

## Pharmacy Medical Necessity Guidelines: Attention Deficit Hyperactivity Disorder Medications

Effective: August 11, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit		Department to Review	
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans</li> <li>• CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)</li> <li><input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans</li> <li><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan</li> </ul>		<p><b>Fax Numbers:</b></p> <p>RXUM: 617.673.0988 MM: 888.415.9055 PRECERT: 617.972.9409</p>	

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

### OVERVIEW

The following central nervous system (CNS) stimulant medications are indicated for the treatment of attention deficit hyperactivity disorder (ADHD):

- Adderall
- Adderall XR
- Adzenys XR-ODT
- Concerta
- Daytrana
- Dexedrine spansule
- Dyanavel XR
- Focalin XR
- Metadate CD
- Methylin
- Procentra
- Quillivant XR
- Ritalin
- Ritalin LA and Ritalin SR
- Zenzedi

### Vyvanse®

Vyvanse is indicated for the treatment of ADHD and for moderate to severe binge eating disorder in adults.

### COVERAGE GUIDELINES

**Note:** Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
<b>Step-1</b>		
dexmethylphenidate HCl	Covered for Members under the age of 25 years  Prior Authorization required for members 25 years of age and older.	
dexmethylphenidate XR		
dextroamphetamine/amphetamine		
dextroamphetamine/amphetamine XR		
dextroamphetamine sulfate		
dextroamphetamine sulfate XR		
dextroamphetamine sulfate solution		
Metadate ER 20 mg		
methamphetamine HCl		
methylphenidate		
methylphenidate chewable tablets		
methylphenidate ER 20 mg (generic Ritalin SR)		
methylphenidate ext-rel (generic Metadate CD)		
methylphenidate ext-rel (generic Ritalin LA)		
methylphenidate SR (generic Concerta)		
Methylphenidate oral solution		
<b>Step-2</b>		
Daytrana	Requires prior use of a drug on Step-1 or Step-2  Requires prior use of a drug on Step-1 or Step-2  Not Covered	
Dyanavel XR		
Quillivant XR		
Vyvanse		
Procentra		
Adderall		
Adderall XR		
Concerta		
Focalin XR		
Metadate CD		
Methylin Oral Solution		
Ritalin		
Ritalin LA		
Ritalin SR		

**Automated Step Therapy Coverage Criteria**

The following stepped approach applies to coverage of the Step-2 medications by the plan:

**Step 1:** Medications on Step-1 are covered without prior authorization for Members under the age of 25 years

**Step 2:** The plan may cover medications on Step-2 for Members under the age of 25 years if the following criteria are met:

- The Member has had a trial of one (1) Step-1 or Step-2 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan.

**Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale**

The following stepped approach applies to ADHD medications covered by the plan:

**Step 2:** The plan may cover Step-2 medications for Members under the age of 25 years if the following criteria are met:

1. The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples.

**Note:** The plan may cover medications on Step-2 if a Member has received one of the non-covered medications, listed below under the limitations section, as evidenced by physician documented use, excluding the use of samples.

**Coverage criteria for Members 25 years and older**

In addition to the stepped approach that applies to ADHD medications, the plan may cover ADHD medications for Members 25 years and older if the following criteria are met:

1. Documented diagnosis of one of the following:
  - Narcolepsy
  - ADHD before the age of 12 years
  - Depressive condition in which the stimulant will be used as an augmenting agent with concomitant antidepressant medication(s)
  - Traumatic brain injury

**OR**
2. Documentation by the provider there was evidence of signs or symptoms of ADHD before the age of 18 years

**OR**

3. The Member has documented excessive daytime 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 (lisdexamphetamine)**

Vyvanse (lisdexamphetamine) may be covered for Binge Eating Disorder (B.E.D.) if **ALL** of the following criteria are met and a PA request to Tufts Health Plan using the Universal Pharmacy Medical Review Request Form is submitted:

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

**AND**

2. The Member is at least 18 years of age

**Note: The provider attests that the information provided, for any request above, is accurate and true, and that documentation supporting this information is available for review if requested by the plan.**

**LIMITATIONS**

- Medications on Step-2 are not covered unless the above step therapy criteria are met.
- Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.
- The plan does not cover the following medications on all Commercial formularies: Adhansia, Adzenys XR-ODT, Aptensio XR, Cotelpla, Desoxyn, Dexedrine spansule, Evekeo, Focalin, Jornay PM, Mydayis, Quillichew ER, or Zenedi. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.

