

Clinical Policy: Dexmethylphenidate ER (Focalin XR)

Reference Number: PA.CP.PMN.63

Effective Date: 01/18

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

Description

Dexmethylphenidate ER (Focalin XR[®]) is a central nervous system stimulant.

FDA approved indication

Focalin XR is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients aged 6 years and older.

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 Pennsylvania Health and Wellness[®] that Focalin XR is **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 (ADHD);
2. Age \geq 6 years;
3. Member must meet one of the following (a or b):
 - a. Age \geq 6 to $<$ 18 years, and both (i and ii):
 - i. Failure of an extended release amphetamine at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
 - ii. Failure of an extended release methylphenidate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
 - b. Age \geq 18 years, and both (i and ii):
 - i. Failure of a \geq 4 week trial of an extended release amphetamine at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
 - ii. Failure of a \geq 4 week trial of an extended release methylphenidate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed one of the following (a or b):
 - a. Children: 30 mg/day (1 capsule/day);
 - b. Adults: 40 mg/day (1 capsule/day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following:
 - a. Children: 30 mg/day (1 capsule/day);
 - b. Adults: 40 mg/day (1 capsule/day).

Approval duration: 12 months

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy or the Continuity of Care Policy, PA.LTSS.PHAR.01, applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to PA.CP.PMN.53 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 – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADHD: attention deficit hyperactivity disorder

FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ADHD	Once daily in the morning	30 mg per day in children 40 mg per day in adults

VI. Product Availability

Extended-release capsule: 5, 10, 15, 20, 25, 30, 35, and 40 mg

VII. References

1. Focalin XR Prescribing Information. East Hanover, NJ: Novartis Pharmaceutical Corporation; January 2017. Available at <http://www.focalinxr.com/>. Accessed April 3, 2017.
2. Dexmethylphenidate Drug Monograph. Clinical Pharmacology. Accessed April 2017. <http://www.clinicalpharmacology-ip.com>.

CLINICAL POLICY
Dexmethylphenidate ER



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