MEDICAL MUTUAL®

Drug Policy

Policy:	Attention-Deficit Hyperactivity Disorder (ADHD) Stimulant Step Therapy Policy	Annual Review Date: 12/19/2024 Last Revised Date: 12/19/2024

OVERVIEW

All of the long-acting stimulants are indicated for the treatment of attention-deficit hyperactivity disorder (ADHD). Some products are also indicated for the treatment of narcolepsy. Vyvanse is the only stimulant medication indicated for the treatment of binge eating disorder (BED). Approval for this indication was based on two 12-week randomized, double-blind, multi-center, parallel-group, placebo-controlled, dose-optimization studies in adults aged 18 to 55 years (n = 374 and n = 350) with moderate to severe BED. Patients from both studies on Vyvanse had a statistically significantly greater reduction from baseline in mean number of binge days/week at Week 12. All of these products have abuse potential and are Schedule II controlled substances.

Table 1. FDA-Approved Indications for Long-Acting Stimulants.[1-24]

Product	*FDA-Approved Indication(s)*
Adderall XR® (generic)	• ADHD in children 6 to 12 years of age, adolescents 13 to 17 years of age, and adults
Adhansia XR®	• ADHD in patients ≥ 6 years of age
Adzenys ER™	• ADHD in patients ≥ 6 years of age
Adzenys XR-ODT™	• ADHD in patients ≥ 6 years of age
Aptensio XR® (generic)	• ADHD in patients ≥ 6 years of age
Azstarys™	• ADHD in patients ≥ 6 years of age
Concerta® (generic)	• ADHD in children ≥ 6 years of age, adolescents 13 to 17 years of age, and adults ≤ 65 years of age
Cotempla XR-ODT™	• ADHD in patients 6 to 17 years of age
Daytrana®	• ADHD in children 6 to 12 years of age, and adolescents 13 to 17 years of age
Dexedrine® Spansule® (generic)	• ADHD in children ≥ 6 years of age and adolescents up to 16 years of age • Narcolepsy
Dyanavel® XR	• ADHD in children ≥ 6 years of age and adults
Focalin® XR (generic)	• ADHD in patients ≥ 6 years of age
Jornay PM®	• ADHD in patients ≥ 6 years of age
Metadate® CD (generic)	• ADHD in children 6 to 15 years of age
Metadate® ER (generic, brand product considered generic per FDB)	• ADHD in children ≥ 6 years of age and adults • Narcolepsy
Methylin™ ER (generic only, brand discontinued)	• ADHD in children ≥ 6 years of age and adults • Narcolepsy

Mydayis® (generic)	• ADHD in patients ≥ 13 years of age and adults
QuilliChew E®	• ADHD in children ≥ 6 years of age and adults
Quillivant® XR	• ADHD in patients ≥ 6 years of age
Relexxii®	• ADHD in children and adolescents ≥ 6 years of age and adults up to 65 years of age
Ritalin® LA (generic)	• ADHD in children 6 to 12 years of age
Ritalin-SR® (generic only, brand discontinued)	• ADHD in children ≥ 6 years of age and adults • Narcolepsy
Vyvanse® (generic)	• ADHD in children 6 to 12 years of age, adolescents 13 to 17 years of age, and adults • Binge eating disorder in adults
Xelstrym®	• ADHD in children ≥ 6 years of age and adults

ADHD – Attention-deficit hyperactivity disorder.

POLICY STATEMENT

A step therapy program has been developed to encourage use of one Preferred product prior to the use of a Non-Preferred product. If the step therapy rule is not met for a Non-Preferred agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Preferred drug within the 130-day look-back period are excluded from step therapy.

Preferred Medications:

- Generic amphetamine/dextroamphetamine extended-release capsules (generics to Adderall XR)
- Generic dexmethylphenidate extended-release capsules (generics to Focalin XR)
- Generic dextroamphetamine extended-release capsules (generics to Dexedrine Spansules)
- Generic lisdexamfetamine capsules
- Generic methylphenidate extended-release capsules (generics to Metadate CD and Ritalin LA)
- Metadate ER (generic according to FDB)
- Generic methylphenidate sustained-release tablets (generics to Ritalin SR)
- Generic methylphenidate extended-release tablets (generics to Concerta)
- Generic mixed salts of a single-entity amphetamine product extended-release capsules (generic to Mydayis)

Non-Preferred Medications:

- Adderall XR
- Adhansia XR
- Adzenys XR-ODT
- Adzenys ER suspension
- Aptensio XR (brand and generics)
- Azstarys
- Concerta

- Cotempla XR-ODT
- Daytrana (brand and generic methylphenidate transdermal system)
- Dexedrine Spansules
- Dyanavel XR (tablets and oral solution)
- Focalin XR
- Jornay PM
- Metadate CD
- Mydayis
- QuilliChew ER
- Quillivant XR
- Relexxii (brand and authorized generic)
- Ritalin LA
- Vyvanse capsules
- Vyvanse chewable tablets (brand and generic)
- Xelstrym

PREFERRED STEP THERAPY CRITERIA
Exceptions for a Non-Preferred agent can be made for patients with one of the following conditions/situations:

1. If the patient has tried one Preferred agent, then authorization for a Non-Preferred agent may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 2 years

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR

2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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