Pharmacy Medical Necessity Guidelines: CNS Stimulant Medications

Effective: July 20, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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
Evekeo ODT	amphetamine orally disintegrating tablet	PA	PA	n/a
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

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**
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
Adhansia ER	methylphenidate ER capsules	PA; QL	PA; QL	1 tablet/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
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 ***(Vyvanse only)***
    c. Narcolepsy
    d. 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
    e. Traumatic Brain Injury
    f. 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.

*Vyvanse will **only** be approved for the treatment of binge-eating disorder or ADHD, while Daytrana will **only** be approved for the treatment of ADHD

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) and Amphetamine orally disintegrating tablet (Evekeo ODT)

1. Documentation the Member has failed a course of therapy 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 failed a course of therapy 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)

Approval is limited to the diagnosis of ADHD and BED and is not available for narcolepsy, traumatic brain injury, or depression

1. For the diagnosis of ADHD,
    a. Documentation the member has tried and failed therapy with at least two generic stimulant medications with different active ingredients (i.e., methylphenidate product, amphetamine product)

2. For the diagnosis of binge-eating disorder,
    b. Documentation the Member has tried and failed therapy 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 failed a course of therapy 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 failed a course of therapy 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 extended-release capsules (Adhansia XR)

1. Documentation that the Member has failed a course of therapy with an alternative generic methylphenidate extended-release medication and a least one additional generic CNS ADHD stimulant

Methylphenidate transdermal (Daytrana)

Approval is limited to the diagnosis of ADHD

1. Documented diagnosis of ADHD

AND

2. Documentation the member has failed a course of therapy 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. Lisdexamfetamine (Vyvanse) will only be approved for the treatment of ADHD and binge-eating disorder
4. Methylphenidate transdermal (Daytrana) will only be approved for the treatment of ADHD
5. Requests for brand-name products, with AB-rated generics, will be reviewed according to Non-covered Medications criteria.
6. 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 capsule) [prescribing information]. Stamford, CT: Purdue Pharma L.P.; February 2019.
2. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 5th edition. Arlington, VA., American Psychiatric Association, 2013.
3. Daytrana (methylphenidate) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; October 2019.
4. 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.
5. Dyanavel XR (amphetamine) [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; February 2019.
6. Evekeo ODT (amphetamine sulfate orally disintegrating tablet) [prescribing information]. Atlanta, Ga: Arbor Pharmaceuticals, LLC; January 2019.
7. Focalin XR (dexmethylphenidate) [prescribing information]. East Hanover, NJ.: Novartis; November 2019.
8. 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.
9. 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.
10. Quillivant XR (methylphenidate oral solution extended-release) [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; August 2018.
11. Ritalin LA (methylphenidate) [prescribing information]. East Hanover, NJ: Novartis; November 2019.
12. The American Academy of Pediatrics: Subcommittee on Attention-Deficit/Hyperactivity Disorder and Committee on Quality Improvement. Clinical practice guideline: treatment of the school-aged child with attention-deficit/hyperactivity disorder. Pediatrics. 2001 Oct;108(4):1033-44.
13. 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.
14. Vyvanse (lisdexamphetamine) [prescribing information]. Lexington, MA: Shire US, Inc.; January 2018.

APPROVAL HISTORY

April 14, 2015: Reviewed by Pharmacy & Therapeutics Committee; consolidated individual criteria; established criteria for Focalin XR 25mg and 35 mg, Vyvanse, Ritalin LA 10 mg, for Members 25 years of age and older and for Members less than 3 years of age; approval duration is limited to two years.

Subsequent endorsement date(s) and changes made:

1. October 6, 2015: Removed criteria related to review of the online Prescription Monitoring Program, however, included as a recommendation; included criteria specific to Ritalin LA 60 mg.

2. January 1, 2016: Administrative change to rebranded template.
3. March 6, 2016: Removed Limitation #3 "Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria."
4. June 14, 2016: Added Dyanavel XR to the criteria.
5. August 9, 2016: Updated criteria for children less than 3 years of age.
6. September 13, 2016: Changed the title of the policy from "ADHD – Stimulant Medications" to "Stimulant Medications". Updated Vyvanse criteria for members greater than 25 years of age. Added to the limitations "quantities that exceed the quantity limit will be reviewed according to the Drugs with Quantity Limitations criteria". Clarified approvable diagnoses for Vyvanse and Daytrana for members 25 years of age and older.
7. November 15, 2016: Added criteria for excessive daytime sleepiness for Members 25 years of age and older.
8. March 14, 2017: Reflected generic availability of Ritalin LA 60 mg capsules and Focalin XR 25 mg and 35 mg capsules. Removed "Quantities that exceed the quantity limit will be reviewed according to the Drugs with Quantity Limitations criteria" from the Limitations section
9. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Removed age edits for Pediatric Behavioral Health Medication Initiative. Updated criteria for Dyanavael XR, Quillivant XR, and Daytrana to require a trial and failure of at least two generic CNS ADHD stimulant medications.
10. September 18, 2018: Updated quantity limit for Metadate ER.
11. December 11, 2018: Administrative updates made to template.
12. August 13, 2019: Added Adhansia ER and Evekeo ODT to the Medical Necessity Guideline.
13. July 14, 2020: Administrative update, added language concerning samples to the limitations section of the MNG.

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.