Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date**: **6/1/2018**	
Policy Number: PA.CP.PPA.03	**Effective Date: 01/2018** **Revision Date: 04/18/2018**	
Policy Name: Lisdexamfetamine (Vyvanse)	**HC Approval Date:**	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

- **PA.CP.PMN.121 Lisdexamfetamine (Vyvanse)**

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

CLINICAL POLICY
Lisdexamfetamine

Clinical Policy: Lisdexamfetamine (Vyvanse)
Reference Number: PA.CP. PPA.03
Effective Date: 01/18
Last Review Date: 05/17
Line of Business: Medicaid

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. Prescribed by or in consultation with a psychiatrist;
3. Failure of ≥ 3 month trial of cognitive behavioral therapy (CBT) with supporting documentation;
4. Failure of ≥ 3 month trial of topiramate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of ≥ 6 week trial of an SSRI ~~one of the following~~: ~~citalopram, sertraline, or escitalopram~~; at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 70 mg per day (1 capsule per day).

Approval duration: 3 months

B. Pediatric/Adolescent Attention Deficit Hyperactivity Disorder (ADHD) (must meet all)**:**
1. Diagnosis of ADHD;
2. Failure of one extended release amphetamine at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of one extended release methylphenidate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;

4. Dose does not exceed 70 mg per day (1 capsule per day).

Approval duration: 6 months

C. Adult Attention Deficit Hyperactivity Disorder (ADHD) (must meet all)**:**
1. Diagnosis of ADHD;
2. ~~Prescribed by or in consultation with a mental health provider;~~
3. Dose does not exceed 70 mg per day (1 capsule per day);
4. Failure of a ≥ 4 week trial of one extended release amphetamine at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a ≥ 4 week trial of one extended release methylphenidate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 6 months

D. 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. Binge Eating Disorder (BED) (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive 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. Attention Deficit Hyperactivity Disorder (ADHD) (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive 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

C. 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 under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

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 – PA.CP.PMN.53 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
PDL: preferred drug list
SSRI: selective serotonin reuptake inhibitor

Appendix B: Additional Information
Vyvanse should be titrated to the recommended therapeutic dose of 50 mg to 70mg for the treatment of BED.

V. Dosage and Administration

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

VI. Product Availability

Capsules: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg

VII. References

1. Vyvanse Prescribing Information. Lexington, MA: Shire US Inc., October 2016. Available at http://www.vyvanse.com/. Accessed January 10, 2017.
2. Vyvanse Drug Monograph. Clinical Pharmacology. Accessed January 2016. http://www.clinicalpharmacology-ip.com
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. 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.
5. 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.

6. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date