

Clinical Policy: Epinephrine (Auvi-Q, EpiPen, EpiPen Jr, Neffy) Quantity Limit Override

Reference Number: CP.PMN.144

Effective Date: 08.01.16

Last Review Date: 08.24

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Epinephrine (Auvi-Q[®], EpiPen[®], EpiPen Jr[®], Neffy[®]) is a non-selective alpha and beta-adrenergic receptor agonist.

FDA Approved Indication(s)

Auvi-Q, EpiPen, and EpiPen Jr are indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis.

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

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation[®] that a quantity of Auvi-Q, EpiPen, EpiPen Jr, and Neffy in excess of the health plan quantity limit is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Auvi-Q/EpiPen/EpiPen Jr/Neffy in Excess of the Health Plan Quantity Limit (must meet all):

1. One of the following (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;
2. For Neffy requests: Member weighs \geq 30 kg.

Approval duration: one Auvi-Q 2-pack, one EpiPen 2-Pak, one EpiPen Jr 2-Pak, or one Neffy 2-pack

B. Other diagnoses/indications: Not applicable

II. Continued Therapy

A. Auvi-Q/EpiPen/EpiPen Jr/Neffy in Excess of the Health Plan Quantity Limit

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

Approval duration: Not applicable

B. Other diagnoses/indications: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Epinephrine (Auvi-Q)	IM/SC into the anterolateral aspect of the thigh: <ul style="list-style-type: none"> ≥ 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 	2 sequential doses
Epinephrine (EpiPen)	≥ 30 kg (66 lbs): 0.3 mg IM/SC into the anterolateral aspect of the thigh	2 sequential doses (0.6 mg)
Epinephrine (EpiPen Jr)	15 to 30 kg (33 lbs to 66 lbs): 0.15 mg IM/SC into the anterolateral aspect of the thigh	2 sequential doses (0.3 mg)
Epinephrine (Neffy)	One spray into one nostril; In the absence of clinical improvement or if symptoms worsen after initial treatment, a second dose of Neffy may be administered in the same nostril with a new nasal spray starting 5 minutes after the first dose.	2 sequential doses (4 mg)

VI. Product Availability

Drug Name	Availability
Epinephrine (Auvi-Q)	Pre-filled auto-injector: 0.3 mg/0.3 mL, 0.15 mg/0.15 mL, 0.1 mg/0.1 mL (2 auto-injectors per package)
Epinephrine (EpiPen)	Pre-filled auto-injector: 0.3 mg/0.3 mL (2 pens per package)
Epinephrine (EpiPen Jr)	Pre-filled auto-injector: 0.15 mg/0.3 mL (2 pens per package)
Epinephrine (Neffy)	Nasal spray: 2 mg/0.1 mL per spray (2 nasal spray devices per carton)

VII. References

1. EpiPen and EpiPen Jr Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; February 2023. Available at: <https://www.epipen.com>. Accessed May 14, 2024.
2. Auvi-Q Prescribing Information. Richmond, VA: Kaleo, Inc.; February 2024. Available at: <https://www.auvi-q.com>. Accessed May 14, 2024.
3. Neffy Prescribing Information. San Diego, CA: ARS Pharmaceuticals Operations, Inc.; August 2024. Available at: https://www.ars-pharma.com/wp-content/uploads/pdf/Prescribing_Information.pdf. Accessed August 22, 2024.
4. Golden DBK, Wang J, Waserman S, et al. Anaphylaxis: a 2023 practice parameter update. *Ann Allergy Asthma Immunol.* 2024;132:124–76.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2021 annual review: no significant changes; references reviewed and updated.	03.22.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	03.24.22	08.22
3Q 2023 annual review: adjusted the stated existing quantity limit from 4 pens per 365 days to 8 pens per 365 days to reflect the actual current quantity limit; references reviewed and updated.	05.18.23	08.23
3Q 2024 annual review: no significant changes; references reviewed and updated.	05.14.24	08.24
RT4: added criteria for newly FDA-approved Neffy nasal spray product.	08.22.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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