Clinical Policy: Lisdexamfetamine (Vyvanse)
Reference Number: CP.PMN.121
Effective Date: 02.01.09
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.

<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>References updated.</td>
<td>05.13</td>
<td>05.13</td>
</tr>
<tr>
<td>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.</td>
<td>05.14</td>
<td>05.14</td>
</tr>
<tr>
<td>Updated indications, updated references.</td>
<td>05.15</td>
<td>05.15</td>
</tr>
<tr>
<td>Converted to new template</td>
<td>08.15</td>
<td>08.15</td>
</tr>
<tr>
<td>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</td>
<td>12.15</td>
<td>12.15</td>
</tr>
<tr>
<td>Removed criteria C &amp; 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;</td>
<td>12.15</td>
<td>12.15</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.
CLINICAL POLICY
Lisdexamfetamine

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.

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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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