safety of drugs for attention deficit hyperactivity disorder in children and adolescents: a network meta-analysis. *Eur Child Adolesc Psychiatry*. 2018 Oct;27(10):1335-1345. doi: 10.1007/s00787-018-1125-0. Epub 2018 Feb 19.
20. Reas DL, Gril CM. Pharmacological treatment of binge eating disorder: update review and synthesis. *Expert Opin Pharmacother*. 2015;16(10):1463-78. doi:10.1517/14656566.2015.1053465.
21. Vyvanse (lisdexamfetamine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; October 2023.
22. Vyvanse (lisdexamfetamine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; January 2022.
23. Vyvanse Drug Monograph. Clinical Pharmacology. Accessed Sept 2021. Available at: <http://www.clinicalpharmacology-ip.com>.
24. Wolraich ML, Hagan JF Jr, Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents [published correction appears in Pediatrics. 2020 Mar;145(3)]. *Pediatrics*. 2019;144(4):e20192528. doi:10.1542/peds.2019-2528
25. Yager J, Devlin MJ, Halmi KA et al. Treatment of patients with eating disorders, 3rd edition. American Psychiatric Association. *Am J Psychiatry*. 2006 Jul;163(7 Suppl):4-54.

#### Clinical Guideline Revision / History Information

Original Date: 10/14/2021

Reviewed/Revised: 12/01/2021, 06/23/2022, 06/29/2023, 12/19/2024, 11/01/2025, 02/02/2026