Clinical Policy: Lisdexamfetamine (Vyvanse)

Reference Number: CP.PMN.121
Effective Date: 02.01.09
Last Review Date: 02.22
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lisdexamfetamine (Vyvanse®) is a central nervous stimulant.

FDA Approved Indication(s)

Vyvanse is indicated for the treatment of:

- Attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older
- Moderate to severe binge eating disorder (BED) in adults

Limitation(s) of use:

- Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
- Vyvanse is not indicated for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Vyvanse for the treatment of obesity have not been established.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Vyvanse is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Binge Eating Disorder (must meet all)**:**

1. Diagnosis of BED;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with a psychiatrist;
4. Failure of ≥ 3 month trial of cognitive behavioral therapy (CBT) with supporting documentation;
5. Failure of ≥ 3 month trial of topiramate at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of ≥ 6 week trial of one of the following, unless clinically significant adverse effects are experience or all are contraindicated: citalopram, sertraline, escitalopram;
7. If request is for Vyvanse chewable tablet, member must use Vyvanse capsule, unless contraindicated onr clinically significant adverse effects are experienced;
8. Dose does not exceed 70 mg per day (1 capsule or 2 chewable tablets per day).

Approval duration: 3 months

B. Attention Deficit Hyperactivity Disorder (must meet all)**:**
1. Diagnosis of ADHD;
2. Age ≥ 6 years;
3. Failure of one extended release amphetamine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of one extended release methylphenidate at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. If request is for Vyvanse chewable tablet, member must use Vyvanse capsule, unless contraindicated onr clinically significant adverse effects are experienced;
6. Dose does not exceed 70 mg per day (1 capsule or 2 chewable tablets per day).

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively response to therapy;
3. If request is for a dose increase, new dose does not exceed 70 mg per day (1 capsule per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADHD: attention deficit hyperactivity disorder
BED: binge eating disorder
CBT: cognitive behavioral therapy
FDA: Food and Drug Administration
MAO: monoamine oxidase

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
topiramate (Topamax®)	Varies	40 mg/day
citalopram (Celexa®)	Varies	40 mg/day
sertraline (Zoloft®)	Varies	200 mg/day
escitalopram (Lexapro®)	Varies	20 mg/day
methylphenidate extended release (Ritalin LA®, Concerta®, Metadate CD®)	Concerta: 18 - 36 mg PO QD Ritalin LA, Metadate CD: 20 mg PO QD	Concerta: 72 mg/day Ritalin LA, Metadate CD: 60 mg/day
amphetamine (Adderall XR®)	Patients 6-17 years: 10 mg PO QD Adults: 20 mg PO QD	30 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity; use with monoamine oxidase (MAO) inhibitor, or within 14 days of last MAO inhibitor dose
- Boxed warning(s): abuse and dependence

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ADHD	30 mg to 70 mg PO QD	70 mg per day
BED	50 mg to 70 mg PO QD	70 mg per day

VI. Product Availability

- Capsules: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg
- Chewable tablets: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg

VII. References

1. Vyvanse Prescribing Information. Lexington, MA: Shire US Inc., July 2021. Available at http://www.vyvanse.com/. Accessed September 30, 2021.
2. Yager J, Devlin MJ, Halmi KA et al. Treatment of patients with eating disorders,third edition. American Psychiatric Association. *Am J Psychiatry*. 2006;163(7 Suppl):4-54.
3. American Academy of Child and Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with Attention-Deficit/Hyperactivity Disorder. *J Am Acad Child Adolesc Psychiatry*. 2007;46(7):894-921.
4. 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.
5. 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.
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7. Amianto F, Ottone L Daga A et al. Binge-eating disorder diagnosis and treatment: a recap in front of DSM-5. *BMC Psychiatry*. 2015;15:70. doi: 10.1186/s12888-015-0445-6.
8. 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.
9. Hilbert A, Hoek H, and Schmidt R. Evidence-based clinical guidelines for eating disorders: international comparison. *Curr Opin Psychiatry*. 2017; 30:423-437. doi:10.1097/YCO.0000000000000360

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: no significant changes; reference number changed from PPA to PMN; added age; references reviewed and updated	02.23.18	05.18
1Q 2019 annual review: for adult ADHD removed 4 week trial duration requirement for alternatives as effects from amphetamine and methylphenidate are expected to be immediate; combined adult and pediatric ADHD into one criteria set and removed requirement for age ≥18 to be prescribed by a mental health provider to align with CP.PMN.92 CNS Stimulant policy; references reviewed and updated.	10.10.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.26.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.16.20	02.21
1Q 2022 annual review: added requirement if request is for Vyvanse chewable tablet, member must use Vyvanse capsule to align with formulary placement between these two formulations; clarified quantity limit for tablets as 2 per day; updated FDA approved indications per prescribing information; references reviewed and updated.	09.30.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.03.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.