Clinical Policy Title:	epinephrine
Policy Number:	RxA.019
Drug(s) Applied:	Auvi-Q®
Original Policy Date:	02/07/2020
Last Review Date:	01/17/2022
Line of Business Policy Applies to:	All Line of Business

Background

Auvi-Q® 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 intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-dose injection	2 sequential doses. More than 2 sequential doses should only be administered under direct medical supervision.

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, 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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Auvi-Q® 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® fills, including the date(s) of use, and that immediate medical or hospital care was received in conjunction with administration of Auvi-Q®;
   b. Provider submits documentation supporting that the most recent fill for Auvi-Q® has expired, including the expiration date.

Approval Duration
Commercial: 1 Auvi-Q® 2-pack
Medicaid: 1 Auvi-Q® 2-pack

II. Continued Therapy Approval

A. Auvi-Q® 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):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Not applicable

References

1. EpiPen® and EpiPen Jr® Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; December 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=7560c201-9246-487c-a13b-6295db04274a&type=display. Accessed December 07, 2021.
2. Auvi-Q® Prescribing Information. Richmond, VA: Kaleo, Inc.; September 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. Available at: https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/2015-Anaphylaxis-PP-Update.pdf. Accessed December 07, 2021.
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. Available at: https://pubmed.ncbi.nlm.nih.gov/26525001/. Accessed December 07, 2021.
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. Available at: https://pubmed.ncbi.nlm.nih.gov/28193791/. Accessed December 07, 2021
6. epinephrine. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed December 07, 2021.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed December 07, 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
Policy was reviewed: 1. Dosing Information, Maximum Dose,	12/07/2021	01/17/2022

a. Auvi-Q®: Updated maximum dosing information to add," More than 2 sequential doses should only be administered under direct medical supervision" and indication for therapy for indication allergic reactions (Type I) including anaphylaxis. 2. Updated the policy title background, dosing information, dosage forms, clinical policy to remove information about EpiPen and EpiPen Jr as they currently do not need prior authorization. 3. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 4. References were reviewed and updated.		