



<b>Policy Title</b>	Lisdexamfetamine Dimesylate (Vyvanse®)
<b>Policy Number</b>	FS.CLIN.45

**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

<b>Policy</b>	<p><b>Lisdexamfetamine dimesylate (Vyvanse®)</b> is indicated for the treatment of attention-deficit hyperactivity disorder (ADHD).</p> <p>The use of lisdexamfetamine dimesylate (Vyvanse®) requires prior authorization (i.e., clinical pharmacy and/or medical director review).</p>
<b>Policy description</b>	<p><b>Lisdexamfetamine dimesylate (Vyvanse®)</b> is a pro-drug of dextroamphetamine. Following oral absorption, lisdexamfetamine dimesylate (Vyvanse®) is rapidly absorbed and converted into dextroamphetamine, which is responsible for the drug's activity. The exact mode of therapeutic action in attention-deficit hyperactivity disorder (ADHD) is unknown. Dextroamphetamine is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space. Dextroamphetamine may also stimulate inhibitory receptors in the brain, which may contribute to its efficacy in ADHD. At this time there are no studies showing Lisdexamfetamine dimesylate (Vyvanse®) to have superior efficacy to other medications used to treat ADHD.</p>
<b>Policy guideline inclusion</b>	<p><b>Lisdexamfetamine dimesylate (Vyvanse®)</b> is approved when there is documentation of a diagnosis of attention-deficit hyperactivity disorder (ADHD) and when <b>one</b> of the following inclusion criteria is met:</p> <ul style="list-style-type: none"> <li>• Documentation of a trial and failure or contraindication/intolerance/allergy to any <b>two</b> of the following medications: <ul style="list-style-type: none"> <li>○ A methylphenidate containing product</li> <li>○ A mixed amphetamine salts containing product (eg, amphetamine-dextroamphetamine [Adderall or Adderall XR])</li> <li>○ Atomoxetine hydrochloride (Strattera®)</li> <li>○ A dextroamphetamine containing product</li> <li>○ Methamphetamine hydrochloride (Desoxyn®)</li> <li>○ A dexmethylphenidate containing product</li> </ul> </li> <li>• Documentation of a history of or a potential for drug abuse among the individual or a member of the individual's household</li> </ul>
<b>Policy guideline exclusion</b>	<p><b>Lisdexamfetamine dimesylate (Vyvanse®)</b> is denied when <b>both</b> of the</p>

following exclusion criteria are present:

- No documentation of a diagnosis of ADHD and trial and failure or contraindication/intolerance/allergy to any **two** of the following medications:
  - A methylphenidate containing product
  - A mixed amphetamine salts containing product (eg, amphetamine-dextroamphetamine [Adderall or Adderall XR])
  - Atomoxetine hydrochloride (Strattera®)
  - A dextroamphetamine containing product
  - Methamphetamine hydrochloride (Desoxyn®)
  - A dexmethylphenidate containing product
- No documentation of a diagnosis of ADHD and a history of or a potential for drug abuse among the individual or a member of the individual's household

**Policy List of Applicable Drugs**

Brand Name	Generic Name
Vyvanse	Lisdexamfetamine Dimesylate

**Dosing and administration**

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

**Policy references**

American Academy of Pediatrics. Subcommittee on Attention-Deficit/Hyperactivity Disorder and Committee on Quality Improvement. Clinical practice guideline: treatment of the school-aged child with attention-deficit/hyperactivity disorder. *Pediatrics*. 2001;108(4):1033-1044. Also available on the American Academy of Pediatrics Web site at: <http://www.aap.org/>. Accessed July 15, 2010.

Amphetamine monograph. In: DrugPoints [database on CD-ROM]. Greenwood Village, CO: Thomson Micromedex; 2006.

Biederman J, Boellner SW, Childress A, et al. Lisdexamfetamine dimesylate and mixed amphetamine salts extended-release in children with ADHD: a double-blind, placebo-controlled crossover analog classroom study. *Biol Psychiatry*. 2007;62(9):970-976.

Biederman J, Krishnan S, Zhang Y, McGough JJ, Findling RL. Efficacy and tolerability of lisdexamfetamine dimesylate (NRP-104) in children with attention-deficit/hyperactivity disorder: a phase III, multicenter, randomized, double-blind, forced-dose, parallel-group study. *Clin Ther*. 2007;29(3):450-463.

Pink Sheet on the Web, The: Prescription Pharmaceuticals and Biotechnology. Shire turns attention to Vyvanse two years before Adderall XR goes generic. [The Pink Sheet Web site]. Available at: <http://www.thepinksheet.com> [via subscription only]. Accessed July 15, 2010.

Vyvanse® [package insert]. Wayne, PA: Shire US, Inc; 2007.

**Policy Link to Related Policies**

**Version Effective Date**

07/01/2011

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