# Pharmacy Medical Necessity Guidelines:
# CNS Stimulant Medications

*Effective: November 1, 2026*

| | | | |
|---|---|---|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review | RXUM |
| These pharmacy medical necessity guidelines apply to the following:<br>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan | | **Fax Numbers:**<br>RXUM: 617.673.0939 | |

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

### FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

The following non-preferred central nervous system (CNS) stimulant medications are indicated for the treatment of attention deficit hyperactivity disorder (ADHD): dexmethylphenidate extended-release 25 mg and 35 mg (Focalin XR), lisdexamfetamine (Vyvanse), methylphenidate transdermal (Daytrana), methylphenidate extended-release 10 mg (Ritalin LA 10 mg), and methylphenidate oral suspension (Quillivant XR). Vyvanse is also indicated for the treatment of moderate to severe binge eating disorder.

**Please note: Tufts Health Plan recommends the Provider review member-specific medication usage through state(s) Online Prescription Monitoring Program(s).**

| Tufts Health Together Preferred Drug List Status | | | | |
|---|---|---|---|---|
| **Brand Name*** | **Generic Name** | **Member Age –less than 24 yrs old** | **Member Age ≥ 25 yrs old** | **Quantity Limitations** |
| Dyanavel XR | amphetamine ER oral suspension | PA; QL | PA; QL | 8 ml/day |
| Dyanavel XR | amphetamine ER chewable tablet | PA; QL | PA; QL | 1 tablet/day |
| Adderall | amphetamine/dextroamphetamine IR tablets | QL | PA; QL | 3 tablets/day |
| Adderall XR | amphetamine/dextroamphetamine ER capsules | QL | PA; QL | 2 capsules/day |
| Focalin XR 5mg, 10mg, 15mg, 20mg, 30mg, 40mg | dexmethylphenidate ER capsules | QL | PA; QL | 1 capsule/day |
| Focalin XR 25mg, 35mg | dexmethylphenidate ER capsules | PA; QL | PA; QL | 1 capsule/day |
| Focalin | dexmethylphenidate IR tablets | QL | PA; QL | 2 tablets/day |
| Dexedrine | dextroamphetamine 24HR CR capsules | QL | PA; QL | 3 capsules/day |
| Procentra | dextroamphetamine oral solution | QL | PA; QL | 40 ml/day |
| Dexedrine/Zenzedi 5mg, 10mg | dextroamphetamine IR tablets | QL | PA; QL | 3 tablets/day |
| Vyvanse capsule | lisdexamfetamine | PA; QL | PA; QL | 1 capsule/day |
| Desoxyn | methamphetamine tablets | QL | PA; QL | 5 tablets/day |
| Metadate CD | methylphenidate DR capsules | QL | PA; QL | 1 capsule/day |
| Ritalin LA 20mg, 30mg, 40mg | methylphenidate ER capsules | QL | PA; QL | 1 capsule/day |

| Tufts Health Together Preferred Drug List Status | | | | |
|---|---|---|---|---|
| **Brand Name*** | **Generic Name** | **Member Age –less than 24 yrs old** | **Member Age ≥ 25 yrs old** | **Quantity Limitations** |
| Ritalin LA 10mg, 60mg | methylphenidate ER capsules | PA; QL | PA; QL | 1 capsule/day |
| Methylin Tablets | methylphenidate chewable tablets | QL | PA; QL | 3 tablets/day |
| Quillivant XR Suspension | methylphenidate ER oral suspension | PA; QL | PA; QL | 12ml/day |
| Methylin Solution | methylphenidate oral solution | QL | PA; QL | 30ml/day |
| Ritalin | methylphenidate IR tablets | QL | PA; QL | 3 tablets/day |
| Methylphenidate ER 10mg | methylphenidate ER tablets | QL | PA; QL | 1 tablet/day |
| Ritalin SR 20mg | methylphenidate ER tablets | QL | PA; QL | 1 tablet/day |
| Concerta 18 mg, 27 mg, 54 mg | methylphenidate ER tablets | QL | PA; QL | 1 tablet/day |
| Concerta 36mg | methylphenidate ER tablets | QL | PA; QL | 2 tablets/day |
| Daytrana | methylphenidate transdermal | PA; QL | PA; QL | 1 patch/day |

## COVERAGE GUIDELINES

The plan may authorize coverage of a CNS stimulant medication for Members when **ALL** of the following criteria are met:

### Age-Specific Criteria

***Members 25 years of age and older***

The plan may authorize coverage of a preferred or non-preferred stimulant medication for Members 25 years of age or older when **ALL** of the following age-specific criteria are met. Additionally, if the medication is non-preferred, the non-preferred stimulant medication criteria must also be met.

1. Member has one of the following diagnoses:
   a) Attention Deficit Hyperactivity Disorder (ADHD)
   b) Binge-eating disorder
   b) Narcolepsy
   c) Depressive condition in which the stimulant will be used as an augmenting agent with concomitant antidepressant medication(s), and bipolar disease, thyroid disease, cardiovascular conditions have been ruled out
   d) Traumatic Brain Injury
   e) Documented excessive sleepiness associated with a documented diagnosis of one of the following chronic medical conditions
      - Depression
      - Chronic fatigue syndrome
      - Multiple sclerosis
      - Organic brain disorder
      - Obstructive Sleep Apnea/Hypopnea Syndrome
      - Parkinson's Disease

   ***Note:*** *The Plan recommends the Provider reviews Member-specific medication usage through the state's Online Prescription Monitoring Program.*

   **AND**

2. For immediate-release products:
   a) The provider indicates there is no concern with active substance abuse or diversion

   **AND**

   b) The provider indicates clinical rationale of therapy with an immediate-release formulation instead of long-acting/extended-release formulations

