

Clinical Policy: Attention Deficit Hyperactivity Disorder Agents

Reference Number:OH.PHAR.PPA.38

Effective Date: 01.01.2020 Last Review Date: 11.2021 Line of Business: Medicaid

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents

NO PA REQUIRED "PREFERRED"	STEP THERAPY "PREFERRED"	PA REQUIRED "NON- PREFERRED"
Amphetamine/Dextroamphetamine ER	Qelbree	Adhansia XR
Amphetamine/Dextroamphetamine IR		Adzenys ER
Atomoxetine Cap		Adzenys XR ODT
Clonidine ER		Amphetamine Tab
Concerta		Cotempla XR ODT
Dexmethylphenidate Tab		Daytrana
Dexmethylphenidate ER		Dyanavel XR
(generic of Focalin XR)		Evekeo ODT
Dextroamphetamine ER Cap		Jornay PM
Dextroamphetamine Solution \leq 12 years of age		Methamphetamine
Dextroamphetamine Tab		Methylphenidate Chewable Tab
Focalin XR		Methylphenidate ER
Guanfacine ER		(generic of Aptensio XR, Relexxii)
Methylphenidate ER Cap		Mydayis
(generic of Metadate CD, Ritalin LA)		Vyvanse Chewable Tab
Methylphenidate ER Tab		Zenzedi
(generic of Concerta, Methylin ER, Ritalin SR)		
Methylphenidate Solution (≤ 12 years of age)		Methylphenidate solution
Methylphenidate Tab		(PA required > 12 years of age)
Quillichew ER		Dextroamphetamine solution
Quillivant XR		(PA required > 12 years of age)
Ritalin LA		
Vyvanse Cap		



FDA Approved Indication(s)

- Extended release and immediate release methylphenidate and amphetamine products are indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD).
- Atomoxetine, guanfacine, clonidine and Vyvanse are indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD).
- Vyvanse is also indicated for the treatment of binge eating disorder (BED)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that the non-preferred medications listed in the above table are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- A. ADHD (must meet all):
 - 1. Diagnosis of ADHD;
 - 2. Member must meet labeled age requirements for requested medication;
 - 3. For a medication requiring prior authorization there must have been a failed therapeutic trial of at least 14 days with at least two medications not requiring prior approval unless any of the following:
 - a. Allergy to at least two medications not requiring prior approval
 - b. Contraindication to all medications not requiring prior approval
 - c. History of unacceptable/toxic side effects to at least two medications not requiring prior approval
 - d. Preferred long-acting non-solid dosage forms may be approved for a patient over age 12 if the patient is unable to swallow pills
 - 4. For a medication requiring step therapy there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least two preferred products unless any of the following:
 - a. Allergy to at least two medications not requiring prior approval
 - b. Contraindication to all medications not requiring prior approval
 - c. History of unacceptable/toxic side effects to at least two medications not requiring prior approval
 - d. Preferred long-acting non-solid dosage forms may be approved for a patient over age 12 if the patient is unable to swallow pills



Approval duration: 12 months

B. Binge eating disorder (must meet all):

- 1. Medication is Vyvanse
- 2. Diagnosis of binge eating disorder
- 3. Age \geq 18 years;
- 4. Prescribed by or in consultation with a psychiatrist;
- 5. Failure of \geq 3 month trial of cognitive behavioral therapy (CBT) with supporting documentation;
- 6. Failure of \geq 3 month trial of topiramate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
- 7. Failure of \geq 6 week trial of one of the following: citalopram, sertraline, or escitalopram, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
- 8. Dose does not exceed 70 mg per day

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage Documents

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADHD: Attention Deficit Hyperactivity Disorder

BED: Binge eating disorder

Appendix B: Therapeutic Alternatives

• Dosing varies by drug product. See FDA approved dosing and administration.

Appendix C: Contraindications/Boxed Warnings

• Refer to clinical pharmacology or other appropriate clinical resource

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate



clinical resource for product availability

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	
Updated preferred/non-preferred drug table. Added step therapy criteria	11.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible



for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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