

## Vyvanse (lisdexamfetamine)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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### Summary

Attention-deficit/hyperactivity disorder (ADHD) is a chronic condition that is often characterized by difficulty with paying attention, hyperactivity, impulsivity, and poor self-control.. It is a neurological condition that affects an individual's development and functioning, often impacting their academic performance and social relationships. It is a neurological condition that affects an individual's development and functioning, often impacting their academic performance and social relationships.

Symptoms of ADHD can vary from person to person, and can be further divided into three primary categories: inattention, hyperactivity, and impulsivity. Inattention symptoms may include a lack of focus, not listening when spoken to, difficulty following instructions, disorganization, and easily distracted. Hyperactivity symptoms may include fidgeting, talking excessively, and a need for constant activity or motion. Impulsivity symptoms can include difficulty waiting for their turn, blurting out answers, and interrupting others. Treatment for ADHD is often a combination of counseling and medication, depending on the individual and the severity of their symptoms. Cognitive Behavioral Therapy (CBT) is often used to help those with ADHD better manage their thoughts and behaviors, while medications such as stimulants, nonstimulants, and antidepressants can help regulate dopamine levels, which often play an important role in the disorder.

Binge eating disorder (BED) is an eating disorder characterized by recurrent episodes of eating a large quantity of food (e.g., more than 1000 calories) in a finite amount of time (e.g., several hours). Additional core features include: weekly binge eating episodes (for at least three months), compensatory behaviors not being present that you may see with other eating disorders (e.g., fasting, purging), and, prior to an episode an environmental or emotional trigger or stressor is typically present. Binge eating disorders can often be chronic, and those with BED are more likely to experience other comorbidities such as arthritis, chronic pain, high blood pressure and diabetes. First line treatment for BED is cognitive-behavioral therapy (CBT) or similar psychotherapies. Pharmacotherapies are considered less effective than psychotherapies, but can be used first-line in those without access to, or who deny interest in, psychotherapy. Medication management may include antidepressants like, selective serotonin reuptake inhibitors, anti-seizure medications (e.g., topiramate, zonisamide), atomoxetine (Strattera), Vyvanse (lisdexamfetamine), and armodafinil (Nuvigil).

Vyvanse (lisdexamfetamine) is a centrally acting stimulant that is FDA approved for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and those 6 years of age and older, as well as binge-eating disorder (BED) in adults. Vyvanse (lisdexamfetamine) is considered first-line therapy in the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) and is utilized as part of a comprehensive approach including psychological, educational, and/or social interventions. Vyvanse (lisdexamfetamine) is available as oral tablets or capsules.

### Definitions

“ADHD” is a chronic psychological condition characterized by inattention, hyperactivity and impulsivity. While the exact cause of ADHD is not clear, possible factors that may be involved are genetics, the environment or problems with the central nervous system at key moments in development.

“Binge Eating Disorder (BED)” is a severe, treatable eating disorder characterized by recurrent episodes of eating large quantities of food (often very quickly and to the point of discomfort); a feeling of a loss of control during the binge; experiencing shame, distress or guilt afterwards; and often using unhealthy

compensatory measures like purging to counter the binge eating. It is the most common eating disorder in the United States.

## Clinical Indications

### Medical Necessity Criteria for Initial Clinical Review

#### Initial Indication-Specific Criteria

##### Binge Eating Disorder

The Plan considers Vyvanse (lisdexamfetamine) medically necessary when ALL of the following criteria are met for the applicable indication below:

1. The requested medication is being prescribed by or in consultation with a psychiatrist; *AND*
2. The member is at least 18 years of age; *AND*
3. The member has a diagnosis of binge-eating disorder; *AND*
4. The member has a documented prior, concurrent or planned course of therapy or counseling (such as interpersonal psychotherapy, cognitive-behavioral therapy, dialectical behavior therapy); *AND*
5. IF the request is for brand Vyvanse, the member is unable to use, or has tried and failed generic lisdexamfetamine from two or more ( $\geq 2$ ) manufacturers, when available; *AND*
6. Chart documentation must be provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met for the applicable indication, Vyvanse (lisdexamfetamine) will be approved for up to a lifetime.

##### Attention Deficit Hyperactivity Disorder (ADHD)

The Plan considers Vyvanse (lisdexamfetamine) medically necessary when ALL of the following criteria are met for the applicable indication below:

1. The member is at least 6 years of age; *AND*
2. The member has a documented diagnosis of attention-deficit/hyperactivity disorder (ADHD) ; *AND*
3. The member is unable to use, or has adequately tried and failed (at maximum tolerated dose for a minimum of 30 days) ONE (1) of the following:
  - a. An extended-release amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine); *or*
  - b. An extended-release methylphenidate product (e.g., dexamethylphenidate, methylphenidate); *AND*
4. IF the request is for brand Vyvanse, the member is unable to use, or has tried and failed generic lisdexamfetamine from two or more ( $\geq 2$ ) manufacturers, when available; *AND*
5. Chart documentation must be provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met for the applicable indication, Vyvanse (lisdexamfetamine) will be approved for up to a lifetime.

#### Experimental or Investigational / Not Medically Necessary

Vyvanse (lisdexamfetamine) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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#### Clinical Guideline Revision / History Information

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