

Clinical Policy: Epinephrine (EpiPen and EpiPen Jr)

Reference Number: CP.PPA.09

Effective Date: 08/16

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

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

### **Description**

Epinephrine (EpiPen<sup>®</sup>, EpiPen Jr<sup>®</sup>) is a non-selective alpha and beta-adrenergic receptor agonist.

### **FDA approved indication**

EpiPen and EpiPen Jr. are indicated in 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, mosquitoes), 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 (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that coverage of EpiPen and/or EpiPen Jr in excess of plan approved quantity limits is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

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

**Approval duration: One EpiPen 2-Pak or one EpiPen Jr 2-Pak**

#### **II. Continued Therapy**

##### **A. 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: N/A**

#### **III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

**V. Dosage and Administration**

| <b>Indication</b>   | <b>Dosing Regimen</b>  | <b>Maximum Dose</b>   |
|---|--|---|
| Emergency treatment of allergic reactions (Type I) including anaphylaxis. | <p>Patients greater than or equal to 30 kg (66 lbs): EpiPen 0.3 mg;<br/>                     Patients 15 to 30 kg (33 lbs to 66 lbs): EpiPen Jr 0.15 mg.</p> <p>Inject EpiPen or EpiPen Jr intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. With severe persistent anaphylaxis, repeat injections with an additional EpiPen or EpiPen Jr may be necessary.</p> | More than two sequential doses of epinephrine should only be administered under direct medical supervision. |

**VI. Product Availability**

| <b>Drug</b>             | <b>Availability</b>   |
|-------------------------|---|
| 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 |

**VII. Workflow Document**

N/A

**VIII. References**

1. EpiPen and EpiPen Jr Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; May 2016. Available at <https://www.epipen.com/>. Accessed March 27, 2017.

| <b>Reviews, Revisions, and Approvals</b> | <b>Date</b> | <b>P&amp;T Approval Date</b> |
|--|-------------|------------------------------|
| New policy.                              | 07/16       | 08/16                        |
| Converted to new template.               | 03/17       | 08/17                        |
|  |             |                              |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|-----------------------------------|------|-------------------|
|                                   |      |                   |

**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.

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.

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