Clinical Policy: Methylphenidate ER (Adhansia XR, Aptensio XR, Cotempla XR-ODT, Quillichew ER, Quillivant XR)

Reference Number: ERX.NPA.118
Effective Date: 09.01.19
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Methylphenidate extended-release (ER) (Adhansia XR™, Aptensio XR™, Cotempla XR-ODT®, Quillichew ER®, Quillivant XR®) is a central nervous system (CNS) stimulant.

FDA Approved Indication(s)
Adhansia XR, Aptensio XR, Cotempla XR-ODT, Quillichew ER, and Quillivant XR are indicated for the treatment of 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Aptensio XR, Cotempla XR-ODT, 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 ≥ 6 years;
3. Member meets one of the following (a or b):
   a. Failure of two formulary, extended-release formulations of methylphenidate, each tried at maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
   b. Request is for Adhansia XR, Cotempla XR-ODT, Quillichew ER, or Quillivant ER, 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 any of the following (a-e):
   a. Adhansia XR: 85 mg (1 capsule) per day;
   b. Aptensio XR: 60 mg (1 capsule) per day;
   c. Cotempla XR-ODT: 51.8 mg (2 tablets) per day;
   d. Quillichew ER: 60 mg (2 tablets) per day;
   e. Quillivant XR: 60 mg (12 mL) per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 any of the following (a-e):
   a. Adhansia XR: 85 mg (1 capsule) per day;
   b. Aptensio XR: 60 mg (1 capsule) per day;
   c. Cotempla XR-ODT: 51.8 mg (2 tablets) per day;
   d. Quillichew ER: 60 mg (2 tablets) per day;
   e. Quillivant XR: 60 mg (12 mL) per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADHD: attention deficit hyperactivity disorder
CNS: central nervous system
ER: extended-release
FDA: Food and Drug Administration
MAO: monoamine oxidase

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
dexmethylphenidate (Focalin®, Focalin XR®)	Focalin: 2.5 mg PO BID Focalin XR: 10 mg PO QD	Focalin: 20 mg/day Focalin XR: 40 mg/day
methylphenidate (Concerta®, Metadate CD®, Metadate ER®, Methylin®, Relexxii®, Ritalin®, Ritalin LA®)	Ritalin, Methylin: 20-30 mg PO in 2-3 divided doses Metadate ER: 20 mg PO TID Concerta, Relexxii: 18-36 mg PO QD Metadate CD, Ritalin LA: 20 mg PO QD	Concerta, Relexxii: 72 mg/day All other formulations: 60 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 to methylphenidate or product components, concomitant use with monoamine oxidase (MAO) inhibitor or within 14 days of last MAO inhibitor dose
- Boxed warning(s): abuse and dependence

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
methylphenidate ER (Aptensio XR)	10 mg PO QD	60 mg/day
Cotempla XR-ODT (methylphenidate ER)	6 to 17 years: 17.3 mg PO QD	51.8 mg/day
Quillichew ER (methylphenidate ER)	20 mg PO QD	60 mg/day
Quillivant XR (methylphenidate ER)	20 mg PO QD	60 mg/day
Adhansia XR (methylphenidate ER)	25 mg PO QD	6 to 17 years: 70 mg Adults: 85 mg

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
Cotempla XR-ODT (methylphenidate ER)	Extended-release orally disintegrating tablets: 8.6 mg, 17.3 mg, 25.9 mg
Quillichew ER (methylphenidate ER)	Extended-release chewable tablets: 20 mg, 30 mg, 40 mg
Quillivant XR (methylphenidate ER)	Extended-release powder for oral suspension, 25 mg/mL (after reconstitution with water): 300 mg, 600 mg, 750 mg, 900 mg in 60 mL, 120 mL, 150 mL, 180 mL, respectively
Adhansia XR (methylphenidate ER)	Extended-release capsules: 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, 85 mg

VII. References

1. Aptensio XR Prescribing Information. Greenville, NC: Rhodes Pharmaceuticals: June 2019. Available at: www.aptensioxr.com. Accessed April 28, 2021.
2. Cotempla XR-ODT Prescribing Information. Grand Prairie, TX: Neos Therapeutics; January 2020. Available at: www.cotemplaxrodt.com. Accessed April 28, 2021.
3. Quillichew ER Prescribing Information. Monmouth Junction, NJ: Tris Pharma, Inc.; August 2018. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=defc1205-8e90-4b1e-b862-05e4c35c7364. Accessed April 28, 2021.
4. Quillivant XR Prescribing Information. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2018. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c2dc2109-44a6-4797-b04e-18761dd9d45a Accessed April 28, 2021.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 28, 2021.
6. 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.
7. 3. American Academy of Pediatrics subcommittee on attention-deficit/hyperactivity disorder, steering committee on quality improvement and management. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics Oct 2019, 144 (4) e20192528; DOI: 10.1542/peds.2019-2528.
8. Adhansia XR Prescribing Information. Wilson, NC: Purdue Pharmaceuticals; April 2021. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=80e15bd0-4d56-75f0-ab5a-885879fc56e9 Accessed April 28, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.02.19	08.19
3Q 2020 annual review: added Quillichew ER and Quillivant XR to the policy as extended-release methylphenidate forms that require prior authorization; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: revised redirection from failure of 1 methylphenidate and 1 amphetamine product to failure of 2 extended-release formulations of methylphenidate only; references reviewed and updated.	04.28.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.