

**Clinical Policy: CNS Stimulants**

Reference Number: CP.PMN.92

Effective Date: 03.01.18

Last Review Date: 02.21

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

The following are central nervous system (CNS) stimulants requiring prior authorization: methylphenidate extended-release (Adhansia XR™, Aptensio XR™, Jornay PM™), methylphenidate transdermal system (Daytrana®), methylphenidate extended-release chewable tablets (Quillichew ER®), methylphenidate extended-release oral suspension (Quillivant XR®), methylphenidate extended-release orally disintegrating tablets (Cotempla XR-ODT®), amphetamine orally disintegrating tablets (Evekeo ODT™), amphetamine extended-release orally disintegrating tablets (Adzenys XR-ODT™), amphetamine extended-release oral suspension (Adzenys ER™, Dyanavel XR®), amphetamine-dextroamphetamine extended-release (Mydayis®), dexamethylphenidate hydrochloride (Focalin XR®), and serdexmethylphenidate – dexamethylphenidate capsules (Azstarys™).

**FDA Approved Indication(s)**

Extended release methylphenidate and amphetamine products are indicated for attention-deficit/hyperactivity disorder (ADHD).

**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 Adhansia XR, Adzenys ER, Adzenys XR-ODT, Aptensio XR, Azstarys, Cotempla XR-ODT, Daytrana, Dyanavel XR, Evekeo ODT, Focalin XR, Jornay PM, Mydayis, Quillichew ER, and Quillivant XR are medically **necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Attention Deficit Hyperactivity Disorder (must meet all):**

1. Diagnosis of ADHD;
2. Age ≥ 6 years;
3. Member meets one of the following (a or b):
  - a. Failure of one formulary extended release amphetamine and one formulary extended release methylphenidate at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced to all relevant formulary extended release amphetamine and methylphenidate products;
  - b. Request is for Adzenys ER, Adzenys XR-ODT, Cotempla XR-ODT, Daytrana, Dyanavel XR, Evekeo ODT, Quillichew ER, or Quillivant XR, and

documentation supports inability to use dosage forms available on the formulary (e.g., inability to swallow tablets or capsules);

4. Dose does not exceed the following:
  - a. Adhansia XR: 85 mg per day (1 tablet per day);
  - b. Adzenys ER: 15 mL per day;
  - c. Adzenys XR-ODT: 12.5-18.8 mg per day (1 tablet per day);
  - d. Azstarys: 52.3 mg/10.4 mg per day;
  - e. Cotempla XR-ODT: 51.8 mg per day (2 tablets per day);
  - f. Daytrana: 30 mg per day (1 patch per day);
  - g. Dyanavel XR: 20 mg per day;
  - h. Evekeo ODT: 40 mg per day (2 tablets per day);
  - i. Focalin XR: 30 mg per day (pediatric patients), 40 mg per day (adults);
  - j. Jornay PM: 100 mg per day (1 tablet per day);
  - k. Mydayis: 50 mg per day;
  - l. Quillichew ER, Quillivant XR, Aptensio XR: 60 mg per day (1 tablet or capsule per day).

**Approval duration:**

**Medicaid/HIM:** 12 months

**Commercial:** Length of Benefit

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Attention Deficit Hyperactivity Disorder (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the following:
  - a. Adhansia XR: 85 mg per day (1 tablet per day);
  - b. Adzenys ER: 15 mL per day;
  - c. Adzenys XR-ODT: 12.5-18.8 mg per day (1 tablet per day);
  - d. Azstarys: 52.3 mg/10.4 mg per day;
  - e. Cotempla XR-ODT: 51.8 mg per day (2 tablets per day);
  - f. Daytrana: 30 mg per day (1 patch per day);
  - g. Dyanavel XR: 20 mg per day;
  - h. Evekeo ODT: 40 mg per day (2 tablets per day);
  - i. Focalin XR: 30 mg per day (pediatric patients), 40 mg per day (adults);
  - j. Jornay PM: 100 mg per day (1 tablet per day);
  - k. Mydayis: 50 mg per day;
  - l. Quillichew ER, Quillivant XR, Aptensio XR: 60 mg per day (1 tablet or capsule per day).

