Clinical Policy: Atomoxetine (Strattera)

Reference Number: ERX.NPA.85
Effective Date: 09.01.18
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
Atomoxetine (Strattera®) is a 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.

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 Strattera is **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. Member or parent/guardian of member has a history of substance abuse;
   b. Failure of two formulary, extended-release, central nervous system stimulants (i.e., amphetamine or methylphenidate) from the same therapeutic class, each tried at maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Member must use generic atomoxetine, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 100 mg (1 capsule) per day.

Approval duration: 12 months

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 100 mg (1 capsule) per day.

Approval duration: 12 months

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
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
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
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® (methylphenidate ER)		51.8 mg/day
Adhansia XR (methylphenidate)		6 to 17 years: 70 mg Adults: 85 mg

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 atomoxetine or other constituents of product
  - 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
- Boxed warning(s): increased risk of suicidal ideation in children and adolescents

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; February 2020. Available at: www.strattera.com. Accessed April 29, 2021.
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. 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.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 29, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from ERX.ST.04; removed time frame for history of substance abuse; removed 2 week length of trial for amphetamine and methylphenidate; removed re-direction to guanfacine ER per current formulary status; references reviewed and updated.	06.05.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.05.19	08.19
3Q 2020 annual review: no significant changes; 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 from one therapeutic class; added redirection to generic atomoxetine; references reviewed and updated.	04.29.21	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.