

Clinical Policy Title: CNS Stimulants

Policy Number: RxA.89

Drug(s) Applied: methylphenidate extended-release (Adhansia XR™, Aptensio XR™, Jornay PM™), 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 dexmethylphenidate hydrochloride (Focalin XR®).

Last Review Date: 04/2020

Line of Business: Commercial, Medicaid

Background

The following are the central nervous system (CNS) stimulants requiring prior authorization: methylphenidate extended-release (Adhansia XR™, Aptensio XR™, Jornay PM™), 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 dexmethylphenidate hydrochloride (Focalin XR®).

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

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 (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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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)	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

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 (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
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)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Attention Deficit Hyperactivity Disorder (must meet all):

1. Diagnosis of ADHD;
2. Age ≥ 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, Cotelma 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. 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. Cotelma XR-ODT: 51.8 mg per day (2 tablets per day);
 - e. Daytrana: 30 mg per day (1 patch per day);
 - f. Dyanavel XR: 20 mg per day;
 - g. Focalin XR: 30 mg per day (pediatric patients), 40 mg per day (adults);
 - h. Jornay PM: 100 mg per day (1 tablet per day);
 - i. Mydayis: 50 mg per day;
 - j. Quillichew ER, Quillivant XR, Aptensio XR: 60 mg per day (1 tablet/capsule per day).

Approval duration: Length of Benefit

II. Continued Therapy

A. Attention Deficit Hyperactivity Disorder (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;

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. Cotempla XR-ODT: 51.8 mg per day (2 tablets per day);
 - e. Daytrana: 30 mg per day (1 patch per day);
 - f. Dyanavel XR: 20 mg per day;
 - g. Focalin XR: 30 mg per day (pediatric patients), 40 mg per day (adults);
 - h. Jornay PM: 100 mg per day (1 tablet per day);
 - i. Mydayis: 50 mg per day;
 - j. Quillichew ER, Quillivant XR, Aptensio XR: 60 mg per day (1 tablet/capsule per day).

Approval duration: Length of Benefit

III. Appendices:

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

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/>. Accessed 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.
13. Adhansia XR Prescribing Information. Wilson, NC: Purdue Pharmaceuticals; February 2019. Accessed March 7, 2019.
14. Jornay PM Prescribing Information. Cherry Hill, NJ: Ironshore Pharmaceuticals, Inc.; April 2019. Accessed October 7, 2019.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updated grammar/formatting	04/2020	05/21/2020