Clinical Policy: CNS Stimulants

Reference Number: CP.PMN.92
Effective Date: 03.01.18
Last Review Date: 02.26
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™, Relexxii®), 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 (Dyanavel XR®), amphetamine-dextroamphetamine extended-release (Mydayis®), dexmethylphenidate hydrochloride (Focalin XR®), dextroamphetamine patches (Xelstrym™), and serdexmethylphenidate-dexmethylphenidate capsules (Azstarys™).

FDA Approved Indication(s)

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

Limitations of Use The use of Adzenys XR-ODT, Aptensio XR, Azstarys, Cotempla XR-ODT, Daytrana, Dyanavel XR, Focalin XR, Jornay PM, Quillichew ER, Quillivant XR, Relexxii, and Xelstrym are not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g. weight loss) than patients 6 years and older at the same dosage.

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 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 or b):
   a. Mydayis: Age ≥ 13 years;
   b. All other requests: Age ≥ 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 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. If request is for a brand product, member must use the generic equivalent, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Request does not exceed health plan-approved quantity limit, if applicable;
6. Dose does not exceed any of the following:
   a. Adhansia XR (both i and ii):
      i. 85 mg per day;
      ii. 3 tablets per day;
   b. Adzenys XR-ODT (i or ii):
      i. Age 6 to 12 years (1 and 2):
         1) 18.8 mg per day;
         2) 1 tablet per day;
      ii. Age ≥ 13 years (1 and 2):
         1) 12.5 mg per day;
         2) 1 tablet per day;
   c. Azstarys: 52.3 mg/10.4 mg per day;
   d. Cotempla XR-ODT (both i and ii):
      i. 51.8 mg per day;
      ii. 2 tablets per day;
   e. Daytrana (both i and ii):
      i. 30 mg per day;
      ii. 1 patch per day;
   f. Dyanavel XR (both i and ii):
      i. 20 mg per day;
      ii. 1 tablet per day;
   g. Evekeo ODT (both i and ii):
      i. 40 mg per day;
      ii. 2 tablets per day;
   h. Focalin XR (i or ii):
      i. Pediatric (both 1 and 2):
         1) 30 mg per day;
         2) 1 capsule per day;
      ii. Adult (both 1 and 2):
         1) 40 mg per day;
         2) 1 capsule per day;
   i. Jornay PM (both i and ii):
      i. 100 mg per day;

ii. 1 capsule per day;
j. Mydayis (both i and ii):
i. 50 mg per day;
ii. 1 capsule per day;
k. Quillichew ER, Quillivant XR, Aptensio XR (both i and ii):
i. 60 mg per day;
ii. 1 tablet or capsule per day;
l. Relexxii (i or ii):
i. Age 6-12 years (both 1 and 2):
1) 54 mg per day;
2) 1 tablet per day;
ii. Age ≥ 13 years (both 1 and 2):
1. 72 mg per day;
2. 1 tablet per day;
m. Xelstrym (both i and ii):
i. 18 mg per day;
ii. 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 brand product, member must use the generic equivalent, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed health plan-approved quantity limit, if applicable;
5. If request is for a dose increase, new dose does not exceed any of the following:
   a. Adhansia XR (both i and ii):
      i. 85 mg per day;
      ii. 3 tablets per day;
   b. Adzenys XR-ODT (i or ii):
      i. Age 6 to 12 years (1 and 2):
         1) 18.8 mg per day;
         2) 1 tablet per day;
      ii. Age ≥ 13 years (1 and 2):
         1) 12.5 mg per day;
         2) 1 tablet per day;
   c. Azstarys: 52.3 mg/10.4 mg per day;
   d. Cotempla XR-ODT (both i and ii):
      i. 51.8 mg per day;
      ii. 2 tablets per day;
   e. Daytrana (both i and ii):
      i. 30 mg per day;
      ii. 1 patch per day;
   f. Dyanavel XR (both i and ii):
      i. 20 mg per day;
      ii. 1 tablet per day;
   g. Evekeo ODT (both i and ii):
      i. 40 mg per day;
      ii. 2 tablets per day;
   h. Focalin XR (i or ii):
      i. Pediatric (both 1 and 2):
         1) 30 mg per day;
         2) 1 capsule per day;
      ii. Adult (both 1 and 2):
         1) 40 mg per day;
         2) 1 capsule per day;
   i. Jornay PM (both i and ii):
      i. 100 mg per day;
      ii. 1 tablet per day;
   j. Mydayis (both i and ii):
      i. 50 mg per day;
      ii. 1 capsule per day;

