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

Evekeo (amphetamine sulfate)

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

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, dexmethylphenidate (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	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	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, dexmethylphenidate (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	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	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. Uncontrolled moderate to severe hypertension; **OR**
IV. Hyperthyroidism; **OR**
V. Agitated states; **OR**
VI. In individuals with a history of drug abuse; **OR**
VII. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

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; **OR**
V. Individual is currently using a monoamine oxidase inhibitor (MAOI) or has used an MAOI in the previous 14 days.

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.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: July 12, 2020.
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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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

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8. 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.
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12. Geffen J, Forster K. Treatment of adult ADHD: A clinical perspective. Therapeutic Advances in Psychopharmacology. 2018;8:25.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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