

Vyvanse for Binge Eating Disorder Drug Use Criteria

Created: June 6, 2019
Reviewed: August 2019

Includes:

Vyvanse® *lisdexamfetamine*

Schedule II CNS stimulant

GUIDELINE FOR USE:

1. Is the member being treated for a funded condition by Oregon Health Plan?
 - a. If yes and diagnosis is Binge Eating Disorder, go to 2. If ADHD, see Stimulant/ADHD criteria.
 - b. If no, deny as Below the Line, with message:
"Your request was received and denied based on the following: The condition being treated is below the funded line for Oregon Health Plan and is therefore not a covered benefit."

2. Has the member been diagnosed with moderate to severe binge eating disorder (BED)?
 - a. If yes, go to 3.
 - b. If no, deny as Criteria Not Met, with message:
"Your request was received and denied based on the following: Vyvanse will only be provided as a covered benefit for FDA approved indications supported by the medication package insert. Off label use of medication is not a covered benefit on Oregon Health Plan."

3. Has the member received psychotherapy (eg, cognitive-behavioral therapy, interpersonal psychotherapy or dialectical behavior therapy) for BED?
 - a. If yes, go to 4.
 - b. If no, deny as Criteria Not Met, with message:
"Your request was reviewed and denied based on the following: Psychotherapy (eg, cognitive-behavioral therapy) is first-line treatment for binge eating disorder. Psychotherapies that have demonstrated efficacy for treating binge eating disorder include cognitive-behavioral therapy (CBT), interpersonal psychotherapy, and dialectical behavior therapy."

4. Has the member trialed a selective serotonin reuptake inhibitor (SSRIs)?
 - a. If yes, continue to 5.
 - b. If no, deny as Criteria Not Met, with message:

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"Your request was received and denied based on the following: The use of selective serotonin reuptake inhibitors (SSRIs) are recommended for BED based on efficacy and tolerability. Note to Reviewer: Doses are comparable or greater than those usually used for unipolar major depression and titration intervals are comparable as well."

5. Does the member have a history of substance abuse?
 - a. If yes, deny as Criteria Not Met, with message:
"Your request was received and denied based on the following: Vyvanse is a schedule II CNS stimulant that has a high potential for abuse and dependence. Use of Vyvanse for BED is not a covered benefit for members with a history of substance abuse."
 - b. If no, go to 6.

6. Does the member have blood pressure that is currently well controlled? (*Chart notes documenting blood pressure will be required, and readings greater than 140/90 will not be approved for Vyvanse*).
 - a. If yes, go to 7.
 - b. If no, deny as Criteria Not Met, with message:
"Your request was received and denied based on the following: Elevated blood pressure and heart rate are common side effects stimulant therapy. Moderate to severe hypertension is a contraindication to Vyvanse therapy."

7. Does the patient have preexisting structural cardiac abnormalities or other serious cardiac problems?
 - a. If yes, deny as Criteria Not Met, with message:
"Your request was received and denied based on the following: Use of CNS stimulants has been associated with serious cardiovascular events including sudden death in patients with preexisting structural cardiac abnormalities or other serious heart problems. Vyvanse should be avoided in patients with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that can increase the risk of sudden death."
 - b. If no, go to 8.

8. Does the patient have bipolar disorder, preexisting psychosis, anxiety disorder, agitated state, narrow angle or angle closure glaucoma, or hyperthyroidism?
 - a. If yes, deny as Criteria Not Met, with message:
"Your request was received and denied based on the following: Vyvanse is not recommended in patients with bipolar disorder, preexisting psychosis, anxiety disorder, agitated state, glaucoma, or hyperthyroidism."
 - b. If no, go to 9.

9. Is the patient taking a MAO inhibitor, or quit taking a MAO inhibitor within 14 days of starting Vyvanse? (e.g. isocarboxazid, phenelzine, tranylcypromine, or selegeline)
 - a. If yes, deny as Criteria Not Met, with message:
"Your request was received and denied based on the following: Concomitant use of Vyvanse and MAO inhibitor therapy, or discontinuation within 14 days, is contraindicated due to increased risk of hypertensive crisis."
 - b. If no, go to 10.

10. Is the prescribed dose supported by the FDA approved package insert dosing guideline for the prescribed product?
 - a. If yes, approve for 12 weeks. *A limitation of the available data on medications for binge eating disorder is that most trials lasted 12 weeks or less, and thus little is known regarding longer term effects on binge eating.*
 - b. If no, deny as Criteria Not Met, with message:
"Your request was reviewed and denied based on the following: Doses above those supported by the FDA approved package insert are not a covered benefit on Oregon Health Plan."

Renewal Request:

Use of Vyvanse for BED beyond 12 weeks has not been studied in clinical trials and therefore lacks clinical evidence of safety and effectiveness supporting long-term use. Chart notes supporting ongoing benefit outweighs risks of therapy will be required for consideration of coverage beyond 12 weeks.

Rationale:

To ensure the safe and effective use of Vyvanse for BED. The potential for adverse effects may limit the utility of Vyvanse as use may cause anorexia, gastrointestinal distress, headaches, insomnia, and sympathetic nervous system arousal (eg, anxiety and dry mouth). CNS stimulants such as Vyvanse have a high potential for abuse or dependence.

FDA Approved Indication:

Binge Eating Disorder
ADHD

Mechanism of Action:

The exact mechanism of lisdexamfetamine in ADHD and binge eating disorder is not known. Lisdexamfetamine dimesylate is a prodrug that is converted to the active component dextroamphetamine (a noncatecholamine, sympathomimetic amine). Amphetamines are noncatecholamine, sympathomimetic amines that cause release of catecholamines (primarily dopamine and norepinephrine) from their storage sites in the presynaptic nerve terminals. A less

significant mechanism may include their ability to block the reuptake of catecholamines by competitive inhibition.

Dosing:

Binge eating disorder, moderate to severe: Adolescents ≥ 18 years: Capsule, chewable tablets: Oral: Initial: 30 mg once daily in the morning; may titrate in increments of 20 mg/day at weekly intervals to target dose of 50 to 70 mg once daily; maximum daily dose: 70 mg/day; discontinue use if binge eating does not improve.

Contraindications:

- Hypersensitivity to amphetamine products or any component of the formulation; concurrent use of MAO inhibitor, or within 14 days of the last MAO inhibitor dose.

References:

UpToDate. Binge eating disorder in adults: Overview of treatment. Literature review current through: May 2019. Topic last updated: Jul 17, 2018. Accessed June 5, 2019.

Vyvanse Prescribing Information. Shire. Accessed June 6, 2019.