Clinical Policy: Lisdexamfetamine (Vyvanse)

Reference Number: CP.PMN.121
Effective Date: 02.01.09 Revision Log
Last Review Date: 02.19
Line of Business: Medicaid

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)
- Moderate to severe binge eating disorder (BED) in adults

Limitation(s) of use: 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: citalopram, sertraline, or escitalopram, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 70 mg per day (1 capsule 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 contraindicated or clinically significant adverse effects are experienced;
4. Failure of one extended release methylphenidate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 70 mg per day (1 capsule per day).

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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

ADD: attention deficit disorder
ADHD: attention deficit hyperactivity disorder
BED: binge eating disorder
CBT: cognitive behavioral therapy
CNS: central nervous system
FDA: Food and Drug Administration
PDL: preferred drug list
SSRI: selective serotonin reuptake inhibitor

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

Appendix D: General Information

- Vyvanse should be titrated to the recommended therapeutic dose of 50 mg to 70 mg for the treatment of BED.

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., January 2018. Available at http://www.vyvanse.com/. Accessed October 10, 2018.
2. Vyvanse Drug Monograph. Clinical Pharmacology. Available at http://www.clinicalpharmacology-ip.com. Accessed October 10, 2018.
3. Yager J, Devlin MJ, Halmi KA et al. Treatment of patients with eating disorders,third edition. American Psychiatric Association. Am J Psychiatry. 2006 Jul;163(7 Suppl):4-54.
4. Yager J, Devlin MJ, Halmi KA et al. Guideline watch (August 2012): Practice Guideline for the treatment of patients with eating disorders, 3rd edition. American Psychiatric Association.

Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/eatingdisorders-watch.pdf. Acceessed October 10, 2018.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
References updated.	05.13	05.13
Updated Criteria for Approval item A to indicate for guideline to be used for children and a separate guideline is to be used for adults. References updated.	05.14	05.14
Updated indications, updated references.	05.15	05.15
Converted to new template Added approval criteria for binge eating disorder; Modified required trial for ADHD to trial of Preferred Drug List (PDL) long acting methylphenidate **and** long acting amphetamine, each used for at least 2 weeks at maximum tolerated doses, unless contraindicated; Added quantity limit of 1 capsule/day Modified continued approval to screen for adequate dosing. Safety criteria removed from renewal criteria to allow prescriber to own responsibility	08.15	08.15
Removed criteria C & D as this should apply to all first line PDL stimulant regardless of PDL status - C- Member does NOT have advanced atherosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, or hypothyroidism; D - Member does NOT have intolerance to sympathomimetic amines, glaucoma, anxiety or agitated state, history of drug abuse, or current monoamine oxidase inhibitor (MAOI) use;	12.15	12.15

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added criteria Adult ADHD approval criteria		
Added Prescribed by or in consultation with a psychiatrist for BED and modified criteria to one SSRI for 6 weeks instead of 2 SSRIs for 4 weeks; Removed requirement for concurrent use of topiramate and CBT.	07.16	08.16
Remove criteria of dose of 50 mg to 70mg within the next 30 days from initial approval criteria for BED because there is no way to verify dose titration occurs in 30 days. Added "Dose of 50 mg to 70 mg requested to treat BED" to the continued approval section; Changed requirement of 1 SSRI trial in BED to a trial of Celexa, Zoloft, or Lexapro. These SSRIs show the best outcomes for treatment of BED; Removed requirement of ≥ 2 week trial for pediatric/adolescent members. A response to the medication should be seen immediately and with a titration to maximum dose, the member would have trialed the medication for a sufficient timeframe; Converted to new template; Removed age criteria as age is not an absolute contraindication per FDA labeling; Separated continued criteria for clarity; Updated references	03.17	05.17
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

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.

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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.