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Step Therapy
Epinephrine Auto-Injectors

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107675
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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Auvi-Q® (epinephrine injection, USP auto-injector)
EpiPen® (epinephrine injection, USP auto-injector, generic)
EpiPen Jr® (epinephrine injection, USP auto-injector, generic)

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 are not targeted in this policy. All approvals are provided for 1 year in duration.

Step 1: epinephrine auto-injector 0.15 mg and 0.3 mg (generic 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

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.
2. If the individual or caregiver is blind or significantly visually-impaired, approve Auvi-Q.
3. If the individual weighs < 15 kg (33 pounds), approve Auvi-Q 0.1 mg auto-injector.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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 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

References

1. Auvi-Q® auto-injector [prescribing information]. Richmond, VA: Kaleo; September 2019.
2. EpiPen® and EpiPen Jr® injection [prescribing information]. Morgantown, WV: Mylan Specialty; February 2023.
3. Epinephrine auto-injector [prescribing information]. Bridgewater, NJ: Amneal; March 2021.
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 15, 2022. Accessed on February 15, 2023.
5. Symjepi® injection [prescribing information]. San Diego, CA: Adamis; June 2021.
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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	03/01/2023

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