Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Medications

Dexmethylphenidate extended-release (Focalin XR), Lisdexamfetamine (Vyvanse), Methylphenidate chewable (Methylin), Methylphenidate extended-release 10 mg (Ritalin LA 10 mg), Methylphenidate suspension (Quillivant XR), Methylphenidate transdermal (Daytrana)

Effective: 7/15/15

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<th>Clinical documentation and prior authorization required</th>
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<th>Type of review – case management</th>
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<td>Not covered</td>
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<td>Type of review – clinical review Fax: 617-673-0988</td>
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<td>Pharmacy (RX) or medical (MED) benefit</td>
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OVERVIEW

FDA-APPROVED INDICATIONS

The following non-preferred stimulant medications are indicated for the treatment of attention deficit hyperactivity disorder (ADHD): dexmethylphenidate extended-release 25 g 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.

In addition to the medication-specific criteria below which require prior authorization, all CNS stimulant medications indicated for ADHD require prior authorization for members less than 3 years of age and for member 25 years of age and older.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of a stimulant ADHD medication for members when all of the following criteria are met and limitations do not apply:

- Diagnosis of one of the following:
  - ADHD
  - Narcolepsy
  - 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
  - Traumatic Brain Injury

- For members 25 years of age and older,
  - Provider attestation that they have reviewed member-specific medication usage through state Online Prescription Monitoring Program(s) within the past year
  - If the request is for an immediate-release (IR) formulation,
    - The provider indicates there is no concern with active substance abuse or diversion, and
    - The provider indicates clinical rationale of therapy with an IR formulation instead of long-acting/extended-release formulations

- For members less than 3 years of age,
  - The member has been evaluated by a specialist and
  - One of the following:
    - The member was recently hospitalized for a behavioral health condition
    - The member has a history of severe risk for harm to oneself or others

- For requests for a non-preferred stimulant ADHD medication,
  - If the request is for dexamethylphenidate 25 mg, 35 mg extended-release (Focalin XR 25 mg, 35 mg),
• 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

  o If the request is for lisdexamfetamine (Vyvanse), the member meets criteria for one of the following diagnoses:
    • ADHD diagnosis and
      • The member tried and failed therapy with at least two stimulant medications with different active ingredients, i.e.,
        ▪ Methylphenidate product
        ▪ Amphetamine product
    • Binge-eating disorder and
      • The member tried and failed at least two alternative non-stimulants therapies, such as cognitive behavioral therapy, antidepressant therapy, mood stabilizers, etc.

  o If the request is for methylphenidate suspension (Quillivant XR),
    • The member failed a course of therapy with generic methylphenidate oral solution

  o If the request is for methylphenidate 10 mg extended-release capsules (Ritalin LA 10 mg),
    • The member failed a course of therapy with an alternative generic methylphenidate 10 mg extended-release methylphenidate medication (e.g., Metadate CD 10 mg or methylphenidate ER 10 mg tablets)

  o If the request is for methylphenidate transdermal (Daytrana),
    • The member is diagnosed with ADHD and
    • One of the following:
      • The member has been stable on the medication for at least 3 months
      • The provider indicates clinical inappropriateness of therapy with oral methylphenidate medications

Upon renewal,
  • 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
• The length of approval will be limited to 2 years.
• Quantity limits apply as follows:
  o Dexmethylphenidate XR (Focalin XR): one tablet per day
  o Lisdexamfetamine (Vyvanse): one capsule per day
  o Methylphenidate chewable tablet (Methylin 2.5, 5mg): three tablets per day
  o Methylphenidate chewable tablet (Methylin 10mg): six tablets per day
  o Methylphenidate ER (Ritalin LA 10 mg, 20 mg): one capsule per day
  o Methylphenidate suspension (Quillivant XR): 15 ml per day
  o Methylphenidate transdermal (Daytrana): one patch per day

• Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria.
• Requests for brand-name products, with AB-rated generics, will be reviewed according to Brand Name criteria.

CODES
None

REFERENCES
4. Daytrana @ http://online.factsandcomparisons.com/, accessed March 2015.
6. Daytrana [methylphenidate transdermal] [prescribing information]. Miami, FL: Noven: October 2013
8. Transdermal Methylphenidate (Daytrana) for ADHD. The Medical Letter June 2006; Vol 48: 1237.

**APPROVAL HISTORY**

- 4/14/15: Reviewed by the Pharmacy and 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.

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to fully insured Tufts Health Together offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Direct (individual and small-group plan), please refer to the Tufts Health Direct Pharmacy Medical Necessity Guidelines.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.