Pharmacy Management Drug Policy

SUBJECT: Attention Deficit Hyperactivity Disorder (ADHD) Policy
POLICY NUMBER: PHARMACY-83
EFFECTIVE DATE: 08/2019
LAST REVIEW DATE: 02/08/2024

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, which is only indicated for use in children ages 3-16, 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), Adzenys ER (and generic amphetamine ER suspension), Cotempla XR ODT (methylphenidate ER 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 ALL the following long-acting stimulants: 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
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.
   - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
2. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and the requesting prescriber provides rationale and documentation for one of the following circumstances, then trial of the preferred drug(s) will not be required.
   - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
   - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   - The required prescription drug(s) is (are) not in the patient’s best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
   - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. 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.
5. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to criteria being added to the policy.
6. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.

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
02/08/2024	Reviewed / P&T Committee Approval
01/24	Revised
12/23	Revised
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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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