- The plan does not cover the following medications, in addition to those noted in limitation #3, on the small group and individual formularies or the Tufts Health Direct formulary: Adderall, Adderall XR, Concerta, Focalin XR, Metadate CD, Methylin Oral Solution, Ritalin, Ritalin LA, Ritalin SR and Procentra.
- The following quantity limitations apply to the listed long-acting ADHD medications

<b>Drug/Formulation*</b>	<b>Dosage (mg)</b>	<b>Quantity Limit Per 30 days supply</b>
Adderall XR (amphetamine-dextroamphetamine) capsules	5, 10, 15	30
Adderall XR (amphetamine-dextroamphetamine) capsules	20, 25, 30	60
Concerta (methylphenidate ER) tablets	18, 27, 54	30
Concerta (methylphenidate ER) tablet	36	60
Daytrana (methylphenidate) patches	10 mg/9hrs, 15mg/9hrs, 20mg/9hrs, 30mg/9hrs	30
Desoxyn (methamphetamine) tablet	5	150
Dexedrine (dextroamphetamine CR) capsule	5	30
Dexedrine (dextroamphetamine CR) capsule	10	150
Dexedrine (dextroamphetamine CR) capsule	15	120
Dyanavel XR (amphetamine) suspension	2.5mg/ml	240 mL
Focalin XR (dexmethylphenidate) capsules	5, 10, 15 ,20, 25, 30, 35, 40	30
Metadate (methylphenidate) capsules and ER tablets	10, 20, 30, 40, 50, 60	30
Methylphenidate ER capsules	10, 20, 30,40, 50, 60	30
Methylphenidate ER tablets	10, 72	30
Quillivant XR (methylphenidate) suspension	25mg/5mL	360ml
Ritalin LA (methylphenidate ER 24 hr) capsules	10,20,40,60	30
Ritalin LA (methylphenidate ER 24 hr) capsule	30	60
Vyvanse (lisdexamfetamine) capsules and chewable tablets	10, 20, 30, 40, 50, 60, 70	30

\* Quantity limitations apply to both generic and brand forms of all the listed drugs

#### **CODES**

None

#### **REFERENCES**

1. Adderall XR (mixed salts of a single-entity amphetamine product) [package insert]. Wayne, PA: Shire US Inc.; November 2018.
2. Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets) [prescribing information]. Grand Prairie, TX: Neos Therapeutics, LP.; December 2017.
3. Aptensio XR (methylphenidate ext-rel) [package insert]. Coventry, RI: Rhodes Pharmaceutical L.P.; April 2015.
4. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 5th edition. Arlington, VA., American Psychiatric Association, 2013.
5. Cantwell DP. Attention deficit disorder: A review of the past 10 years. J Am Acad Child Adolesc Psychiatry. 1996;35:978-87.
6. Concerta (methylphenidate ER) [package insert]. Titusville, NJ, Janssen Pharmaceuticals, Inc.; February 2019.
7. Daytrana (methylphenidate) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; November 2018.
8. Dyanavel XR (amphetamine) [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; February 2019.
9. 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.
10. Focalin XR (dexmethylphenidate) [prescribing information]. East Hanover, NJ.: Novartis. January 2019.

