

Pharmacy Policy Bulletin

Title: Amphetamine sulfate (Evekeo®)

Policy #: Rx.01.173

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▾ Intent:

The intent of this policy is to communicate the medical necessity criteria for amphetamine sulfate (Evekeo®) as provided under the member's prescription benefit.

▾ Description:

Amphetamines are non-catechol, sympathomimetic amines that cause the release and block the reuptake of norepinephrine and dopamine from central noradrenergic neurons. Amphetamines produce central nervous system (CNS) and respiratory stimulation as well as peripheral vasoconstriction. Evekeo® is amphetamine as the racemic mixture of l- and d-isomers. The l-isomer is less potent than the d-isomer in causing CNS stimulatory effects and more potent than the d-isomer in cardiovascular activity. The racemic mixture is less effective as an anorexigenic than the d-isomer.

The exact mechanism of action is unclear, but it is believed amphetamines act in the cerebral cortex and reticular-activating system to exert the CNS stimulating effects. Peripheral effects are thought to be the result of direct effect of amphetamines on the alpha and beta receptors in the periphery in addition to release of stores of norepinephrine in adrenergic nerve terminals. The anorexigenic effects are thought to be the result of stimulation of the hypothalamic feeding center in the CNS.

Evekeo® (amphetamine sulfate) is approved for the following indications:

- A. Narcolepsy
- B. Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program
- C. Exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patient's refractory to alternative therapy.

▶ **Policy:**

Eveko® (amphetamine sulfate) is approved when ONE of the following is met:

- A. Narcolepsy and recommended by a neurologist or sleep specialist with inadequate response or inability to tolerate generic modafinil; or
- B. Attention Deficit Disorder with Hyperactivity (ADHD) with inadequate response or inability to tolerate TWO of the following generic stimulant agents for ADHD:
 - 1. Methylphenidate
 - 2. Mixed amphetamine salts
 - 3. Dextroamphetamine
 - 4. Methamphetamine hydrochloride
 - 5. Dexmethylphenidate

OR

- C. Exogenous Obesity:
 - 1. If member has weight loss agents rider please refer to Weight loss agents policy for approval criteria and duration
 - 2. If member does not have a weight loss agents rider, deny as a benefit exclusion*

***Drugs that are used for weight loss are covered only with weight loss rider**

▶ **Black Box Warning:**

Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependence and must be avoided. Particular attention should be paid to the possibility of subjects obtaining amphetamines for non-therapeutic use or distribution to others, and the drugs should be prescribed or dispensed sparingly.

Misuse of amphetamines may cause sudden cardiac death and serious cardiovascular adverse events.

▶ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.


BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ **References:**

- 1. Amphetamine. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed July 24, 2018.
- 2. 2 Evekeo (amphetamine sulfate) [package insert]. Atlanta GA. Arbor Pharmaceuticals, LLC. September 2016. Accessed July 24, 2018

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Evekeo®	Amphetamine sulfate

Cross References:

Weight loss agents Rx.01.94

Policy Version Number:	4.00
P&T Approval Date:	July 12, 2018
Policy Effective Date:	October 01, 2018
Next Required Review Date:	July 12, 2019

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.