Clinical Policy: Atomoxetine (Strattera)
Reference Number: ERX.ST.04
Effective Date: 09.01.17
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] 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
Strattera is indicated for the treatment of attention-deficit/hyperactivity disorder.

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 health plans affiliated with Envolve Pharmacy Solutions™ that Strattera is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. Step Therapy for Strattera (must meet all)**:**
1. Age ≥ 6 years;
2. Member meets one of the following (a or b):
   a. Previous use of one amphetamine and one methylphenidate based product, each trialed for ≥ 2 weeks, unless all are contraindicated or clinically significant adverse effects are experienced;
   b. Member or parent/guardian of member has a history of substance abuse within the past 2 years;
3. Previous use of guanfacine ER (Intuniv) unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 100 mg/day

Approval duration: 12 months

II. Continued Therapy
A. Step Therapy for Strattera (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. If request is for a dose increase, new dose does not exceed 100 mg/day.

Approval duration: 12 months

III. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Guanfacine ER (Intuniv®)	1 mg to 7 mg (0.05-0.12 mg/kg target weight based dose range) once daily in the morning or evening based on clinical response and tolerability	Monotherapy: children 6 to 12 years: 4 mg/day; adolescents: 13 to 17 years: 7 mg/day Adjunct therapy (with psychostimulants): 4 mg/day
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 (children ≥ 6 years 20-30 mg/day)
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® (methylphenidate ER)		51.8 mg/day

IV. Dosage and Administration

Strattera is recommended to be administered orally once or twice daily.

Indication	Dosing Regimen	Maximum Dose

Attention-deficit/hyperactivity disorder	Body Weight	Initial Daily Dose	Target Total Daily Dose	Maximum Total Daily Dose	100 mg/day
	Children and adolescents up to 70 kg	0.5 mg/kg	1.2 mg/kg	1.4 mg/kg	
	Children and adolescents over 70 kg and adults	40 mg	80 mg	100 mg	

V. Product Availability

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

VI. References

1. Strattera Prescribing Information. Indianapolis, IN: Eli Lilly and Company; May 2017. Available at: www.strattera.com. Accessed July 6, 2017.
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/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from ERX.NSST.06 Non-stimulant ADHD Agents (Strattera, Intuniv, Kapvay) and converted to new template. Initial: modified stimulant trials by removing extended release requirement; added 'within the past 2 years' to criterion related to history of substance abuse; modified failure of guanfacine and clonidine to failure of guanfacine only; updated generalized FDA approved max dose/health plan approved QL statement to specific max dose of drug.	07/17	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.

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.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2017 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.