CENTENE Corporation

Clinical Policy: ~~D~~dexmethylphenidate ER (Focalin XR)
Reference Number: CP.PMN.63
Effective Date: 05/15
Last Review Date: 08/17~~6~~
Line of Business: Medicaid

~~Coding Implications~~
Revision Log

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

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

FDA approved indication
Focalin XR is indicated for the treatment of a~~A~~ttention ~~D~~deficit ~~H~~hyperactivity d~~D~~isorder (ADHD) in patients aged 6 years and older.

Policy/Criteria
Provider must submit documentation (which may include ~~including~~ 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 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 ~~to < 18 years (refer to CP.PPA.14 for adults)~~;
3. Member must meet one of the following (a or b):
   ~~2.~~a. Age ≥ 6 to < 18 years, and both (i and ii):
      i. Failure of an ~~PDL~~ extended release amphetamine ~~AND a PDL extended release methylphenidate~~ at up to maximally indicated doses~~, each~~ unless ~~trialed for ≥ 30 days 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;
      ~~3.~~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);
   ~~4.~~b. Adults: 40 mg/day (1 capsule/day).

Approval duration: 6 months

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B. Other diagnoses/indications

1. Refer to 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 Centene benefit or member has previously met initial approval criteria;
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);
   3. b. Adults: 40 mg/day (1 capsule/day).

Approval duration: 12 months

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.XXXPMN.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 – CP.PMN.53 or evidence of coverage documents;

~~**B.** [Indications/diagnoses/situations in which drug is unsafe/ineffective] (This section should contain uses where the drug has been shown to be ineffective or unsafe or both. Do not list uses that are unproven, under investigation, or not studied here)~~

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADHD: aAttention 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. Workflow Document

Focalin WF.docx

VIII. 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
Policy created.	05/15	05/15
Converted to new template. Added diagnosis, general max dosing, and continuation criteria. Remove criteria regarding MAOI since other CNS stimulants on the PDL are not subject to this criteria. Removed 'Special Instructions' safety addendum. Updated background and references. Added workflow document.	05/16	08/16
~~Clinical changes to criteria~~ Changed trial of amphetamine and methylphenidate from ≥ 4 weeks to no particular timeframe for pediatrics. A response to the medication should be seen immediately ~~(per uptodate)~~ and with a titration to maximum dose, the pediatric member would have trialed for a sufficient timeframe. - Removed age ≥ 6 to < 18 years (refer to CP.PPA.14 for adults. CP.PPA.14 is being retired. Adjusted criteria to age ≥ 6 years per FDA labeling. Added criteria for adult use, including max dose for adults of 40 mg/day.	4/17	08/17

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

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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 applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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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