

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Evekeo (amphetamine sulfate)

Override(s)	Approval Duration
Prior Authorization	1 year – ADHD and narcolepsy
Quantity Limit	12 weeks – exogenous obesity

**Washington Medicaid – See State Specific Information Below*

**Maryland Medicaid – See State Specific Information Below*

Medications	Quantity Limit
Evekeo (amphetamine sulfate) tablets Evekeo (amphetamine sulfate) oral disintegrating tablets (ODT)	May be subject to quantity limit

APPROVAL CRITERIA

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

Requests for Evekeo (amphetamine sulfate) tablets in the treatment of ADHD and narcolepsy may be approved when the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred agent;

Preferred agents: atomoxetine, clonidine extended-release, dexamethylphenidate (IR and XR), dextroamphetamine-amphetamine tablet (IR and ER), dextroamphetamine tablet, dextroamphetamine SR capsules, the following generic methylphenidate agents [methylphenidate ER/SR/CR tablet, methylphenidate tablet/oral solution, methylphenidate ER 24-hr tablet (AB-rated generic Concerta), methylphenidate CD/ER/LA capsule], Metadate ER.

OR

- II. The preferred agent is not FDA-approved for the prescribed indication; **OR**
- III. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to the following:
 - A. Individual's age: **OR**
 - B. Other known disease state or medication contraindication which is not also associated with the requested non-preferred agent;

AND

- IV. Individual is 3 years of age or older; **AND**
- V. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD);

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

OR

- VI. Individual is 6 years of age or older; **AND**
- VII. Individual has a diagnosis of narcolepsy.

Requests for Evekeo (amphetamine sulfate) ODT in the treatment of ADHD may be approved when the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred agent;

Preferred agents: atomoxetine, clonidine extended-release, dexamethylphenidate (IR and XR), dextroamphetamine-amphetamine tablet (IR and ER), dextroamphetamine tablet, dextroamphetamine SR capsules, the following generic methylphenidate agents [methylphenidate ER/SR/CR tablet, methylphenidate tablet/oral solution, methylphenidate ER 24-hr tablet (AB-rated generic Concerta), methylphenidate CD/ER/LA capsule], Metadate ER.

OR

- II. The preferred agent is not FDA-approved for the prescribed indication; **OR**
- III. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to the following:
 - A. Individual's age: **OR**
 - B. Other known disease state or medication contraindication which is not also associated with the requested non-preferred agent;

AND

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

Requests for Evekeo (amphetamine sulfate) tablets as an adjunct treatment of exogenous obesity may be approved for a maximum of **12 weeks** if the individual meets all of the following criteria (**Applicable in CA ONLY**):

- I. Individual has a BMI of 30 kg/m² or greater; **AND**
- II. Individual has attempted to lose weight through a formalized weight management program (hypocaloric diet, exercise, and behavior modification) for at least 6 months prior to request for drug therapy; **AND**
- III. Individual is currently maintained on a reduced calorie diet and exercise program; **AND**
- IV. Individual is refractory to alternative therapy (including, but not limited to, other medications for weight loss); **AND**
- V. Individual is NOT receiving other medications for weight loss at the same time.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Evekeo (amphetamine sulfate) may not be approved in the presence of the following diagnoses:

- I. Advanced arteriosclerosis; **OR**
- II. Symptomatic cardiovascular disease; **OR**
- III. Moderate to severe hypertension; **OR**
- IV. Hyperthyroidism; **OR**
- V. Agitated states; **OR**
- VI. In individuals with a history of drug abuse.

Evekeo (amphetamine sulfate) ODT may not be approved in the presence of the following diagnoses:

- I. Structural cardiac abnormalities; **OR**
- II. Cardiomyopathy; **OR**
- III. Serious heart arrhythmia; **OR**
- IV. Coronary artery disease.

Note: Amphetamine agents have a black box warning for the potential for abuse and dependence. CNS stimulants have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Washington		<ul style="list-style-type: none"> • No Quantity Limits, duplication of therapy or duration will apply for adults 18 years of age and older • Provide indefinite coverage for members 21 years of age and younger ONLY IF PREVIOUSLY PRESCRIBED <ul style="list-style-type: none"> ○ If the member comes to us on the ADHD therapy, they can remain on that therapy regardless of formulary status (would need to have been on the same medication for 30 days within the past 90 days)
Maryland		<ul style="list-style-type: none"> • Behavioral health carved out in Maryland; however, pharmacy coverage is provided for the following agents and above criteria will be applied: <ul style="list-style-type: none"> ○ Kapvay (and generic) ○ Intuniv (and generic)

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 26, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. American Academy of Pediatrics. ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics*. 2011; 128:1007-1022. Available from: <http://pediatrics.aappublications.org/content/128/5/1007.full.pdf>. Accessed: June 26, 2019.
6. 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 26, 2019.
7. 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 26, 2019.