MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** lisdexamfetamine (Vyvanse®)
PAGE: 1 of 5	**REFERENCE NUMBER:** NH.PMN.36
EFFECTIVE DATE: 02/09	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 05/12, 05/13, 12/17
PRODUCT TYPE: Medicaid	**REVISED:** 04/10, 5/11, 05/14, 6/15, 6/16, 03/17

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Vyvanse® is a once daily oral tablet that is a pro-drug to dextroamphetamine as the active ingredient.

Brand: lisdexamfetamine dimesylate (Vyvanse®):
20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg tablets

FDA Labeled Indications: Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥ 6 years of age, or other mental health conditions.

Criteria for Approval:

A. Patient ≥ 6 to <18 years of age (refer to CP.PPA.14 for adults)
B. Documented failure of Preferred Drug List (PDL) or intolerance to such therapy for each of the following: long acting methylphenidate **and** long acting amphetamine.

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Adult Attention Deficit Hyperactivity Disorder (ADHD)

A. Diagnosis of ADHD;
B. Age ≥ 18 years;
C. Prescribed by or in consultation with a mental health provider;
D. Contraindication to or failure of one PDL extended release amphetamine
AND
Contraindication to or failure of one PDL extended release methylphenidate;
E. Request does not exceed one capsule per day.

Binge Eating Disorder (BED**)** (must meet all)

A. Diagnosis of BED;
B. Age ≥ 18 years;
C. Prescribed by or in consultation with a mental health provider;
D. Member is overweight/obese (BMI ≥25);
E. Failure of concurrent use of topiramate and cognitive behavioral therapy (CBT) for ≥3 months with supporting documentation, unless contraindicated
AND
Failure of two PDL SSRIs, unless contraindicated;
F. Dose of 50 mg to 70 mg will be achieved within the next 30 days;
G. Request does not exceed 1 capsule/day.

Approval: Initial Approval: 12 months.
Continued Approval: 12 months.

Special Instructions

> Stimulant medications generally should not be used in children with known structural cardiac abnormalities due to concern that stimulants may further increase the risk of sudden death above the risk that is already present with such abnormalities.

> Vyvanse® should be used with extreme caution in patients with documented hypertension.

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> Watch closely for evidence of dependency, personality changes, and severe depression.

> Vyvanse will not be approved for combination may therapy with other long acting ADHD stimulant medications as this constitutes polypharmacy, which may increase the likelihood of adverse effects.

> Vyvanse is a Schedule II controlled substance. Stimulants, such as amphetamines and methylphenidates, are subject to misuse, abuse, addiction, and criminal diversion. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events.

> The physician who elects to use Vyvanse for extended periods should periodically re-evaluate the long-term usefulness of Vyvanse for the individual patient. Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued treatment.

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References:

1. Vyvanse® prescribing information, Accessed March, 2013. http://pi.shirecontent.com/PI/PDFs/Vyvanse_USA_ENG.pdf
2. Lisdexamfetamine monograph. Clinical Pharmacology. Accessed April 2014.

Revision Log	
Revision	**Date**
Updated FDA Labeled Indication and Criteria for Approval item "a" to reflect the change from ">6" to "> 6".	02/09
Revised Criteria for Approval items "b" and "c" from a "2 month course of both" to a "one month course of all of the following".	02/09
Added the following to Criteria for Approval item "c" after SR formulation: "and/or dextroamphetamine IR at therapeutic dosing".	02/09
Changed Criteria for Approval item "g" from Criteria for Approval item "c" No history of tics or family history of Tourette's syndrome" to "No history of tics or Tourette's syndrome or with a previous history of tics or Tourette's syndrome, a clinical evaluation by the prescriber that weighs the risk/benefit ratio for use of stimulants in terms of the acuity of the ADHD condition."	02/09
Changed Criteria for Approval item "h" from "Documentation that Vyvanse® will be given as part of an integrated care plan which includes involvement with parents, school, psychologist, and the prescriber as appropriate to age." to	02/09

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"Intended use of Vyvanse® is as mono-therapy."	
Removed the criteria for adults as directed by the adult IR stimulant therapy initiative. References updated to reflect current literature search.	04/10
Changed approval age limit to ≥ 6 years to align with FDA- approved labeling. Removed of language on who may prescribe. Removed mono-therapy language.	05/11
Added the following to the Special Instructions section: Vyvanse will not be approved for combination therapy with other long acting ADHD stimulant medications as this constitutes polypharmacy, which may increase the likelihood of adverse effects.	05/11
References updated to reflect current literature search.	05/11
Removed the review for tics and Tourette's.	05/12
Added the following to the Special Instructions section: Vyvanse is a Schedule II controlled substance. Stimulants, such as amphetamines and methylphenidates, are subject to misuse, abuse, addiction, and criminal diversion. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events.	05/12
Added the following to the Special Instructions section: The physician who elects to use Vyvanse for extended periods should periodically re-evaluate the long-term usefulness of Vyvanse for the individual patient. Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued treatment.	05/12
References updated to reflect current literature search.	05/12
References updated.	05/13
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.	05/14
References updated. Changed initial approval to 12 months	06/15

Removed criteria of "one month course" from criteria for approval.	06/16
Removed continued approval criteria "If documentation shows improvement of ADHD treatment measures as evidenced by psychological, educational and social indicators, adherence to therapy and progress notes reflecting no adverse events. Patient must be seen every six months by provider to rule out cardiac problems and other potential adverse events." Removed No history of advanced arteriosclerosis; symptomatic cardiovascular disease; moderate to severe hypertension; hyperthyroidism **and**; No known hypersensitivity or idiosyncrasy to the sympathomimetic amines; glaucoma; anxiety or agitated states; history of drug abuse; or administration of monoamine oxidase inhibitors (MAOIs)." Added ADHD criteria for approval for adult usage with no 4 week trial criteria Added Binge Eating disorder criteria with no 4 week trial criteria Removed "at maximum tolerated doses" from criteria	
Added to binge eating criteria "Prescribed by or in consultation with a mental health provider"	03/17
Annual Review, No Changes	12/17

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POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file

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