## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 11/01/2018** |
| **Policy Number: PA.CP.PMN.63** | **Effective Date: 10/17/2018**<br>**Revision Date: 10/17/2018** |
| **Policy Name: Dexmethylphenidate ER (Focalin XR)** | **HC Approval Date:** |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

This policy is being retired and replaced by the following policy:

**PA.CP.PMN.16 Request for Medically Necessary Drug not on the PDL**

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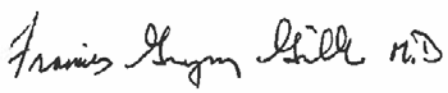
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Francis G. Grillo, MD** | **Signature of Authorized Individual:**<br>  |

# Clinical Policy: Dexmethylphenidate ER (Focalin XR)

Reference Number: PA.CP.PMN.63
Effective Date: 01/18
Last Review Date: 08/17 Revision Log
Line of Business: Medicaid

**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 ≥ 6 years;
3. Member must meet one of the following (a or b):
   a. Age ≥ 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 ≥ 18 years, and both (i and ii):
      i. Failure of a ≥ 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 ≥ 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<br>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.

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