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. Metadate CD (methylphenidate) [package insert]. Smyrna, GA: UCB, Inc.; October 2018.
13. 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
14. Procentra (dextroamphetamine sulfate) [package insert]. Newport, KY: Independence Pharmaceuticals, LLC; February 2017.
15. Quillivant XR (methylphenidate oral solution ext-rel). New York, NY: NextWave Pharmaceuticals Inc.; October 2017.
16. Ritalin (methylphenidate) and Ritalin-SR (methylphenidate sustained release) [package insert] East Hanover, NJ: Novartis; March 2019.
17. Ritalin LA (methylphenidate) [prescribing information] East Hanover, NJ: Novartis; January 2019.
18. Quillichew ER (methylphenidate) [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc; March 2018.
19. 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):1033-44Vyvanse (lisdexamphetamine) [package insert]. Wayne, PA: Shire US, Inc.; January 2015.
20. 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.
21. Vyvanse (lisdexamphetamine) [prescribing information]. Wayne, PA: Shire US, Inc.; January 2018.
22. Zenzedi (dextroamphetamine sulfate) [package insert]. Atlanta, GA: Arbor Pharmaceuticals LLC; December 2018.

#### **APPROVAL HISTORY**

April 11, 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2006: Changed topic from "Focalin™ XR (dexmethylphenidate extended-release) Capsules" to "Medications for the Treatment of ADHD". Added "or Daytrana (methylphenidate transdermal patch)" to clinical coverage criteria. Added "Methylphenidate ER" to formulary agents under coverage criteria
2. July 10, 2007: No changes
3. July 8, 2008: Added Vyvanse (lisdexamfetamine dimesylate) to pharmacy medical necessity guidelines. Added automated step therapy coverage guidelines for the Tufts Health Plan Commercial and Generic Focused Formulary. Added limitation that medications on Step-2 are not covered unless the above step therapy criteria are met.
4. September 9, 2008: Updated step therapy criteria for coverage of a Step-2 medication from a 30-day trial of two (2) Step-1 ADHD medications OR one (1) Step-1 and one (1) Step-2 ADHD medication OR two (2) Step-2 ADHD medications to a 30-day trial of two (2) Step-1 ADHD medications OR a previous paid claim of a Step-2 ADHD medication. Added Liquadd™ (dextroamphetamine oral solution) to Step-2 of the pharmacy medical necessity guidelines.
5. July 14, 2009: Added dextroamphetamine/amphetamine SR to list of Step-1 drugs. Moved Adderall XR to non-covered status for the Generic Focused Formulary (GFF)
6. September 8, 2009: Added Procentra (dextroamphetamine oral solution) to Step-2 of the pharmacy medical necessity guidelines
7. November 10, 2009: Removed Liquadd (dextroamphetamine oral solution) from guidelines, drug has been discontinued. Effective 1/1/2010, for Tufts Health Plan Medicare Preferred formularies, moved ADHD drugs from prior authorization to automated step therapy prior authorization.
8. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
9. July 13, 2010: Added methamphetamine HCl to Step-1 drugs
10. September 14, 2010: Added Concerta, Metadate CD, and Ritalin LA to Step-2. Moved Adderall XR, Adderall, Desoxyn, Dexedrine Spansules, Focalin, Metadate ER, Ritalin and Ritalin SR to not covered (Step-3) and added criteria for coverage. Changed Step-2 criteria to requiring a 30-day trial of one (1) Step-1 medication. Added "or Step-3" as a prerequisite for step-2 drugs.

