Pharmacy Medical Necessity Guidelines:
ADHD 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): amphetamine ER oral suspension (Dyanavel XR), methylphenidate extended-release (CD) capsules (Metadate CD), methylphenidate extended-release (LA) capsules (Ritalin LA), methylphenidate transdermal (Daytrana), and methylphenidate oral suspension (Quillivant XR).

The MassHealth Pediatric Behavioral Health Medication Initiative (PBHMI) has been implemented to encourage safe prescribing of behavioral health medication regimens in members less than 18 years of age. As part of the PBHMI, a prior authorization is required for pediatric members less than 3 years of age who are being prescribed a stimulant medication, regardless as to whether or not the stimulant is preferred on the Plan's formulary. In addition to the medication-specific criteria below for the non-preferred stimulant medications, all preferred and non-preferred CNS stimulant medications require prior authorization for Members less than 3 years of age. Separate from the PBHMI, prior authorization is required for all CNS stimulant medications for Members 25 years of age and older, as well.

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 3 yrs - 24 yrs**	**Member Age < 3 yrs or ≥ 25 yrs**	**Quantity Limitations**
Dyanavel XR	amphetamine ER oral suspension	PA; QL	PA; QL	8 ml/day
Adderall	amphetamine/dextroamphetamine IR tablets	QL	PA; QL	3 tablets/day
Adderall XR*	amphetamine/dextroamphetamine ER capsules	QL	PA; QL	2 capsules/day
Mydayis	amphetamine salts extended-release capsules	PA; QL	PA; QL	1 capsule/day

Tufts Health Together Preferred Drug List Status				
Brand Name	**Generic Name**	**Member Age 3 yrs - 24 yrs**	**Member Age < 3 yrs or ≥ 25 yrs**	**Quantity Limitations**
Evekeo ODT	Amphetamine sulfate orally disintegrating tablet	PA	PA	N/A
Focalin XR*	dexmethylphenidate ER capsules	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	Lisdexamfetamine	QL	PA; QL	1 capsule/day
Desoxyn	methamphetamine tablets	QL	PA; QL	5 tablets/day
Adzenys ER	Amphetamine extended-release suspension	PA	PA	15 mL/day
Adzenys XR-ODT	amphetamine ER orally disintegrating tablets	PA; QL	PA; QL	1 capsule/day
Aptensio XR	methylphenidate ER capsules	PA; QL	PA; QL	1 capsule/day
Adhansia XR	methylphenidate ER	PA; QL	PA QL	1 capsule/day
Cotempla XR-ODT	methylphenidate ER orally disintegrating tablet	PA; QL	PA; QL	1 capsule/day
Jornay PM	methylphenidate ER capsule	PA	PA	N/A
Metadate CD	methylphenidate ER (CD) capsules	PA; QL	PA; QL	1 capsule/day
Ritalin LA	methylphenidate ER (LA) capsules	PA; QL	PA; QL	1 capsule/day
Methylin Tablets	methylphenidate chewable tablets	QL	PA; QL	3 tablets/day
QuilliChew ER	methylphenidate extended-release chewable tablet	PA; QL	PA; QL	1 tablet/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
Metadate ER	methylphenidate ER tablets	QL	PA; QL	3 tablets/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
Methylphenidate ER 72 mg	Methylphenidate ER tablets	PA; QL	PA;QL	1 tablet/day
Daytrana	methylphenidate transdermal	PA; QL	PA; QL	1 patch/day

*Brand is preferred over the interchangeable generic.

