

**Clinical Policy: CNS Stimulants**

Reference Number: CP.PMN.92

Effective Date: 03.01.18

Last Review Date: 02.18

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 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 (Dyanavel XR®), amphetamine-dextroamphetamine extended-release (Mydayis®).

**FDA Approved Indication(s)**

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

**Policy/Criteria**

*Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of health plans affiliated with Centene Corporation® that Aptensio XR, Daytrana, Quillichew ER, Quillivant XR, Cotempla XR-ODT, Adzenys XR-ODT and Dyanavel 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 attention deficit hyperactivity disorder;
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 maximum indicated doses, each trialed for  $\geq$  2 weeks, unless member experiences clinically significant adverse effects or has contraindication(s) to all relevant formulary extended release amphetamine and methylphenidate products;
  - b. Request is for Daytrana, Quillichew ER, Quillivant XR, Cotempla XR-ODT, Adzenys XR-ODT, Dyanavel XR and documentation supports member's inability to use dosage forms (e.g., inability to swallow tablets or capsules) available on the formulary;
4. Dose does not exceed the following:
  - a. Daytrana: 30 mg per day (1 patch/day);

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

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
methylphenidate extended release (Ritalin LA, Concerta, Metadate CD)	Concerta: 18 - 36 mg daily Ritalin LA, Metadate CD: 20 mg daily	Concerta: 72 mg/day Ritalin LA, Metadate CD: 60 mg/day
amphetamine (Adderall XR)	Patients 6-17 years: 10 mg once daily Adults: 20 mg once daily	30 mg/day
dextroamphetamine (Dexedrine SR)	5 mg once or twice daily	60 mg/day
Vyvanse (lisdexamfetamine)	30 mg per day	70 mg/day
Mydayis (amphetamine)	12.5 mg per day	50 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.*

**V. Dosage and Administration**

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
Methylphenidate ER (Aptensio XR)	10 mg daily	60 mg/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 daily	20 mg/day
Adzenys XR-ODT (amphetamine ER orally disintegrating tablet)	Patients 6 to 17 years: 6.3 mg daily Adults: 12.5 mg daily	6 to 12 years: 18.8 mg/day 13 to 17 years: 12.5 mg/day
Cotempla XR-ODT (methylphenidate ER orally disintegrating tablet)	Patients 6 to 17 years: 17.3 mg daily	51.8 mg/day
Quillichew ER (methylphenidate chewable tablet)	20 mg daily	60 mg/day
Quillivant XR (methylphenidate oral suspension)	20 mg daily	60 mg/day

Drug Name	Dosing Regimen	Maximum Dose
amphetamine-dextroamphetamine extended-release (Mydayis)	12.5 mg daily	Adults: 50 mg/day Pediatrics (13 to 17 years): 25 mg/day

**VI. Product Availability**

Drug Name	Availability
Methylphenidate ER (Aptensio XR)	Extended-release capsules: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg
Methylphenidate Transdermal System (Daytrana)	Transdermal patch: 10 mg/9 hours, 15 mg/9 hours, 20 mg/9 hours, and 30 mg/9 hours
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
Cotempla XR-ODT (methylphenidate ER orally disintegrating tablet)	Extended-release orally disintegrating tablets: 8.6 mg, 17.3 mg, 25.9 mg
Dyanavel XR (amphetamine)	Extended-release oral suspension: 2.5 mg/ml
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 (5mg/ml)
amphetamine-dextroamphetamine extended-release (Mydayis)	Extended-release capsules: 12.5 mg, 25 mg, 37.5 mg, 50 mg

**VII. References**

1. Daytrana Prescribing Information. Miami, FL: Noven Therapeutics, LLC; January 2017. Available at: <http://www.daytrana.com/>. Accessed October 30, 2017.
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4. Aptensio XR Prescribing Information. Greenville, NC: Rhodes Pharmaceuticals; May 2015. October 2016.
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7. Quillichew ER Prescribing Information. Monmouth Junction, NJ: Tris Pharma. June 2017. Available at <https://www.quillivantxr-quillichewer.com/>. Accessed November 2017.
8. Quillivant XR Prescribing Information. Monmouth Junction, NJ: Tris Pharma; June 2017. Available at: <https://www.quillivantxr-quillichewer.com/>. Accessed November 2017.
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: [http://pi.shirecontent.com/PI/PDFs/Mydayis\\_USA\\_ENG.pdf](http://pi.shirecontent.com/PI/PDFs/Mydayis_USA_ENG.pdf). Accessed February 2018.

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

**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

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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.

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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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