Pharmacy Management Drug Policy

SUBJECT: Attention Deficit Hyperactivity Disorder (ADHD) Policy
POLICY NUMBER: PHARMACY-83
EFFECTIVE DATE: 08/2019
LAST REVIEW DATE: 07/13/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

All FDA approved short, and long-acting central nervous system stimulants are indicated for the diagnosis of attention deficit hyperactivity disorder (ADHD). Stimulant therapy has been shown to be useful in children with ADHD along with parent and/or teacher-administered behavioral therapy.

The available stimulants are compounds of either amphetamine or methylphenidate and since individual patients respond differently to each compound, it cannot be determined beforehand which category will be more effective for a patient. Thus, when one treatment fails, a drug from the other category should be attempted. ADHD can continue into adulthood for at least 30 percent of patients diagnosed as a child and stimulant therapy is the mainstay of therapy in this population. With the exception of dextroamphetamine (only indicated for children ages 3-16) and Evekeo/Evekeo ODT/Dyanavel XR (only indicated for adolescents and children ages 6-17), all FDA approved stimulants are approved for ADHD in adults.

Stimulant medications have cardiovascular warnings from the FDA with sudden death, stroke, and myocardial infarction having been reported in adults. The benefits of treatment must also be weighed against growth suppression in children, psychotic or manic symptoms, neurological side effects, and potential risks for dependence and diversion.

Other FDA approved indications for stimulants include binge-eating disorder (lisdexamfetamine) and narcolepsy (dextroamphetamine and immediate release amphetamine-dextroamphetamine tablets).

The Pharmacy Management clinical team reviews the following drugs found in this policy. A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

DRUG SPECIFIC POLICIES/CRITERIA:

Azstarys, dextroamphetamine/amphetamine ER capsule (generic Mydayis), Dyanavel XR, Mydayis and Xelstrym
1. Must have a had serious side effects or drug failure with TWO generic, long-acting stimulants such as amphetamine/dextroamphetamine ER, dexmethylphenidate ER or methylphenidate ER 2. This criterion applies to open commercial line of business only and is a step therapy requirement.
Adzenys XR ODT, amphetamine ER ODT (generic Adzenys XR ODT), Cotempla XR ODT, methylphenidate ER ODT (generic Cotempla XR ODT), Dyanavel XR (amphetamine ER suspension), Quillichew ER (methylphenidate ER chewable tablets), Quillivant (methylphenidate ER suspension)
1. Must have a diagnosis of attention deficit hyperactivity disorder (ADHD) 2. Must have had serious side effects or drug failure with TWO of the following long-acting stimulants which can be opened and sprinkled on food or are available as chewable tablets: dextroamphetamine/amphetamine ER, dexmethylphenidate ER, a methylphenidate ER product (such as generic for Concerta, Ritalin LA, or Metadate CD), and lisdexamfetamine capsules or chewable tablets 3. Member must have a swallowing disorder (a swallowing evaluation must be submitted to confirm)
Desoxyn and generic methamphetamine (Rx)
1. Methamphetamine is indicated for ADHD in children aged 6 and older. It is also indicated for adults and children over age 12 with obesity. Based on the risk of dependence/abuse potential and the numerous alternatives available for both indications, methamphetamine is considered not medically appropriate for these FDA approved indications. 2. All other off-label uses will also be considered not medically appropriate.
Jornay PM - methylphenidate ER capsules
1. Member must be 6 years of age or older 2. Must have a diagnosis of attention deficit hyperactivity disorder (ADHD) 3. Must have had serious side effects or drug failure with TWO of the following formulary long-acting stimulants: amphetamine/dextroamphetamine ER, dexmethylphenidate ER, methylphenidate ER, lisdexamfetamine 4. Prescriber must submit progress notes to document before-school functional impairment and/or difficulties performing a morning routine
Onyda XR (clonidine ER oral suspension)
1. Must be between the ages of 6 and 17 years of age **AND** 2. Must have a diagnosis of attention deficit hyperactivity disorder (ADHD) **AND** 3. Must meet one of the following (a or b): a. Must have had serious side effects or drug failure of clonidine ER tablets (generic Kapvay) **OR** b. Member must have a swallowing disorder (a swallowing evaluation must be submitted to confirm 4. Onyda XR will not be covered for any off-label indications (e.g., hypertension)
Qelbree – viloxazine ER capsules
1. Must be 6 years of age or older **AND** 2. Must have diagnosis of attention deficit hyperactivity disorder (ADHD) **AND** 3. Must have had serious side effects or drug failure with atomoxetine **AND** one other long-acting FDA-approved medication for ADHD (i.e., dexmethylphenidate ER, amphetamine/dextroamphetamine ER, guanfacine ER) **OR** a. For individuals with difficulty swallowing and an inability to swallow atomoxetine, a swallowing evaluation is required along with a trial of two long-acting FDA-approved agents for ADHD that are amenable to opening/dissolving (i.e., methylphenidate ER capsules, amphetamine/dextroamphetamine ER capsules, lisdexamfetamine capsules or chewable

tablets) **AND**
4. Quantity limit:
   a. 30 capsules/30 days for the 100 mg strength
   b. 60 capsules/30 days for the 150mg and 200 mg strengths
      i. A quantity limit of 90 capsules/30 days for the 200 mg capsule will be granted for patients 18 years of age or older to obtain a 600 mg daily dose
   c. A one-time loading dose of 70 capsules/30 days for the 100 mg strength may be granted to allow for titration.

POLICY GUIDELINES:

1. Unless otherwise stated above within the individual drug criteria, approval time-period will be for 2 years.
2. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
   a. Coverage criteria may be dependent on the contract renewal date.
   b. Coverage of drugs listed in this policy are contract dependent.
   c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
   d. Not all contracts/benefits cover all medical infusible drugs.
4. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
5. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
6. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
7. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
8. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).

9. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
10. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity

UPDATES:

Date	Revision
07/13/2026	Revised
02/12/2026	P&T Committee Review & Approval
01/01/2026	Revised
09/18/2025	Revised
03/06/2025	Revised
03/01/2025	Revised
02/06/2025	P&T Committee Review & Approval
12/13/2024	Revised
09/13/2024	Revised
02/08/2024	Reviewed / P&T Committee Approval
01/24	Revised
12/23	Revised
11/23	Revised
4/23	Revised
2/23	Reviewed / P&T Committee Approval
12/22	Revised
9/22	Revised
8/22	Revised
5/22	Revised
3/22	Revised
2/22	P&T Committee Approval / Reviewed
12/21	Revised
9/21	Revised
7/21	Revised
5/21	Revised
2/21	P&T Committee Approval
10/20	Revised
2/20	P&T Committee Approval
1/20	Revised
8/19	Created

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