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 less than 3 years of age

The plan may authorize coverage of a preferred or non-preferred stimulant medication for Members less than 3 years of age 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:
   a) Recent psychiatric hospitalization (within the last three months)

   OR

   b) History of severe risk of harm to self or others

   OR

2. Member has all of the following:
   a) An appropriate diagnosis

   AND

   b) Treatment plan, including the names of current cerebral stimulant(s) and corresponding diagnoses

   AND

   c) Clinical rationale for use of cerebral stimulant in member less than 3 years of age

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)***
   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 3 years of age and older and 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 or less than 3 years of age, the age-specific criteria listed above must be met before applying the medication-specific criteria listed below:

Adzenys ER® (amphetamine extended-release oral solution), Adzenys XR-ODT® (amphetamine extended-release orally disintegrating orally tablet) and Dyanavel XR® (amphetamine extended-release oral solution)

1. An appropriate diagnosis (i.e., attention deficit hyperactivity disorder or autism spectrum disorder)

AND

2. Clinical rationale for use of requested agent instead of Adderall XR® (amphetamine salts extended release)

AND

3. Clinical rationale for use of requested agent instead of Vyvanse® (lisdexamfetamine)

Mydayis® (amphetamine salts extended-release capsule)

1. An appropriate diagnosis (i.e., attention deficit hyperactivity disorder or autism spectrum disorder)

AND

2. Member is 13 years of age or older

AND

3. Clinical rationale for the use of the requested agent instead of Adderall XR® (amphetamine salts extended-release)

AND

4. Clinical rationale for the use of the requested agent instead of Vyvanse® (lisdexamfetamine)

Evekeo ODT™ (amphetamine sulfate orally disintegrating tablet)

1. An appropriate diagnosis

AND

2. Clinical rationale for requested formulation over other solid oral formulations

Adhansia XR® (methylphenidate extended-release capsule), Aptensio XR® (methylphenidate exentded-release capsule), Cotempla XR-ODT® (methylphenidate extended-release orally disintegrating tablet), Daytrana® (methylphenidate transdermal), Jornay PM (methylphenidate extended-release capsule), QuilliChew ER® (methylphenidate extended-release chewable tablet), Quillivant XR® (methylphenidate suspension), ,

1. An appropriate diagnosis (i.e., attention deficit hyperactivity disorder or autism spectrum disorder)

AND

2. <u>One</u> of the following:
   a. Clinical rationale for use of the requested agent instead of Concerta® (methylphenidate extended-release)
   b. Clinical rationale for requested formulation over solid oral formulation (e.g., swallowing disorder, dysphagia)

AND

3. Clinical rationale for use of the requested agent instead of Focalin XR® (dexmethylphenidate extended-release)

Methylphenidate 10, 20, 30, 40, and 60 mg extended-release capsules (Ritalin LA®)

1. An appropriate diagnosis (i.e., attention deficit hyperactivity disorder or autism spectrum disorder)

AND

2. <u>One</u> of the following:
   a. Clinical rationale for use of the requested agent instead of Concerta® (methylphenidate extended-release)
   b. Clinical rationale for requested formulation over solid oral formulation (e.g., swallowing disorder, dysphagia)

AND

3. Clinical rationale for use of the requested agent instead of Focalin XR® (dexmethylphenidate extended-release)

AND

4. **If the request is for <u>brand</u> Ritalin LA®**: above criteria must be met and medical records documenting an inadequate response or adverse reaction to the AB-rated generic equivalent must be provided

Methylphenidate extended release capsules (Metadate CD®)

1. An appropriate diagnosis (i.e., attention deficit hyperactivity disorder or autism spectrum disorder)

AND

2. One of the following:
   a. Clinical rationale for use of the requested agent instead of Concerta® (methylphenidate extended-release)
   b. Clinical rationale for requested formulation over solid oral formulation (e.g., swallowing disorder, dysphagia)

AND

3. Clinical rationale for the use of the requested agent instead of Focalin XR® (dexmethylphenidate extended-release)

AND

4. **If the request is for brand Metadate CD®:** above criteria must be met and medical records documenting an inadequate response or adverse reaction to the AB-rated generic equivalent must be provided

Methylphenidate extended-release 72 mg tablet

1. An appropriate diagnosis (i.e., attention deficit hyperactivity disorder or autism spectrum disorder)

AND

2. Clinical rationale for use of methylphenidate ER 72 mg tablet instead of two Concerta 36 mg tablets

AND

3. Clinical rationale for use of methylphenidate ER 72 mg tablet instead of Focalin XR

Upon renewal for all authorized CNS stimulant medications:

