

**Clinical Policy: CNS Stimulants**

Reference Number: CP.PMN.92

Effective Date: 03.01.18

Last Review Date: 02.22

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<sup>™</sup>, Aptensio XR<sup>™</sup>, Jornay PM<sup>™</sup>, Relexxii<sup>®</sup>), methylphenidate transdermal system (Daytrana<sup>®</sup>), methylphenidate extended-release chewable tablets (Quillichew ER<sup>®</sup>), methylphenidate extended-release oral suspension (Quillivant XR<sup>®</sup>), methylphenidate extended-release orally disintegrating tablets (Cotempla XR-ODT<sup>®</sup>), amphetamine orally disintegrating tablets (Evekeo ODT<sup>™</sup>), amphetamine extended-release orally disintegrating tablets (Adzenys XR-ODT<sup>™</sup>), amphetamine extended-release oral suspension (Adzenys ER<sup>™</sup>, Dyanavel XR<sup>®</sup>), amphetamine-dextroamphetamine extended-release (Mydayis<sup>®</sup>), dexamethylphenidate hydrochloride (Focalin XR<sup>®</sup>), dextroamphetamine patches (Xelstrym<sup>™</sup>), and serdexmethylphenidate-dexamethylphenidate capsules (Azstarys<sup>™</sup>).

**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<sup>®</sup> 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, Quillivant XR, Relexxii, and Xelstrym 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. One of the following (a, b, or c):
  - a. Evekeo ODT: Age  $\geq$  3 years;
  - b. Mydayis: Age  $\geq$  13 years;
  - c. All other requests: Age  $\geq$  6 years;
3. Member meets one of the following (a or b):
  - a. Failure of two formulary extended-release products at maximally indicated doses from the same therapeutic class of the requested product (i.e., amphetamine or methylphenidate), unless clinically significant adverse effects are experienced or all are contraindicated;

- b. Request is for Adzenys ER, Adzenys XR-ODT, Cotempla XR-ODT, Daytrana, Dyanavel XR, Evekeo ODT, Quillichew ER, Quillivant XR, or Xelstrym, 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);
  - m. Relexxii: 54 mg per day (age 6-12 years), 72 mg per day (age  $\geq$  13 years);
  - n. Xelstrym: 18 mg per day (1 patch per day).

**Approval duration:**

**Medicaid/HIM:** 12 months

**Commercial:** 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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. Member meets one of the following (a or b):

- a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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. Cotelpla 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);
  - m. Relexxii: 54 mg per day (age 6-12 years), 72 mg per day (age ≥ 13 years);
  - n. Xelstrym: 18 mg per day (1 patch per day).

**Approval duration:**

**Medicaid/HIM:** 12 months

**Commercial:** 12 months or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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
  - Relexxii: known hypersensitivity to methylphenidate or other components of Relexxii
- Boxed warning(s): abuse and dependence

**V. Dosage and Administration**

Drug Name	Dosing Regimen	Maximum Dose
Adhansia XR	25 mg PO QD	6 to 17 years: 70 mg Adults: 85 mg

Drug Name	Dosing Regimen	Maximum Dose
(methylphenidate extended-release capsule)		
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 age 3 to 5 years: 2.5 mg PO QD. Titrate dosage in increments of 2.5 mg at weekly intervals.  Patients 6 to 17 years: 5 mg PO QD or BID. Titrate daily dose in increments of 2.5 or 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  Adult patients: 10 mg PO QD, dose may be titrated weekly in increments of 10 mg	Pediatric: 30 mg per day Adults: 40 mg per day

Drug Name	Dosing Regimen	Maximum Dose
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/tablet)	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
Relexxii (methylphenidate hydrochloride ER)	Pediatric patients 6-17 years: starting dose 18 mg PO QD, dose may be titrated by 18 mg once per day at weekly intervals  Adult patients: starting dose 18 mg or 36 mg PO QD, dose may be titrated by 18 mg once per day at weekly intervals	Pediatrics (6-12 years): 54 mg/day Pediatrics (13-17 years) and adults: 72 mg/day
Xelstrym (dextroamphetamine transdermal patch)	<ul style="list-style-type: none"> <li>• Patients 6-17 years: Recommended starting dose is 4.5 mg/9 hours, dose may be titrated in weekly increments of 4.5 mg</li> <li>• Adults: Recommended starting dose is 9 mg/9 hours</li> </ul> <p>Apply one patch at a time for not more than 9 hours. Use only one patch per 24 hours.</p>	18 mg/9-hour patch per 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

<b>Drug Name</b>	<b>Availability</b>
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
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 Extended-release tablets: 5 mg, 10 mg, 15 mg, 20 mg
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)
Relexxii (methylphenidate hydrochloride ER)	Extended-release tablets: 18 mg, 27 mg, 36 mg, 45 mg, 54 mg, 63 mg, 72 mg
Xelstrym (dextroamphetamine)	Transdermal patch: 4.5 mg/9 hours, 9 mg/9 hours, 13.5 mg/9 hours, 18 mg/9 hours

## 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	11.14.17	02.18



Reviews, Revisions, and Approvals	Date	P&T Approval Date
- 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.		
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	
Revised redirection from failure of 1 methylphenidate and 1 amphetamine product to failure of 2 from the same therapeutic class; RT4: for Evekeo ODT added pediatric extension to 3 years of age and 2.5 mg strength per updated prescribing information; for Mydayis added age requirement for 13 years or older per label.	04.29.21	08.21
1Q 2022 annual review: RT4: for Dyanavel XR added new tablet dose form to policy; modified Commercial approval duration from length of benefit to 12 months or duration of request, whichever is less; references reviewed and updated.	09.27.21	02.22
RT4: added new agent Xelstrym to policy.	04.06.22	
RT4: added new agent Relexxii to policy.	07.21.22	
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	

**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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