Clinical Policy: Lisdexamfetamine (Vyvanse)
Reference Number: CP.PMN.121
Effective Date: 02.01.09
Last Review Date: 02.20
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 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
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.
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>topiramate (Topamax®)</td>
<td>Varies</td>
<td>40 mg/day</td>
</tr>
<tr>
<td>citalopram (Celexa®)</td>
<td>Varies</td>
<td>40 mg/day</td>
</tr>
<tr>
<td>sertraline (Zoloft®)</td>
<td>Varies</td>
<td>200 mg/day</td>
</tr>
<tr>
<td>escitalopram (Lexapro®)</td>
<td>Varies</td>
<td>20 mg/day</td>
</tr>
<tr>
<td>methylphenidate extended release (Ritalin LA®, Concerta®, Metadate CD®)</td>
<td>Concerta: 18 - 36 mg PO QD Ritalin LA, Metadate CD: 20 mg PO QD</td>
<td>Concerta: 72 mg/day Ritalin LA, Metadate CD: 60 mg/day</td>
</tr>
<tr>
<td>amphetamine (Adderall XR®)</td>
<td>Patients 6-17 years: 10 mg PO QD Adults: 20 mg PO QD</td>
<td>30 mg/day</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>30 mg to 70 mg PO QD</td>
<td>70 mg per day</td>
</tr>
<tr>
<td>BED</td>
<td>50 mg to 70 mg PO QD</td>
<td>70 mg per day</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>07.16</td>
<td>08.16</td>
</tr>
<tr>
<td>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</td>
<td>03.17</td>
<td>05.17</td>
</tr>
<tr>
<td>2Q 2018 annual review: no significant changes; reference number changed from PPA to PMN; added age; references reviewed and updated</td>
<td>02.23.18</td>
<td>05.18</td>
</tr>
<tr>
<td>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.</td>
<td>10.10.18</td>
<td>02.19</td>
</tr>
</tbody>
</table>
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.

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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.

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