



Medication Policy Manual

Policy No: dru484

Topic: High-Cost Epinephrine Autoinjectors

Date of Origin: January 27, 2017

- Auvi-Q®
- Adrenaclick®
- Adrenaclick® authorized generic

Committee Approval Date: February 17, 2017

Next Review Date: February 2018

Effective Date: February 17, 2017

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Epinephrine autoinjectors contain epinephrine, a non-selective alpha and beta-adrenergic receptor agonist, and are used in the emergency treatment of allergic reactions (Type I) including anaphylaxis. [1-3]

Policy/Criteria

- I. Most contracts require prior authorization approval of high-cost epinephrine autoinjectors (Auvi-Q[®], Adrenaclick[®], and Adrenaclick[®] authorized generic) prior to coverage. High-cost epinephrine autoinjectors (Auvi-Q[®], Adrenaclick[®], and Adrenaclick[®] authorized generic) may be considered medically necessary when criteria A or B below is met.
- A. Auvi-Q[®] may be considered medically necessary when there is clinical documentation of visual or functional impairment which makes the member or member's caretaker unable to use alternative mechanisms of epinephrine delivery (as specified in Table 1). Please note there is no prior authorization requirement for the epinephrine autoinjectors listed in Table 1.
- OR**
- B. Adrenaclick[®] and Adrenaclick[®] authorized generic may be considered medically necessary when there is a documented intolerance or contraindication to an **INACTIVE** ingredient in the specified alternative in Table 1.
- II. OmedaRx considers high-cost epinephrine autoinjectors to be self-administered medications.
- III. Use of epinephrine autoinjectors is considered investigational when used for all other conditions other than the emergency treatment of allergic (Type I) reactions including anaphylaxis.

Position Statement

Summary

- Epinephrine autoinjectors are considered first-line treatment for relieving symptoms associated with anaphylaxis in the outpatient setting based on years of clinical experience, clinical practice guidelines, and expert consensus.
- There is no clinical data to support efficacy of epinephrine autoinjector products in the outpatient setting. Recommendations are based on clinical experience and expert opinion. [4-6]
- There is no high-quality efficacy or safety data available to distinguish one epinephrine autoinjector product from another. Current clinical practice guidelines from the American Academy of Allergy, Asthma & Immunology (AAAAI), the American College of Allergy, Asthma & Immunology (ACAAI), and the Joint Council of Allergy, Asthma and Immunology as well as international guidelines from the World Allergy Organization (WAO) do not distinguish between epinephrine autoinjector products. [5,6]

Other formulations of epinephrine autoinjectors provide the best value. High-cost epinephrine autoinjectors (Auvi-Q®, Adrenaclick®, and Adrenaclick® authorized generic) have not been proven to be safer or more effective than other products, but are more costly.

- The recommended dose of epinephrine autoinjectors is one prefilled injection administered to the thigh immediately at the time of emergency therapy. No more than two sequential doses should be administered without direct medical supervision. [1-3]
- Patients should immediately seek emergency medical or hospital care in conjunction with administration of epinephrine.

Clinical Efficacy

- There are no clinical trials establishing the efficacy of epinephrine autoinjectors in the outpatient setting.

Investigational Uses

- There are no high-quality published clinical trials evaluating the safety or efficacy of epinephrine autoinjectors outside of the emergency treatment of allergic (Type I) reactions and anaphylaxis.

Table 1. Alternative epinephrine autoinjectors
EpiPen/EpiPen Jr.
EpiPen/EpiPen Jr. authorized generic

Cross References
None

Codes	Number	Description
N/A		None

References

1. AUVI-Q® (epinephrine injection, USP) 0.3 mg, 0.15 mg Auto-Injector, for intramuscular or subcutaneous use. Richmond, VA: Kaleo, Inc.; May 2016
2. EPIPEN® (epinephrine injection, USP), Auto-Injector 0.3 mg, EPIPEN Jr ® (epinephrine injection, USP) Auto-Injector 0.15 mg, for intramuscular or subcutaneous use [Prescribing Information]. Morgantown, WV Mylan Specialty L.P.; May 2016
3. ADRENACLICK® (epinephrine injection, USP) 0.3 mg, 0.15 mg AutoInjector, for intramuscular or subcutaneous use [Prescribing Information] Horsham, PA: Amedra Pharmaceuticals LLC; May 2016
4. Sheikh, A, Simons, FE, Barbour, V, Worth, A. Adrenaline auto-injectors for the treatment of anaphylaxis with and without cardiovascular collapse in the community. *The Cochrane database of systematic reviews*. 2012 Aug 15(8):CD008935. PMID: 22895980
5. Lieberman, P, Nicklas, RA, Oppenheimer, J, et al. The diagnosis and management of anaphylaxis practice parameter: 2010 update. *J Allergy Clin Immunol*. 2010;126:477-80 e1-42. PMID: 20692689
6. Simons, FE, Arduoso, LR, Dimov, V, et al. World Allergy Organization Anaphylaxis Guidelines: 2013 update of the evidence base. *Int Arch Allergy Immunol*. 2013;162:193-204. PMID: 24008815

Revision History

Revision Date	Revision Summary
02/17/2017	Adrenaclick and Adrenaclick authorized generic criteria added
01/27/2017	New policy (effective 2/1/2017)