**Non-Preferred CNS Stimulant Criteria**

The plan may authorization coverage of a non-preferred stimulant for Members less than 25 years of age when **ALL** of the following medication-specific criteria are met. Additionally, if the Member is 25 years of age or older, the age-specific criteria listed above must be met before applying the medication-specific criteria listed below:

**Amphetamine extended-release oral solution (Dyanavel XR), amphetamine extended-release chewable tablet (Dyanavel XR)**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with generic amphetamine/ dextroamphetamine extended-release capsules and at least one additional generic CNS ADHD stimulant

**Dexmethylphenidate 25 mg and 35 mg extended-release (Focalin XR)**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with at least two alternative generic extended-release methylphenidate medications, such as generic formulations of Concerta, Metadate CD, Focalin XR (20 mg, 40 mg) or Ritalin LA

**Lisdexamfetamine capsule (Vyvanse)**

1. The Member meets ONE of the following:
   a. Documentation the member has had an inadequate response, adverse reaction, or contraindication to treatment with at least two generic stimulant medications with different active ingredients (i.e., methylphenidate product, amphetamine product)

   **OR**

   b. The Member has a diagnosis of binge-eating disorder AND documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with at least two alternative generic non-stimulant therapies (e.g., cognitive behavioral therapy, antidepressant therapy, mood stabilizers)

**Methylphenidate suspension (Quillivant XR)**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with generic methylphenidate oral solution and at least one additional generic CNS ADHD stimulant

**Methylphenidate 10 and 60 mg extended-release (Ritalin LA) capsules**

1. Documentation the Member has had an inadequate response, adverse reaction, or contraindication to treatment with an alternative generic methylphenidate extended-release medication of comparable strength (e.g., Metadate CD 10 mg, Metadate CD 60 mg, methylphenidate extended-release 10 mg tablets)

**Methylphenidate transdermal (Daytrana)**

1. Documentation the member has had an inadequate response, adverse reaction, or contraindication to treatment with at least two generic alternative CNS ADHD stimulants

**Upon renewal for all authorized CNS stimulant medications,**

1. Documentation the Member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is considered medically necessary

## LIMITATIONS

1. Approval duration will be limited to 2 years.
2. Quantity limitations that apply to the stimulant medications are listed in the table in the Overview section.
3. Requests for brand-name products, with AB-rated generics, will be reviewed according to Non-covered Medications criteria.
4. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception, but will be considered on an individual basis for prior authorization.

## CODES

None

## REFERENCES


1. Adhansia XR (methylphenidate extended-release) [prescribing information]. Stamford, CT: Adlon Therapeutics, LP; June 2021.
2. Adzenys ER (amphetamine) oral suspension [prescribing information]. Grand Prairie, TX: Neos Therapeutics; March 2024.

3. Adzenys XR-ODT (amphetamine) [prescribing information]. Grand Prairie, TX: Neos Therapeutics; March 2022.
4. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 5th edition. Arlington, VA., American Psychiatric Association, 2013.
5. Aptensio XR (methylphenidate) [prescribing information]. Greenville, NC: Patheon Manufacturing Services, LLC; April 2024.
6. Daytrana (methylphenidate) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; April 2024.
7. Dulcan M. Practice parameters for the assessment and treatment of children, adolescents, and adults with attention deficit/hyperactivity disorder. American Academy of Child and Adolescent Psychiatry. *J Am Acad Child Adolesc Psychiatry*. 1997;36(10 Suppl):85S-121S.
8. Dyanavel XR (amphetamine) [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
9. Evekeo ODT (amphetamine sulfate orally disintegrating tablet) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
10. Focalin XR (dexmethylphenidate) [prescribing information]. East Hanover, NJ.: Novartis; October 2023.
11. Gibbons, C, Weiss, M. Clinical recommendations in current practice guidelines for diagnosis and treatment of ADHD in adults. *Curr Psychiatry Rep*. 2007 Oct;9(5):420-6.
12. Jornay PM (methylphenidate extended-release) [prescribing information]. Morrisville, NC: Ironshore Pharmaceuticals; June 2021.
13. Mydayis (amphetamine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; October 2023.
14. Pliszka S; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2007;46(7):894-921.
15. QuilliChew ER (methylphenidate extended-release chewable tablet) [prescribing information]. Monmouth Junction, NJ: Tris Pharma Inc: October 2023.
16. Quillivant XR (methylphenidate oral solution extended release). Monmouth Junction, NJ: Tris Pharma Inc; October 2023.
17. Ritalin LA (methylphenidate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
18. Sysko R, Devlin M. Binge-eating disorder in adults: overview of treatment. UpToDate. Available at: www.uptodate.com. Accessed 13 September 2023.
19. The American Academy Of Pediatrics: Subcommittee On Attention-Deficit/Hyperactivity Disorder, Steering Committee On Quality Improvement And Management ADHD: Clinical Practice Guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. 2011 Nov;128(5):1-16.
20. Vyvanse (lisdexamfetamine) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; October 2023.

## APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee

Subsequent endorsement date(s) and changes made:

1. October 10, 2023: Effective January 1, 2024, updated MNG to remove restriction that lisdexamfetamine and methylphenidate transdermal (Daytrana) will only be approved for select diagnoses (i.e., ADHD, binge-eating disorder). Also removed restriction that only lisdexamfetamine will be approved for binge-eating disorder. Updated previous trial language throughout the MNG.
2. October 8, 2024: No criteria changes. Administrative update to fax number.
3. October 14, 2025: No changes
4. October 13, 2026: Effective November 1, 2026, removed amphetamine ODT (Evekeo ODT) and methylphenidate ER capsule (Adhansia XR) from the MNG due to drug discontinuation.

## 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.

Provider Services