11. January 11, 2011: Removed Dexedrine Spansules and Metadate ER 10 mg from Step Therapy criteria as they have been discontinued by the manufacturer.
12. May 10, 2011: Added methylphenidate SR (generic Concerta) to Step-2 of the Medical Necessity Guidelines.
13. July 12, 2011: Removed the Not Covered (Step 3) criteria. Added Adderall XR to Step-2 of the Medical Necessity Guideline due to the unavailability of the generic.
14. September 9, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
15. September 13, 2011: Moved methylphenidate SR (generic Concerta) to Step 1 of the Medical Necessity Guidelines.
16. November 15, 2011: Added Adderall to Step-1 of the medical necessity guidelines as the generic is unavailable.
17. January 10, 2012: Added methylphenidate ext-rel (generic Ritalin LA) to Step-1 of the medical necessity guidelines. Added Ritalin back on Step-2 of the Medical Necessity guidelines due to shortage of generic.
18. May 8, 2012: Added Ritalin SR back to Step-2 of the Medical Necessity guidelines and moved Ritalin LA to not covered status for GFF due to generic launch.
19. June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
20. November 6, 2012: Removed Methylin ER, product has been discontinued. Added generic methylphenidate ext-rel (Metadate CD) to Step-1 of the Medical Necessity Guidelines and moved Metadate CD to not covered status for GFF. Added use of samples or vouchers/coupons for brand name medications limitation. Added Ritalin LA 10mg to Step-2 of Medical Necessity Guidelines for the GFF. Moved Adderall, Adderall XR, Concerta, Ritalin, Ritalin LA 20mg, 30mg, 40mg and Ritalin SR to not covered status for the GFF. Moved Adderall to Step-2 of Medical Necessity Guidelines.
21. February 12, 2013: Added Methylin Oral Solution to Step-2 of the Medical Necessity Guidelines for Comm MA/RI, not covered for Generic Focused Formulary. Added Quillivant XR to Step-2 of the Medical Necessity Guidelines for Comm MA/RI and the Generic Focused Formulary.
22. October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
23. January 14, 2014: Added dexmethylphenidate ext-rel 15 mg and 30 mg and dextroamphetamine sulfate solution to Step 1. Moved Focalin XR and Procentra to Not covered for the GFF.
24. April 1, 2014: Removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI Formulary.
25. July 8, 2014: Added the note Tufts Health Plan may cover medications on Step-2 if a member has received one of the following noncovered medications within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan or by physician documented use for those not meeting the automated step therapy: Desoxyn, Focalin, or Zenedi.
26. March 10, 2015: Added Evekeo to the list of Non-covered drugs. Also, added criteria for Vyvanse for Binge Eating disorder.
27. July 14, 2015: For effective date October 1, 2015: Updated step therapy to note that the step therapy applies to members under the age of 25 years. Added criteria for members 25 years and older.
28. September 16, 2015: Effective 10/1/15: Added Aptensio XR to the list of non-covered drugs. Also, clarified the criteria for 25 and older requests require documentation of diagnosis.
29. November 10, 2015: Added the following note: ***The provider attests that the information provided, for any request above, is accurate and true, and that documentation supporting this information is available for review if requested by the health plan.***
30. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
31. March 8, 2016: Effective March 14, 2016 – added the following criteria for members 25 and older: Documentation by the provider there was evidence of signs or symptoms of ADHD before the age of 18 years **OR** The member has documented excessive daytime 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.
32. June 14, 2016: Added Dyanavel XR to the Step Therapy program. Added Adzenys XR-ODT to the list of non-covered drugs.
33. July 12, 2016: Added Quillichew ER to the list of non-covered drugs.

34. September 13, 2016: Removed the following language from "and bipolar disease, thyroid disease, cardiovascular conditions have been ruled out" from criterion #1 under Coverage Criteria for Members 25 Years of Age or Older for a documented diagnosis of a depressive condition in which the stimulant will be used as an augmenting agent with concomitant antidepressant medications.
35. November 15, 2016: Moved brand Methylin chewable tablets to Non-covered for Small Group and Individual formularies.
36. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template. Effective August 1, 2017: Move Adderall, Adderall XR, Concerta, Focalin XR, Metadate CD, Methylin Oral Solution, Ritalin, Ritalin LA, and Ritalin SR to not covered.
37. September 12, 2017: added dextroamphetamine ER to the list of step-1 medications. Added Cotelpla and Mydayis to the list of non-covered drugs.
38. April 10, 2018: Added quantity limitation to all long acting stimulant ADHD medications.
39. May 7, 2019: Administrative update: added Dexedrine capsules to the list of NC drugs. Administrative update to the template, overview section, and step therapy table.
40. August 11, 2020: Added Adhansia and Jornay PM to the list of non-covered drugs.

### **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](#)