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Epinephrine Injection (Self-Administered)

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for self-administered epinephrine products:

- Auvi-Q® (epinephrine) 0.3 mg, 0.15 mg, 0.1 mg auto-injector
• epinephrine 0.3 mg, 0.15 mg auto-injector (Adrenaclick® authorized generic)
• EpiPen® or EpiPen Jr. (epinephrine) 0.3 mg, 0.15 mg auto-injector
• Symjepi™ (epinephrine) 0.3 mg, 0.15 mg pre-filled syringe

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage for self-administered epinephrine products varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and Preferred Covered Alternatives:

Non-Covered Product	Criteria
<b>Auvi-Q</b> (epinephrine) 0.1 mg auto-injector	There is documentation of the following (A): A. Individual weighs 16.5 to 33 pounds (7.5 to 15 kg)
<b>Auvi-Q</b> (epinephrine) 0.3 mg, 0.15 mg auto-injector	There is documentation of <b>ONE</b> of the following (A, B <u>or</u> C): A. The individual has had an intolerance to epinephrine auto-injector (EpiPen/EpiPen Jr. generics) B. Documented inability to obtain epinephrine auto-injector (EpiPen/EpiPen Jr. generics) C. Individual or his/her caregiver is blind or significantly visually impaired
<b>epinephrine</b> 0.3 mg, 0.15 mg auto-injector (Adrenaclick authorized generic)	There is documentation of <b>ONE</b> of the following (A <u>or</u> B): A. The individual has had an intolerance to epinephrine auto-injector (EpiPen/EpiPen Jr. generics) B. Documented inability to obtain epinephrine auto-injector (EpiPen/EpiPen Jr. generics)
<b>EpiPen or EpiPen Jr.</b> (epinephrine) 0.3 mg, 0.15 mg auto-injector	There is documentation of <b>ONE</b> of the following (A <u>or</u> B): A. The individual has had an intolerance to epinephrine auto-injector (EpiPen/EpiPen Jr. generics) B. Documented inability to obtain epinephrine auto-injector (EpiPen/EpiPen Jr. generics)
<b>Symjepi</b> (epinephrine) 0.3 mg, 0.15 mg pre-filled syringe	There is documentation of <b>ONE</b> of the following (A <u>or</u> B): A. The individual has had an intolerance to epinephrine auto-injector (EpiPen/EpiPen Jr. generics) B. Documented inability to obtain epinephrine auto-injector (EpiPen/EpiPen Jr. generics)

**When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.**

## Reauthorization Criteria

Self-administered epinephrine products are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

## 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.<sup>1,2</sup> 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.<sup>5</sup> However, these agents are not targeted in this policy.

All of the epinephrine auto-injectors are administered and dosed similarly.<sup>1-3</sup> Auvi-Q differs from the other auto-injectors in that it provides audible (electronic voice instructions, beeps) and visual (LED light) cues for use.<sup>1</sup>

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.<sup>6</sup>

## 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.

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