**Approval duration:**

**Medicaid/HIM:** 12 months  
**Commercial:** Length of Benefit

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. 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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ADHD: attention-deficit and hyperactivity disorder

CNS: central nervous system

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methylphenidate extended release (Ritalin LA <sup>®</sup> , Concerta <sup>®</sup> , Metadate CD <sup>®</sup> )	Concerta: 18 - 36 mg PO QD Ritalin LA, Metadate CD: 20 mg PO QD	Concerta: 72 mg/day Ritalin LA, Metadate CD: 60 mg/day
amphetamine (Adderall XR <sup>®</sup> )	Patients 6-17 years: 10 mg PO QD Adults: 20 mg PO QD	30 mg/day
dextroamphetamine (Dexedrine SR <sup>®</sup> )	5 mg PO QD/BID	60 mg/day
Vyvanse <sup>®</sup> (lisdexamfetamine)	30 mg PO QD	70 mg/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Hypersensitivity; use with monoamine oxidase (MAO) inhibitor, or within 14 days of last MAO inhibitor dose

- Azstarys: Known hypersensitivity to serdexmethylphenidate, methylphenidate, or product components
- Daytrana: marked anxiety, tension, or agitation; glaucoma; tics or family history of Tourette’s syndrome
- Boxed warning(s): abuse and dependence

**V. Dosage and Administration**

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Adhansia XR (methylphenidate extended-release capsule)	25 mg PO QD	6 to 17 years: 70 mg Adults: 85 mg
Adzenys ER (amphetamine ER oral suspension)	Patients 6 to 17 years: 6.3 mg PO QD Adults: 12.5 mg PO QD	6 to 12 years: 15 ml/day 13 year and older: 10 ml/day
Adzenys XR-ODT (amphetamine ER orally disintegrating tablet)	Patients 6 to 17 years: 6.3 mg PO QD Adults: 12.5 mg PO QD	6 to 12 years: 18.8 mg/day 13 to 17 years: 12.5 mg/day
Azstarys (serdexmethylphenidate-dexmethylphenidate capsule)	Patients 6 to 12 years: 39.2 mg/7.8 mg PO in the morning. Dosage may be increased to 52.3 mg/10.4 mg daily or decreased to 26.1 mg/5.2 mg daily after one week  Adults and pediatric patients 13-17 years: 39.2 mg/7.8 mg PO in the morning. Increase the dosage after one week to 52.3 mg/10.4 mg once daily	52.3 mg/10.4 mg/day
Evekeo ODT (amphetamine orally disintegrating tablet)	Patients 6 to 17 years: 5 mg PO QD or BID. Titrate daily dose in increments of 5 mg at weekly intervals.	40 mg/day
Methylphenidate ER (Adhansia XR)	Patients 6 and older: 25 mg PO QD. Dose may be increased in increments of 10 to 15 mg at intervals of at least 5 days.	85 mg/day
Methylphenidate ER (Aptensio XR)	10 mg PO QD	60 mg/day
Methylphenidate ER (Jornay PM)	Starting dose 20 mg PO QHS, dose may be increased weekly in increments of 20 mg/day	100 mg/day
Cotempla XR-ODT (methylphenidate ER orally disintegrating tablet)	Patients 6 to 17 years: 17.3 mg PO QD	51.8 mg/day
Dexmethylphenidate (Focalin XR)	Pediatric patients: 5 mg PO QD, dose may be titrated weekly in increments of 5 mg	Pediatric: 30 mg per day

