Clinical Policy: Lisdexamfetamine (Vyvanse)

Reference Number: PA.CP.PMN.121
Effective Date: 01/18
Last Review Date: 03/19

Coding Implications
Revision Log

Description
Lisdexamfetamine (Vyvanse®) is a central nervous stimulant.

FDA approved indication
Vyvanse is indicated:

- For the treatment of attention deficit hyperactivity disorder (ADHD)
- For the treatment of moderate to severe binge eating disorder (BED) in adults

Limitation 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 (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Vyvanse is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Binge Eating Disorder (BED) (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 an SSRI 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 (ADHD) (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 PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Member is responding positively to therapy;
3. Member meets age and diagnosis criteria, and is currently stabilized on Vyvanse;
4. 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed

Approval duration: 12 months

III. 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	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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(Ritalin LA®, Concerta®, Metadate CD®)		
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.

IV. 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

V. 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

VI. References

1. Vyvanse Prescribing Information. Lexington, MA: Shire US Inc., January 2018. Available at http://www.vyvanse.com/. Accessed October 10, 2018.
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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.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: reference number changed from PPA to PMN; added age; references reviewed and updated	2.23.18	
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.	03/19	