

Clinical Policy Title:	epinephrine
Policy Number:	RxA.19
Drug(s) Applied:	Auvi-Q®, EpiPen®, EpiPen Jr®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All Line of Business

Background

Auvi-Q®, EpiPen®, EpiPen Jr® is a non-selective alpha and beta-adrenergic receptor agonist, indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
epinephrine (Auvi-Q®)	allergic reactions (Type I) including anaphylaxis	Greater than or equal to 30 kg (66 lbs): 0.3 mg 15 to 30 kg (33 lbs to 66 lbs): 0.15 mg 7.5 to 15 kg (16.5 to 33 lbs): 0.1 mg IM/SC into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-dose injection	2 sequential doses
epinephrine (EpiPen®)	allergic reactions (Type I) including anaphylaxis	Greater than or equal to 30 kg (66 lbs): 0.3 mg IM/SC into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-dose injection.	2 sequential doses (0.6 mg)
epinephrine (EpiPen Jr®)	allergic reactions (Type I) including anaphylaxis	15 to 30 kg (33 lbs to 66 lbs): 0.15 mg IM/SC into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-dose injection.	2 sequential doses (0.3 mg)

Dosage Forms

- epinephrine (Auvi-Q®): Injection, 0.3 mg: 0.3 mg/0.3 mL epinephrine, USP, pre-filled auto-injector; Injection, 0.15 mg: 0.15 mg/0.15 mL epinephrine, USP, pre-filled auto-injector; Injection, 0.1 mg: 0.1 mg/0.1 mL epinephrine,

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

USP, pre-filled auto-injector.

- epinephrine (EpiPen®): Injection, 0.3 mg: 0.3 mg/0.3 mL epinephrine, USP, pre-filled auto-injector.
- epinephrine (EpiPen Jr®): Injection, 0.15 mg: 0.15 mg/0.3 mL epinephrine, USP, pre-filled auto-injector.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Auvi-Q®/EpiPen®/EpiPen Jr® in Excess of 4 Pens per 365 Days (must meet all):

1. One of the following requirements is met (a or b):
 - a. Provider submits documentation supporting the use of previous Auvi-Q®, EpiPen®, or EpiPen® Jr fills, including the date(s) of use, and that immediate medical or hospital care was received in conjunction with administration of Auvi-Q®, EpiPen®, or EpiPen® Jr;
 - b. Provider submits documentation supporting that the most recent fill for Auvi-Q®, EpiPen®, or EpiPen® Jr has expired, including the expiration date.

Approval Duration

Commercial: 1 Auvi-Q® 2-pack, 1 EpiPen® 2-Pak, or 1 EpiPen® Jr 2-Pak

Medicaid: 1 Auvi-Q® 2-pack, 1 EpiPen® 2-Pak, or 1 EpiPen® Jr 2-Pak

II. Continued Therapy Approval

A. Auvi-Q®/EpiPen®/EpiPen Jr® in Excess of 4 Pens per 365 Days (must meet all):

1. Continuation of therapy will not be granted. Member must be evaluated against the initial approval criteria.

Approval Duration

Commercial: Not applicable

Medicaid: Not applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - o None
- Boxed Warning(s):
 - o None

APPENDIX D: General Information

- N/A

References

1. EpiPen® and EpiPen Jr® Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; November 24, 2020.

Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/019430s091lbl.pdf . Accessed February 4, 2021.

2. Auvi-Q® Prescribing Information. Richmond, VA: Kaleo, Inc.; November 28, 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/201739s015lbl.pdf. Accessed February 4, 2021.
3. Lieberman P, Nicklas RA, Randolph C, et al. Anaphylaxis--a practice parameter update 2015. *Ann Allergy Asthma Immunol.* 2015;115(5):341-384.
4. Simons FE, Ebisawa M2, Sanchez-Borges M, et al. 2015 update of the evidence base: World Allergy Organization anaphylaxis guidelines. *World Allergy Organ J.* 2015 Oct 28;8(1):32.
5. Sicherer SH, Simons FER; Section on Allergy and Immunology. epinephrine for first-aid management of anaphylaxis. *Pediatrics.* 2017;139(3). doi: 10.1542/peds.2016-4006.
6. epinephrine. Lexi-Drugs. Hudson, OH: Lexicomp, 2020. <http://online.lexi.com/>. Updated February 1, 2021. Accessed February 4, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
References updated	05/07/2020	05/20/2020
Policy was reviewed: 1. Clinical policy title table was updated. 2. Drug(s) applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Dosing information was updated for indication. 5. Appendix B: "Therapeutic alternatives verbiage was updated to below are suggested therapeutic alternatives based on clinical guidance...." 6. Appendix D added. 7. References were reviewed and updated. 8. Updated dosing information to include IM/SC into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-dose injection. 9. Background rephrased to: Auvi-Q®, EpiPen®, EpiPen Jr® is a non-selective alpha and beta-adrenergic receptor agonist, indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis.	02/05/2021	03/09/2021