Clinical Policy: Atomoxetine (Strattera)

Reference Number: CP.PST.17
Effective Date: 08.01.17
Last Review Date: 08.18 Revision Log
Line of Business: Medicaid

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

Description

Atomoxetine (Strattera®) is selective norepinephrine reuptake inhibitor.

FDA Approved Indication(s)

Strattera is indicated for the treatment of 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.

It is the policy of health plans affiliated with Centene Corporation® that Strattera is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Step Therapy for Strattera (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Member or parent/guardian of member has a history of substance abuse;
   b. Both of the following (i and ii):
      i. Previous use of one amphetamine-based stimulant at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced to any amphetamine product;
      ii. Previous use of one methylphenidate-based stimulant at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced to any methylphenidate product;
2. Dose does not exceed 100 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

II. Continued Therapy

A. Step Therapy for Strattera (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed 100 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADHD: attention-deficit/hyperactivity disorder
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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Short-Acting Amphetamines		
Evekeo® (amphetamine)	Refer to prescribing information	60 mg/day
amphetamine/dextroamphetamine salts (Adderall®)		60 mg/day
dextroamphetamine (Dexedrine®, Procentra®, Zenzedi®)		40 mg/day
methamphetamine (Desoxyn®)		25 mg/day
Long-Acting Amphetamines		
Adzenys XR ODT™ (amphetamine ER)	Refer to prescribing information	12.5 mg/day
Dyanavel® XR (amphetamine ER)		20 mg/day
amphetamine/ dextroamphetamine salts ER (Adderall® XR)		20 mg/day (20-30 mg/day if ≥ 6 years)
dextroamphetamine ER (Dexedrine Spansule®)		40 mg/day
Short-Acting Methylphenidates		
dexmethylphenidate (Focalin®)	Refer to prescribing information	20 mg/day
methylphenidate (Methylin®, Ritalin®)		60 mg/day
Long-Acting Methylphenidates		
dexmethylphenidate ER (Focalin XR®)	Refer to prescribing information	40 mg/day (30 mg/day if 6-17 years)
methylphenidate ER (Aptensio XR™, Metadate CD®, QuilliChew ER®, Quillivant XR®, Ritalin LA®)		60 mg/day
methylphenidate ER (Concerta®)		72 mg/day
Daytrana® (methylphenidate transdermal)		One 30 mg/9-hour patch/day
Cotempla XR-ODT®		51.8 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(methylphenidate ER)		

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

- Use with or within 2 weeks after discontinuing a monoamine oxidase inhibitor or other drugs that might affect brain monoamine concentrations
- Narrow angle glaucoma
- Pheochromocytoma or history of pheochromocytoma
- Severe cardiovascular disorders that might deteriorate with clinically important increases in heart rate and blood pressure

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ADHD, children and adolescents weighing ≤ 70 kg	Initial daily dose: 0.5 mg/kg PO QD or BID Target daily dose: 1.2 mg/kg PO QD or BID	1.4 mg/kg
ADHD, children and adolescents weighing > 70 kg and adults	Initial daily dose: 40 mg PO QD or BID Target daily dose: 80 mg PO QD or BID	100 mg/day

VI. Product Availability

Capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg

VII. References

1. Strattera Prescribing Information. Indianapolis, IN: Eli Lilly and Company; May 2017. Available at: https://www.strattera.com. Accessed June 5, 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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed March 26, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New step therapy policy created – replaces CP.PMN.01	07.31.17	11.17
3Q 2018 annual review: removed time frame for history of substance abuse; references reviewed and updated.	06.05.18	08.18

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 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.

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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.