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 4 years of age and older who weigh 15 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 ≥ 15 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

1. 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: • ≥ 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)	15 to < 30 kg kg (33 to < 66 lbs): One spray of Neffy 1 mg into one nostril ≥ 30 kg (66 lbs): One spray of Neffy 2 mg 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)

Drug Name	Availability
Epinephrine (EpiPen Jr)	Pre-filled auto-injector: 0.15 mg/0.3 mL (2 pens per package)
Epinephrine (Neffy)	Nasal spray: 1 mg/0.1 mL per 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.; March 2025. Available at: https://www.ars-pharma.com/wp-content/uploads/pdf/Prescribing_Information.pdf. Accessed March 13, 2025.
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	
RT4: updated Neffy indication and weight minimum and added new 1 mg strength to Section VI per updated prescribing information.	03.13.25	

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.