

Pharmacy Policy Bulletin

Title: Epinephrine Pen Policy

Policy #: Rx.01.142

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 Auvi-Q® as provided under the member's prescription drug benefit.

▶ **Description:**

Epinephrine pens are indicated for the emergency treatment of allergic reactions (type I), including anaphylaxis, which may result from allergic reactions to insect stings, biting insects, foods, drugs, sera, diagnostic testing substances and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Epinephrine is a sympathomimetic catecholamine that is an agonist at alpha and beta adrenergic receptors. Through its effects at the alpha adrenergic receptors, epinephrine cause vasoconstriction to counter vasodilation and increased vascular permeability that may occur during an anaphylactic reaction.

Currently available products include Epi-Pen® and Auvi-Q®, and epinephrine auto-injectors.

▶ **Policy:**

Auvi Q® is approved when ONE of the following is met:

1. Documentation of a demonstrated inability to use BOTH Epi-Pen and one chemically equivalent generic agent; or
2. The member has a genuine allergic reaction to an inactive ingredient in generic agent(s) or EpiPen (allergic reaction(s) must be clearly documented in the patient's medical record); or

3. Documentation that the member or the member's caregivers would be unable to utilize the alternative epinephrine auto-injector devices (e.g. Epi-Pen®, epinephrine) due to significant visual, physical, or functional impairment

Epi-Pen® does not require prior authorization

Black Box Warning:

None

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:

Auvi-Q® (epinephrine injection) [package insert]. Richmond, VA. Kaleo, Inc. Nov 2017. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=6180fb40-7fca-4602-b3da-ce62b8cd2470&type=display>. Accessed July 20, 2018.

Applicable Drugs:

i 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
Auvi-Q®	Epinephrine

Cross References:

Quantity Level Limits for Pharmaceuticals Covered Under the Pharmacy Benefit

Policy Version Number:	6.00
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.