1. Documentation from the prescriber that the Member had a positive response to therapy.

LIMITATIONS

1. Approval duration will be limited to 1 year.
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 unless otherwise stated in the above criteria.
4. Requests for ADHD CNS stimulant medications in which the Pediatric Behavioral Health Medication Initiative (PBHMI) polypharmacy limits are exceeded will also be reviewed against the PBHMI polypharmacy criteria.
5. 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

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14. QuilliChew ER (methylphenidate) [prescribing information]. Monmouth Junction, NJ. NextWave Pharmaceuticas, Inc.: August 2018.
15. Mydayis (amphetamine) [prescribing information]. Lexington, MA. Shire; June 2017.
16. Adzenys XR-ODT (amphetamine) [prescribing information]. Neos Therapeutics. Grand Prairie, TX; December 2017.
17. Adzenys ER (amphetamine) oral suspension [prescribing information]. Neos Therapeutics. Grand Prairie, TX; September 2017.
18. Aptensio XR (methylphenidate) [prescribing information]. Rhodes Pharmaceuticals. Coventry, RI. January 2017.
19. Evekeo ODT (amphetamine sulfate orally disintegrating tablet) [prescribing information]. Arbor Pharmaceuticals, LLC: Atlanta, GA; January 2019.
20. Journay PM (methyphenidate extended-release) [prescribing information]. Ironshore Pharmaceuticals: Cherry Hill, NJ; April 2019.
21. Adhansia XR (methylphenidate extended-release) [prescribing information]. Purdue Pharmaceuticals; Wilson, NC; July 2019.

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, Adding Tufts Health RITogether to the template
10. December 12, 2017: Noted that brand Adderall XR, Concerta, and Focalin XR are preferred over their interchangeable generics. Removed criteria for dexmethylphenidate extended release 25 mg and 35 mg as well as Vyvanse from the Medical Necessity Guideline. Removed from limitations section and the criteria for members 25 years of age and older that Vyvanse will only be approved for ADHD and binge-eating disorder.
11. February 16, 2018: Effective 3/1/18: Added criteria for all strengths of Mydayis, Adzenys XR-ODT, Quillichew ER, Cotempla XR-ODT, Aptensio XR, generic Ritailn LA, and generic Metadate CD to the Medical Necessity Guideline. Added quantity limits for Mydayis, Adzenys XR-ODT, Aptensio XR, and Cotempla XR-ODT. Updated the existing approval criteria for Dyanavel XR, Quillivant XR, Ritalin La 10 mg and 60 mg, and Daytrana. Added criteria for brand specific requests for Metadate CD and Ritalin LA. Removed the stipulation from the age specific criteria for members 25 years of age and older for Daytrana that Daytrana will only be approved for the treatment of ADHD.

Changed the length of the approval criteria to 1 year. Updated the renewal criteria to require that new medication-specific criteria be met at the time of re-authorization. Also updated the renewal criteria to require the member have a positive response to therapy.

12. September 18, 2018: Updated quantity limit for Metadate ER.
13. December 11, 2018: Administrative updates made to template. Added criteria and quantity limit for Adzenys ER oral suspension to Medical Necessity Guideline. Removed specified strengths for brand Ritalin LA.
14. January 8, 2019: Effective 2/1/19, added criteria and quantity limit for methylphenidate ER 72 mg tablets to the Medical Necessity Guideline.
15. December 12, 2019: Effective 1/1/2020, added criteria for Evekeo ODT to the Medical Necessity Guideline.
16. January 14, 2020: Added Jornay PM and Adhansia XR to the Medical Necessity Guideline. Added to the limitations section that requests for members who exceed the PBHMI polypharmacy limits will be reviewed against the PBHMI polypharmacy criteria.
17. July 14, 2020: Administrative update, added language concerning samples to the limitations section of the MNG. Updated reauthorization criteria to remove approval scenarios prior to March 1, 2018.

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.