ADHD – Non Stimulant Agents

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Comments
Note: prior authorization applies to the brand, generic and branded generic name of all dose forms for the following products. Step therapy applies to only those specifically listed as Non-Preferred	
Atomoxetine: Strattera Atomoxetine	 Non-Preferred Preferred
Clonidine (extended release): Kapvay Onyda XR (clonidine extended-release) clonidine extended release	 Non-Preferred Non-Preferred Preferred (CA SG, CT, FL, GA, IN, KY, MD, ME, MO, NH, NV, NY, OH, TX, VA, WA, WI) and Non-Preferred (CA IND, CO)
Guanfacine (extended release): Intuniv guanfacine extended release	 Non-Preferred Preferred (CA SG, CT, FL, GA, IN, KY, MD, ME, MO, NH , NV, NY, OH, TX, VA, WA. WI) and Non-Preferred (CA IND, CO)
Viloxazine: Qelbree	 Non-Preferred

Attention deficit hyperactivity disorder (ADHD) may also be referred to as attention deficit disorder (ADD).

STEP THERAPY APPROVAL CRITERIA

Requests for a non-preferred, non-stimulant ADHD agent (Intuniv, Kapvay, Onyda XR Suspension, Strattera, Qelbree) may be approved if the following criteria are met:

I. Individual has had a trial and inadequate response or intolerance to one preferred non-stimulant agent atomoxetine (generic Strattera), clonidine extended-release (generic Kapvay) or guanfacine ER (generic Intuniv). Medication samples/coupons/discount cards are excluded from

consideration as a trial.; **OR**

II. If request is for Onyda XR, individual is unable to swallow oral clonidine extended-release (generic Kapvay) tablets due to a clinical condition, including but not limited to the following:
    A. Dysphagia; **OR**
    B. Individual's age.

PRIOR AUTHORIZATION APPROVAL CRITERIA

I. Requests for guanfacine extended-release (Intuniv), clonidine extended-release (Kapvay)**,** and atomoxetine (Strattera) may be approved if the following criteria are met:

    A. Individual is 6 years of age or older; **AND**
    B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD);

II. Requests for viloxazine (Qelbree) may be approved if the following criteria are met:

    A. Individual is 6 years of age or older; **AND**
    B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD).

III. Initial requests for Onyda XR (clonidine extended-release) suspension may be approved if the following criteria are met:

    A. Individual is 6 to 17 years of age; **AND**
    B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD).

    Continuation requests for Onyda XR (clonidine extended-release) suspension may be approved if the following criteria are met:

    A. Individual is 6 years of age or older; **AND**
    B. There is clinically significant improvement or stabilization in clinical symptoms of ADHD.

Requests for Strattera (atomoxetine) may not be approved for the following:

I. Individual has a diagnosis of narrow angle glaucoma; **OR**
II. Individual has a diagnosis of pheochromocytoma; **OR**
III. Individual has severe cardiac or vascular disorders whose condition would be expected to deteriorate if they experience increases in blood pressure or heart rate that could be clinically important; for example, 15 to 20 mm Hg in blood pressure or 20 beats per minute in heart rate; **OR**
IV. Individual is a child or adolescent with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased risk due to noradrenergic effects; **OR**
V. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days**; OR**
VI. Individual has active liver disease as noted by jaundice or laboratory evidence of liver injury.

Requests for Qelbree (viloxazine) may not be approved for the following:

I. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days; **OR**
II. Individual is currently using a sensitive CYP1A2 substrate or a CYP1A2 substrate with a narrow therapeutic range (such as, alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline, and melatonin) and cannot discontinue the agent.

Notes:
Strattera (atomoxetine) has a black box warning for suicidal ideation in children and adolescents. Strattera was noted to increase the risk of suicidal ideation in short-term studies in children or adolescents with ADHD. The risk of use with the clinical need should be considered. Comorbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Individuals who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Strattera is approved for ADHD in pediatric and adult individuals and not approved for major depressive disorder.

Qelbree (viloxazine) has a black box warning for suicidal thoughts and behaviors. In clinical studies, higher rates of suicidal thoughts and behavior were reported in pediatric patients with ADHD treated with Qelbree than in patients treated with placebo. Closely monitor all Qelbree-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors.

Key References:

1. American Academy of Pediatrics. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528. Available at: https://pediatrics.aappublications.org/content/pediatrics/144/4/e20192528.full.pdf. Accessed: June 25, 2024.
2. Charach A, Dashti B, Carson P, et al. Attention Deficit Hyperactivity Disorder: Effectiveness of Treatment in At-Risk Preschoolers; Long-Term Effectiveness in All Ages; and Variability in Prevalence, Diagnosis, and Treatment. Comparative Effectiveness Review No. 44. (Prepared by the McMaster University Evidence-based Practice Center under Contract No. MME2202 290-02-0020.) AHRQ Publication No. 12-EHC003-EF. Rockville, MD: Agency for Healthcare Research and Quality. October 2011. Last Review July 2012. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm. Accessed: June 25, 2024.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 25, 2024.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.
6. Post RE and Kurlansik SL. Diagnosis and Management of Attention-Deficit/Hyperactivity Disorder in Adults. Am Fam Physician. 2012; 85(9):890-896. Available from: http://www.aafp.org/afp/2012/0501/p890.html. Accessed June 25, 2024.