Clinical Policy:
CNS Stimulants

Reference Number: IL.PMN.92
Effective Date: 1.1.23
Last Review Date: 1.21.26
Line of Business: 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®), 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).

Policy/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, Jornay PM, Mydayis, Quillichew ER, Quillivant XR, Relexxii, and Xelstrym are medically **necessary** when the following criteria are met: 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, b, c, d, e, or f):
   a. Request is Jornay and failure of an adequate trial of at least two preferred* ADHD agents at maximum indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated in the past 18 months.
   b. Request is for Daytrana and documentation supports inability to use dosage forms available on the formulary (e.g., inability to swallow tablets or capsules), or clinically significant adverse effect are experienced with preferred agents;
   c. Request is for Dyanavel XR Chewable or Suspension and failure of an adequate trial of one preferred* ADHD agent at maximum indicated doses, unless documentation supports inability to use dosage forms available on the formulary (e.g., inability to swallow tablets or capsules), clinically significant adverse effect are experienced or contraindications.

d. Request is for Quillichew and failure of an adequate trial of one preferred* ADHD agent at maximum indicated doses, unless documentation supports inability to use dosage forms available on the formulary (e.g., inability to swallow tablets or capsules), clinically significant adverse effect are experienced or contraindications.
e. Request is for Quillivant XR suspension and failure of an adequate trial of one preferred* ADHD agent at maximum indicated doses, unless documentation supports inability to use dosage forms available on the formulary (e.g., inability to swallow tablets or capsules), clinically significant adverse effect are experienced or contraindications.
f. For all other requests: 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;

4. 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;
   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: 12 months

B. Other diagnoses/indications

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 PDL, refer to the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, refer to the non-formulary policy: CP.PMN.16; 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: 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 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:12 months

B. Other diagnoses/indications (must meet 1 and 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.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.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.PMN.53 for Medicaid.

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

1. 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 Policy CP.PMN.53 for Medicaid, or evidence of coverage documents.

III. 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
Vyvanse® (lisdexamfetamine)	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	**25 mg PO QD**	**6 to 17 years: 70**

Adzenys XR-ODT	**Patients 6 to 17 years: 6.3 mg PO QD**	**6 to 12 years: 18.8**
Aptensio XR	**10 mg PO QD**	**60 mg/day**
Azstarys	**Patients 6 to 12 years: 39.2 mg/7.8 mg PO**	**52.3 mg/10.4**
Evekeo ODT	**Patients 6 to 17 years: 5 mg PO QD or BID.**	**40 mg/day**
Methylphenidate ER	**10 mg PO QD**	**60 mg/day**
Methylphenidate ER	**Starting dose 20 mg PO QHS, dose may be**	**100 mg/day**
Cotempla XR-ODT	**Patients 6 to 17 years: 17.3 mg PO QD**	**51.8 mg/day**
Dexmethylphenidate	**Pediatric patients: 5 mg PO QD, dose may**	**Pediatric: 30 mg**
Methylphenidate	**10 mg applied to the hip area (using**	**30 mg/9-hour**
Dyanavel XR	**2.5 – 5 mg PO QD**	**20 mg/day**
amphetamine-	**12.5 mg PO QD**	**Adults: 50 mg/day**
Quillichew ER	**20 mg PO QD**	**60 mg/day**
Quillivant XR	**20 mg PO QD**	**60 mg/day**
Relexxii	**Pediatric patients 6-17 years: starting dose**	**Pediatrics (6-12**
Xelstrym	**• Patients 6-17 years: Recommended**	**18 mg/9-hour**

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
Criteria created for migration to HFS PDL	12.1.22	
Included criteria for Daytrana, updated section II, added Appendix B therapeutic alternatives, updated sections V and VI, and references reviewed and updated.	11.20.23	
1Q Annual Review 2025: no significant changes; reference reviewed and updated.	1.10.25	
2026 Annual Review: updated title and policy to reflect HFS PDL stimulant changes; appendix C updated, sections V and VI updated; references reviewed and updated.	1.21.26	

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.