

## STEP THERAPY POLICY

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

**REVIEW DATE:** 01/24/2024

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### OVERVIEW

EpiPen and EpiPen Jr. (generics) 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.<sup>1</sup> Auvi-Q® (epinephrine injection, USP auto-injector), 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 EpiPen/EpiPen auto-injectors.<sup>2-5</sup> However, these agents are not targeted in this policy.

All of the epinephrine auto-injectors are administered and dosed similarly.<sup>1</sup> Patients who weigh  $\geq 30$  kg should be administered a dose of 0.3 mg (given via EpiPen [generic]), while patients weighing 15 kg to 30 kg should be administered 0.15 mg (EpiPen Jr. [generic]).

### 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. All approvals are provided for 1 year in duration.

Note: Auvi-Q, Symjepi, Adrenaclick (no longer available) and the authorized generic to Adrenaclick are not targeted in this policy.

**Automation:** None.

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

**Step 2:** 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. No other exceptions are recommended.

01/24/2024

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**REFERENCES**

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2. Auvi-Q® auto-injector [prescribing information]. Richmond, VA: Kaleo; September 2019.
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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 January 4, 2024. Accessed on January 16, 2024.
5. Symjepi® injection [prescribing information]. San Diego, CA: Adamis; June 2021.