

STEP THERAPY POLICY

- POLICY:** Epinephrine Auto-Injectors Step Therapy Policy
- Auvi-Q® (epinephrine injection, USP auto-injector – Kaleo)
 - EpiPen® (epinephrine injection, USP auto-injector – Mylan Specialty, generics)
 - EpiPen Jr® (epinephrine injection, USP auto-injector – Mylan Specialty, generics)

REVIEW DATE: 02/03/2021

OVERVIEW

Auvi-Q, EpiPen, and EpiPen Jr. are indicated for the emergency treatment of **severe allergic reactions** (Type I) including anaphylaxis to stinging and biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens, as well as anaphylaxis to unknown substances and exercise-induced anaphylaxis.^{1,2} An authorized generic to Adrenaclick® (epinephrine injection, USP auto-injector) and Symjepi™ (epinephrine injection, USP prefilled syringe), a self-administered epinephrine prefilled syringe, are also available and have the same indication as the other auto-injectors.⁵ However, these agents are not targeted in this policy.

All of the epinephrine auto-injectors are administered and dosed similarly.¹⁻³ Auvi-Q differs from the other auto-injectors in that it provides audible (electronic voice instructions, beeps) and visual (LED light) cues for use.¹ Auvi-Q is also the only epinephrine auto-injector available as a 0.1 mg strength indicated in patients weighing 7.5 kg to 15 kg. There are no clinical trials comparing the efficacy of the available epinephrine auto-injectors. However, a 2013 single-blind, crossover study compared the bioavailability of epinephrine injected via Auvi-Q or EpiPen in healthy adults and found that a single injection of 0.3 mg epinephrine from either device resulted in similar peak and total epinephrine exposure.⁶

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. Note: Symjepi, Adrenaclick (no longer available) and the authorized generic to Adrenaclick (Amneal Pharmaceuticals) are not targeted in this policy. All approvals are provided for 1 year in duration.

Automation: None

Step 1: epinephrine auto-injector 0.15 mg and 0.3 mg (generics to EpiPen/EpiPen Jr.)

Step 2: Auvi-Q 0.1 mg, Auvi-Q 0.15 mg, Auvi-Q 0.3 mg, EpiPen 0.15 mg, EpiPen Jr. 0.3 mg

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient or caregiver is blind or significantly visually-impaired, approve Auvi-Q.
3. If the patient weighs < 15 kg (33 pounds), approve Auvi-Q 0.1 mg auto-injector.
4. No other exceptions are recommended.

REFERENCES

1. Auvi-Q[®] auto-injector [prescribing information]. Richmond, VA: Kaleo, Inc.; September 2019.
2. EpiPen[®] and EpiPen Jr[®] injection [prescribing information]. Morgantown, WV: Mylan Specialty LP; December 2020.
3. Epinephrine auto-injector [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; June 2019.
4. FDA listing of authorized generics. U.S. Food and Drug Administration Web site. Available at: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm>. Updated December 28, 2020. Accessed on January 4, 2021.
5. Symjepi[™] injection [prescribing information]. San Diego, CA: Adamis Pharmaceuticals Corporation; September 2018.
6. Edwards ES, Gunn R, Simons ER, et al. Bioavailability of epinephrine from Auvi-Q compared with EpiPen. *Ann Allergy Asthma Immunol*. 2013;111(2):132-137.