

Clinical Policy: Respiratory Agents: Epinephrine Auto-Injectors

Reference Number: OH.PHAR.PPA.84

Effective Date: 01/01/2020

Last Review Date: 01/01/2020

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

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

RESPIRATORY AGENTS: EPINEPHRINE AUTO-INJECTORS

| NO PA REQUIRED “PREFERRED” | PA REQUIRED “NON-PREFERRED” |
|---|---|
| EPINEPHRINE manufactured by labeler 49502 (authorized generic of EpiPen®) SYMJEPI™ (epinephrine) | EPINEPHRINE not manufactured by labeler 49502 (generic of Adrenaclick®, EpiPen®) EPIPEN® (epinephrine) EPIPEN JR® (epinephrine) |

Description

The following epinephrine auto-injectors require prior authorization: EPINEPHRINE not manufactured by labeler 49502 (generic of Adrenaclick, EpiPen), EPIPEN (epinephrine), EPIPEN JR (epinephrine).

FDA Approved Indication(s)

Epinephrine Auto-Injectors are indicated in the emergency treatment of allergic reactions (Type I) including 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 Buckeye Health Plan, an affiliate of Centene Corporation®, that EPINEPHRINE not manufactured by labeler 49502 (generic of Adrenaclick, EpiPen), EPIPEN, EPIPEN JR are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prescribed indication is FDA-approved or supported by standard pharmacopeias:

1. Documented therapeutic failure of **two** preferred medications unless one of the following are met: (a, b or c)
 - a. Intolerance to medications not requiring prior approval
 - b. Contraindication to or drug interaction with medications not requiring prior approval
 - c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

CLINICAL POLICY
Infectious Disease Agents: Antibiotics - Cephalosporins



- 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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

PA: Prior Authorization

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

IV. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|-------------------------|--|-----------------------------|
| Epinephrine (EpiPen) | Greater than or equal to 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 (Symjepi) | Greater than or equal to 30 kg (66 lbs): 0.3 mg IM/SC into the anterolateral aspect of the thigh | 2 sequential doses (0.6 mg) |
| | 15 to 30 kg (33 lbs to 66 lbs): SYMJEPi 0.15 mg IM/SC into the anterolateral aspect of the thigh | 2 sequential doses (0.3 mg) |

V. Product Availability

| Drug Name | Availability |
|-------------------------|---|
| 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, prefilled auto-injector |
| Epinephrine (Symjepi) | Injection: Single-dose pre-filled syringe for manual injection, containing 0.15 mg/0.3 mL epinephrine sterile solution for injection, USP |
| | Injection: Single-dose pre-filled syringe for manual injection, containing 0.3 mg/0.3 mL epinephrine sterile solution for injection, USP |

VI. References

1. EpiPen and EpiPen Jr Prescribing Information. Basking Ridge, NJ: Mylan Specialty L.P.; August 2012. Available at <https://www.epipen.com/>. Accessed Nov 21 2019.

2. Symjepi Prescribing Information. San Diego, CA: Adamis Pharmaceuticals Corporation; June 2017. Available at <https://www.symjepi.com/>. Accessed Nov 21 2019.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|-----------------------------------|-------|-------------------|
| New policy | 01.01 | |

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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