k. Quillichew ER, Quillivant XR, Aptensio XR (both i and ii):
   i. 60 mg per day;
   ii. 1 tablet or capsule per day;
l. Relexxii (both i and ii):
   i. Age 6-12 years (both 1 and 2):
      1) 54 mg per day;
      2) 1 tablet per day;
   ii. Age ≥ 13 years (both 1 and 2):
      1) 72 mg per day;
      2) 1 tablet per day;
m. Xelstrym (both i and ii):
   i. 18 mg per day; 7
   ii. 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®, Concerta®, Metadate CD®)	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®)	Patients 6-17 years: 10 mg PO QD Adults: 20 mg PO QD	30 mg/day
dextroamphetamine (Dexedrine SR®)	5 mg PO QD/BID	60 mg/day
lisdexamfetamine (Vyvanse®)	30 mg PO QAM	70 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) 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
  - Relexxii: known hypersensitivity to methylphenidate or other components of Relexxii
- Boxed warning(s):
  - Abuse and dependence (*Adhansia XR*)
  - Abuse, misuse, and addiction (*Adzenys XR-ODT, Aptensio XR, Azstarys, Cotempla XR-ODT, Daytrana, Dyanavel XR, Evekeo ODT, Focalin XR, Jornay PM, Mydayis, Quillichew ER, Quillivant XR, Relexxii, Xelstrym*)

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Adhansia XR (methylphenidate ER capsule)	25 mg PO QD	6 to 17 years: 70 mg Adults: 85 mg
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, Adults: 12.5 mg/day
Aptensio XR (methylphenidate hydrochloride ER capsule)	10 mg PO QD	60 mg/day

Drug Name	Dosing Regimen	Maximum Dose
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 (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
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 ER (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	Pediatrics (6-12 years): 54 mg/day

Drug Name	Dosing Regimen	Maximum Dose
	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 (13-17 years) and adults: 72 mg/day
Xelstrym (dextroamphetamine transdermal patch)	• Patients 6-17 years: Recommended starting dose is 4.5 mg/9 hours, dose may be titrated in weekly increments of 4.5 mg • Adults: Recommended starting dose is 9 mg/9 hours Apply one patch at a time for not more than 9 hours. Use only one patch per 24 hours.	18 mg/9-hour patch per day

VI. Product Availability

Drug Name	Availability
Adhansia XR (methylphenidate)	Extended-release capsule: 35 mg
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
Aptensio XR (methylphenidate ER)	Extended-release capsules: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 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 (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 ER (Mydayis)	Extended-release capsules: 12.5 mg, 25 mg, 37.5 mg, 50 mg

Drug Name	Availability
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
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	
1Q 2023 annual review: modified age requirement for Evekeo ODT from at least 3 years to at least 6 years, removed 2.5 mg strength per	01.17.23	02.23

Reviews, Revisions, and Approvals	Date	P&T Approval Date
updated prescribing information, and updated Evekeo dosing in section V; added Aptensio dose in section V and VI; references reviewed and updated.		
1Q 2024 annual review: added "abuse, misuse, and addiction" for boxed warnings for Adzenys XR-ODT, Aptensio XR, Azstarys, Cotempla XR-ODT, Daytrana, Dyanavel XR, Evekeo ODT, Focalin XR, Jornay PM, Mydayis, Quillichew ER, Quillivant XR, Relexxii, Xelstrym per prescriber information; for Daytrana, removed "marked anxiety, tension, or agitation; glaucoma; tics or family history of Tourette's syndrome" in contraindications section per prescribing information; references reviewed and updated.	11.08.23	02.24
1Q 2025 annual review: removed Adzenys ER from criteria as drug has been discontinued; for Adhansia XR, removed discontinued strengths [25 mg, 45 mg, 55 mg, 70 mg, 80 mg]; updated Adhansia XR quantity limit to 3 tablets per day; for Adzenys XR-ODT, split dosing based on 6 to 12 years and ≥ 13 years per prescriber information; references reviewed and updated. Updated Vyvanse in Appendix B as "lisdexamfetamine (Vyvanse)" to reflect generic availability.	01.08.25	02.25
1Q 2026 annual review: no significant changes; per template added requirement that "Request does not exceed health plan-approved quantity limit, if applicable"; references reviewed and updated.	10.21.25	02.26
Added the following requirement per health plan request: If request is for a brand product, member must use the generic equivalent, if available, unless contraindicated or clinically significant adverse effects are experienced.	03.03.26	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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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