Drug Name	Dosing Regimen	Maximum Dose
	Adult patients: 10 mg PO QD, dose may be titrated weekly in increments of 10 mg	Adults: 40 mg per day
Methylphenidate Transdermal System (Daytrana)	10 mg applied to the hip area (using alternating sites) 2 hours before an effect is needed and should be removed 9 hours after application	30 mg/9-hour patch per day
Dyanavel XR (amphetamine oral suspension)	2.5 - 5 mg PO QD	20 mg/day
amphetamine-dextroamphetamine extended-release (Mydayis)	12.5 mg PO QD	Adults: 50 mg/day Pediatrics (13 to 17 years): 25 mg/day
Quillichew ER (methylphenidate chewable tablet)	20 mg PO QD	60 mg/day
Quillivant XR (methylphenidate oral suspension)	20 mg PO QD	60 mg/day

**VI. Product Availability**

Drug Name	Availability
Adhansia XR (methylphenidate)	Extended-release capsules: 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, 85 mg
Adzenys ER (amphetamine)	Extended-release oral suspension: 1.25 mg/mL
Adzenys XR-ODT (amphetamine)	Extended-release orally disintegrating tablets: 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, 18.8 mg
Azstarys (serdexmethylphenidate-dexmethylphenidate capsule)	Capsules: 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, 52.3 mg/10.4 mg
Evekeo ODT (amphetamine orally disintegrating tablet)	Orally disintegrating tablets: 5 mg, 10 mg, 15 mg, 20 mg
Methylphenidate ER (Adhansia XR)	Extended-release capsules: 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, 85 mg
Methylphenidate ER (Aptensio XR)	Extended-release capsules: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg
Methylphenidate ER (Jornay PM)	Extended-release capsules: 20 mg, 40 mg, 60 mg, 80 mg, 100 mg
Cotempla XR-ODT (methylphenidate ER orally disintegrating tablet)	Extended-release orally disintegrating tablets: 8.6 mg, 17.3 mg, 25.9 mg
Dexmethylphenidate (Focalin XR)	Extended-release capsules: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg

Drug Name	Availability
Methylphenidate Transdermal System (Daytrana)	Transdermal patch: 10 mg/9 hours, 15 mg/9 hours, 20 mg/9 hours, and 30 mg/9 hours
Dyanavel XR (amphetamine)	Extended-release oral suspension: 2.5 mg/mL
amphetamine-dextroamphetamine extended-release (Mydayis)	Extended-release capsules: 12.5 mg, 25 mg, 37.5 mg, 50 mg
Quillichew ER (methylphenidate chewable)	Extended-release chewable tablets, scored: 20 mg, 30 mg Extended-release chewable tablets, not scored: 40 mg
Quillivant XR (methylphenidate oral suspension)	Extended-release oral suspension: 25 mg/5 mL (5 mg/mL)

## VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created - Policies created from existing Centene Medicaid and Commercial lines of business policies for CNS Stimulants - No significant changes from previous corporate approved policy - Age requirement is new for the Centene Commercial and changed requirement from failure of 2 methylphenidate products to failure of 1 methylphenidate and 1 amphetamine. - References reviewed and updated.	11.14.17	02.18
Added Cotempla XR-ODT and Mydayis to policy	02.13.18	
Medicaid: Revised approval duration to length of benefit	03.08.18	05.18
Per SDC: added Adzenys ER to policy	06.14.18	
1Q 2019 annual review: removed 2 week trial duration requirement for alternatives as effects from amphetamine and methylphenidate are expected to be immediate; added Focalin XR to policy; references reviewed and updated.	10.10.18	02.19
No significant changes; added Adhansia XR to policy.	03.07.19	
Added Jornay PM to policy per SDC and prior clinical guidance.	10.01.19	
1Q 2020 annual review: added HIM line of business as Daytrana requires PA on HIM (all other agents are either generic on formulary (Focalin XR) or NF for HIM); references reviewed and updated. Added Evekeo ODT to policy per SDC and prior clinical guidance.	12.02.19	02.20
1Q 2021 annual review: no significant changes; changed auth duration for Medicaid to 12 months from Length of Benefit to align with customary auth duration for the Medicaid line of business; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	12.01.20	02.21
RT4: Added new agent Azstarys to policy.	03.25.21	

**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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