

Clinical Policy: CNS Stimulants

Reference Number: CP.PMN.92

Effective Date: 03.01.18

Last Review Date: 02.19

Line of Business: Commercial, 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 (Aptensio XR™), 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 extended-release orally disintegrating tablets (Adzenys XR-ODT™), amphetamine extended-release oral suspension (Adzenys ER™, Dyanavel XR®), amphetamine-dextroamphetamine extended-release (Mydayis®), and dexamethylphenidate hydrochloride (Focalin XR®).

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 Adzenys ER, Adzenys XR-ODT, Aptensio XR, Cotempla XR-ODT, Daytrana, Dyanavel XR, Focalin XR, 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 \geq 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, 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. Adzenys ER: 15 mL per day;

- b. Adzenys XR-ODT: 12.5-18.8 mg per day (1 tablet per day);
- c. Cotempla XR-ODT: 51.8 mg per day (2 tablets per day);
- d. Daytrana: 30 mg per day (1 patch per day);
- e. Dyanavel XR: 20 mg per day;
- f. Focalin XR: 30 mg per day (pediatric patients), 40 mg per day (adults);
- g. Mydayis: 50 mg per day;
- h. Quillichew ER, Quillivant XR, Aptensio XR: 60 mg per day (1 tablet/capsule per day).

Approval duration: 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 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. Adzenys ER: 15 mL per day;
 - b. Adzenys XR-ODT: 12.5-18.8 mg per day (1 tablet per day);
 - c. Cotempla XR-ODT: 51.8 mg per day (2 tablets per day);
 - d. Daytrana: 30 mg per day (1 patch per day);
 - e. Dyanavel XR: 20 mg per day;
 - f. Focalin XR: 30 mg per day (pediatric patients), 40 mg per day (adults);
 - g. Mydayis: 50 mg per day;
 - h. Quillichew ER, Quillivant XR, Aptensio XR: 60 mg per day (1 tablet/capsule per day).

Approval duration: 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 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 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 |
| Vyvanse [®] (lisdexamfetamine) | 30 mg PO QD | 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
 - 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

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| 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 |
| Methylphenidate ER (Aptensio XR) | 10 mg PO QD | 60 mg/day |
| Cotempla XR-ODT (methylphenidate ER) | Patients 6 to 17 years: 17.3 mg PO QD | 51.8 mg/day |

| Drug Name | Dosing Regimen | Maximum Dose |
|--|--|---|
| orally disintegrating tablet) | | |
| 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) | 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 |
|---|---|
| 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 |
| Methylphenidate ER (Aptensio XR) | Extended-release capsules: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 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 |

| Drug Name | Availability |
|--|---|
| 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: 20 mg, 30 mg, 40 mg |
| Quillivant XR (methylphenidate oral suspension) | Extended-release oral suspension: 25 mg (5 mg/mL) |

VII. References

1. Daytrana Prescribing Information. Miami, FL: Noven Therapeutics, LLC; November 2017. Available at: <http://www.daytrana.com/>. Accessed October 10, 2018.
2. American Academy of Child and Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry. 2007; 46(7):894-921.
3. American Academy of Pediatrics subcommittee on attention-deficit/hyperactivity disorder, steering committee on quality improvement and management. ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics 2011; 128(5):1007-1022.
4. Aptensio XR Prescribing Information. Greenville, NC: Rhodes Pharmaceuticals; January 2017. Accessed October 10, 2018.
5. Dyanavel XR Prescribing Information. Monmouth Junction, NJ: Tris Pharma; May 2017. Available at <http://dyanavelxr.com/>. Accessed October 10, 2018.
6. Adzenys XR-ODT Prescribing Information. Grand Prairie, TX: Neos Therapeutics. January 2017. Available at: <https://www.adzenysxrodt.com/>. October 10, 2018.
7. Quillichew ER Prescribing Information. Monmouth Junction, NJ: Tris Pharma. March 2018. Available at <https://www.quillivantxr-quillichewer.com/>. Accessed October 10, 2018.
8. Quillivant XR Prescribing Information. Monmouth Junction, NJ: Tris Pharma; June 2017. Available at: <https://www.quillivantxr-quillichewer.com/>. Accessed October 10, 2018.
9. Cotempla XR-ODT Prescribing Information. Grand Prairie, TX: Neos Therapeutics; June 2017. Available at: <https://www.cotemplaxrodthcp.com/>. Accessed February 2018.
10. Mydayis Prescribing Information. Lexington, MA: Shire US Inc.; June 2017. Available at <https://www.mydayis.com/>. Accessed October 10, 2018.
11. Adzenys ER Prescribing Information. Grand Prairie, TX: Neos Therapeutics; September 2017. Accessed October 10, 2018.
12. Focalin XR Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2019. Accessed January 22, 2019.

| 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 | 11.14.17 | 02.18 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|--|----------|-------------------|
| - 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 |

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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