

Effective: September 12, 2023

<b>Guideline Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
<b>Applies to:</b>	
<b>Commercial Products</b>	
<input checked="" type="checkbox"/> Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988 <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617-673-0988 CareLink <sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization	
<b>Public Plans Products</b>	
<input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988	

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

### Food and Drug Administration – Approved Indications

Central Nervous System (CNS) stimulants indicated for treatment of ADHD include:

- **Amphetamine-dextroamphetamine mixed salts (Adderall, Adderall XR, Mydayis)**
- **Amphetamine (Adzenys XR-ODT, Dyanavel XR, Evekeo, Evekeo ODT)**
- **Dexmethylphenidate (Focalin, Focalin XR)**
- **Dextroamphetamine (Dexedrine, ProCentra, Zenzedi)**
- **Lisdexamfetamine (Vyvanse)** - also approved for moderate to severe binge eating disorder in adults
- **Methamphetamine (Desoxyn)**
- **Methylphenidate (Adhansia XR, Aptensio XR, Concerta, Cotelpla XR-ODT, Daytrana, Jornay PM, Methylin, QuilliChew ER, Quillivant XR, Relexxii, Ritalin, Ritalin LA)**
- **Serdexmethylphenidate and Dexmethylphenidate (Azstarys)**

Other Classes of ADHD Drugs:

- **Qelbree (viloxazine)** is a selective norepinephrine reuptake inhibitor indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

### Clinical Guideline Coverage Criteria

The plan may authorize coverage of central nervous system (CNS) stimulant medications for members 25 years and older if the following criteria are met:

1. Patient is 25 years of age or older

**AND**

2. One of the following:
  - a. Documented diagnosis of one of the following:
    - i. Attention Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) before the age of 12
    - ii. Narcolepsy
    - iii. Traumatic Brain Injury, s/p cerebrovascular event (e.g. ischemic stroke)

- iv. Excessive daytime sedation associated with a chronic medical condition (e.g. cancer, terminal illness, organic brain disorder, obstructive sleep apnea/hypopnea syndrome, multiple sclerosis, depression, chronic fatigue syndrome, Parkinson's disease)
- v. Depressive condition in which the stimulant will be used as an augmenting agent with concomitant antidepressant(s)

**OR**

- b. Documentation by the provider there was evidence of signs or symptoms of ADHD before the age of 18 years

**In addition to above criteria, the plan may authorize coverage of Vyvanse (lisdexamfetamine) when the following criteria is met:**

- 1. Documented diagnosis of Binge Eating disorder (B.E.D.)

**AND**

- 2. The patient is at least 18 years of age

**The plan may authorize coverage of Qelbree (viloxazine) when the following criteria is met:**

- 1. Diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD)

**AND**

- 2. The patient is 6 years of age or older

**AND**

- 3. The patient has demonstrated an inadequate response to an appropriate trial with, or a contraindication and/or intolerance to atomoxetine (Strattera)

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## Limitations

- 1. Duration of coverage for other non-FDA-approved indications that have been deemed medically necessary will be determined based on the dosing and length of treatment recommended by compendia for the requested indication. Subsequent approvals for non-FDA-approved indications will be reviewed on a case by case basis.

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## Codes

None

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## References

- 1. Please refer to the prescribing information for references of individual CNS ADHD stimulants.
- 2. McIntyre RS, Lee Y, Zhou AJ, et al. The efficacy of psychostimulants in major depressive episodes: A systematic review and meta-analysis. *J Clin Psychopharmacol.* 2017 Aug;37(4):412-418.
- 3. Nierenberg, A. Unipolar major depression in adults: Augmentation of antidepressants with stimulants and stimulant-like drugs. In: Solomon D, ed. UpToDate [database online]. Waltham, MA: UpToDate, 2021. <https://www.uptodate.com>. Accessed August 12, 2021.
- 4. Qelbree (viloxazine) [Prescribing information]. Rockville, MD: Supernus Pharmaceuticals; April 2022.

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## Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- September 12, 2023: no changes to criteria, minor administrative wording clean up.

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## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population

of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.