Clinical Policy: Epinephrine Injection Device – Quantity Limit Override

Reference Number: GA.PMN.03
Effective Date: 03/01/15
Last Review Date: 1/2025
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Injectable epinephrine 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.

FDA Approved Indication(s)
Epinephrine is indicated for 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, mosquitos), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

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 Epinephrine is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Type I Allergic Reactions – Quantity Limit Override (must meet all)**:**

1. Diagnosis of type I allergic reactions;
2. Member meets one of the following:
   a. Documentation of the use of previous medication fills. In conjunction with the administration of epinephrine, member should seek immediate medical or hospital care;
   b. Documentation of the injectable epinephrine expiration.

Approval duration: one 2-pack device

B. Other diagnosis/indications:
Not applicable

II. Continued Therapy

A. Type I Allergic Reactions – Quantity Limit Override (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Authorization for an additional 2-pack will be approved on a case-by-case basis

Approval duration: not to exceed a total of four 2-packs per 365 days

B. Other diagnosis/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

V. Dosage and Administration

Indication	Dosing Regimen
Type I allergic reactions	• 15-30kg: 0.15 mg • ≥30kg: 0.3 mg

VI. Product Availability
Refer to the respective package inserts for product availability.

VII. References
1. Epinephrine Injection® Prescribing Information. Basking Ridge, NJ: Mylan Specialty LP; Feb 2023. Available at: http://www.epipen.com. Accessed January 23, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.01.15	03.15
2Q 2016 annual review: no significant changes	05.01.16	05.16
1Q 2017 annual review: removed Epipen and replaced with injectable epinephrine	01.01.17	01.17
1Q 2018 annual review: no significant changes	01.01.18	01.18
2Q 2018 annual review: no significant changes	05.01.18	05.18
Changed current Georgia policy templates to corporate standard templates for drug coverage criteria to meet corporate compliance. Changes/revisions included; new formatting, font size, use of standard policy language for each section of policy, and rearranged order of certain steps in criteria and sections.	2/21/19	2/2019
Annual review. No changes made.	1/2020	1/2020
Annual review. No changes made	1/2021	1/2021
1Q 2022 annual review. No changes made.	1/2022	1/2022
1Q 2023 annual review. No changes made.	1/2023	1/2023
1Q 2024 annual review. References reviewed and updated	1/2024	1/2024

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2025 annual review. References reviewed and updated.	1/2025	1/2025

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.

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.

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.