

QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

AUVI-Q
(epinephrine solution auto-injector)

(epinephrine solution auto-injector)

EPIPEN, EPIPEN JR
(epinephrine solution auto-injector)

NEFFY
(epinephrine nasal spray)

SYMJEPI
(epinephrine solution prefilled syringe)

Status: CVS Caremark® Criteria

Type: Quantity Limit; Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

AUVI-Q

AUVI-Q is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

AUVI-Q is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Anaphylactic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

AUVI-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care.

Epinephrine Injection (generic for Adrenaclick)

Epinephrine injection is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which includes bees, wasps, hornets, yellow jackets and fire ants), and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media), and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Epinephrine injection is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Anaphylactic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria, or angioedema.

Epinephrine injection is intended for immediate administration as emergency supportive therapy only and

Epinephrine Injectable, Nasal Limit, Post PA Policy UDR 02-2024 v2.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2024 CVS Health and/or its affiliates. All rights reserved. 106-58428J 021423

is not a replacement or substitute for immediate medical care.

EpiPen and EpiPen Jr.

EpiPen and EpiPen Jr are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

EpiPen and EpiPen Jr are intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Anaphylactic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

EpiPen and EpiPen Jr are intended for immediate administration as emergency supportive therapy only and are not a substitute for immediate medical care.

Neffy

Neffy is indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.

Symjepi

Symjepi is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Symjepi is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Anaphylactic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

Symjepi is intended for immediate administration as emergency supportive therapy only and is not a substitute for immediate medical care.

INITIAL QUANTITY LIMIT**

INITIAL LIMIT QUANTITY

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed.

Drug	1 Month Limit*	3 Month Limit*
epinephrine solution auto-injector	4 auto-injectors / 25 days	12 auto-injectors / 75 days
epinephrine prefilled syringe	4 prefilled syringes / 25 days	12 prefilled syringes / 75 days
epinephrine nasal spray	4 nasal sprays / 25 days	12 nasal sprays / 75 days

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

**If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

Epinephrine Injectable, Nasal Limit, Post PA Policy UDR 02-2024 v2.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2024 CVS Health and/or its affiliates. All rights reserved. 106-58428J 021423

Authorization may be granted for the requested drug when the following criteria is met:

- The patient needs more than 4 epinephrine auto-injectors, prefilled syringes, or nasal sprays per 30 days due to a need for availability in multiple locations or as replacement due to use

QUANTITY LIMITS APPLY

8 auto-injectors, prefilled syringes, or nasal sprays / 25 days* or 24 auto-injectors, prefilled syringes, or nasal sprays / 75 days*

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

DURATION OF APPROVAL (DOA)

- 2927-HJ: DOA: 12 months

REFERENCES

1. Auvi-Q [package insert]. Richmond, VA: Kaleo, Inc.: December 2022.
2. EpiPen [package insert]. Morgantown, WV: Mylan Specialty L.P.: February 2023.
3. Symjepi [package insert]. Louisville, KY: USWM, LLC: July 2021.
4. Epinephrine [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC.: January 2021.
5. Neffy [package insert]. San Diego, CA: ARS Pharmaceuticals Operations, Inc.: August 2024.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed December 29, 2023.
7. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/27/2023).