BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

NEFFY® (epinephrine) nasal spray Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for NEFFY (epinephrine nasal spray)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by or in consultation with a physician specializing in allergy or immunology

Indication
- Emergency treatment of type I allergic reactions, including anaphylaxis

Age Requirement
- 4 years of age or older and weighing at least 15 kg

ORIGINAL EFFECTIVE DATE: 11/21/2024 | ARCHIVE DATE: | LAST REVIEW DATE: 11/20/2025 | LAST CRITERIA REVISION DATE: 11/20/2025

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Baseline Clinical Evaluation

- Confirmed diagnosis of type I allergic reactions, including anaphylaxis
- No underlying structural or anatomical nasal conditions (e.g., polyps, history of nasal fracture or injuries, or history of nasal surgery)

Alternative Therapies

- Failure, contraindication per FDA label, intolerance, or not a candidate for epinephrine auto injection
- No caregiver or family member willing or able to assist with home administration of epinephrine auto injection
- **ONE** of the following additional criteria:
  - Diagnosis of phobia preventing self administration (documentation from psychiatric evaluation required)
  - Unable to successfully self administer medication using proper technique due to physical or mental impairment

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications

- Continues to be seen by or in consultation with a physician specializing in allergy or immunology

Indication

- Emergency treatment of type I allergic reactions, including anaphylaxis

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Additional Requirements

- No underlying structural or anatomical nasal conditions (e.g., polyps, history of nasal fracture or injuries, or history of nasal surgery)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Neffy (epinephrine nasal spray) is an alpha and beta-adrenergic receptor agonist indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for Specific Phobias: (page 197)

A. Marked fear or anxiety about a specific object or situation (e.g., flying, heights, animals, receiving an injection, seeing blood). **Note**: In children, the fear or anxiety may be expressed by crying, tantrums, freezing, or clinging.

B. The phobic object or situation almost always provokes immediate fear or anxiety.

C. The phobic object or situation is actively avoided or endured with intense fear or anxiety.

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D. The fear or anxiety is out of proportion to the actual danger posed by the specific object or situation and to the sociocultural context.

E. The fear, anxiety, or avoidance is persistent, typically lasting for six months or more.

F. The fear, anxiety, or avoidance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

G. The disturbance is not better explained by the symptoms of another mental disorder, including fear, anxiety, and avoidance of situations associated with panic-like symptoms or other incapacitating symptoms (as in agoraphobia); objects or situations related to obsessions (as in obsessive-compulsive disorder); reminders of traumatic events (as in posttraumatic stress disorder); separation from home or attachment figures (as in separation anxiety disorder); or social situations (as in social anxiety disorder).

Specifiers based on the phobic stimulus:
- Animal (e.g., spiders, insects, dogs)
- Natural environment (e.g., heights, storms, water)
- Blood-injection-injury (e.g., needles, invasive medical procedures)
- Situational (e.g., airplanes, elevators, enclosed places)
- Other (e.g., situations that may lead to choking or vomiting; in children; e.g., loud sounds or costumed characters)

Resources:

Neffy (epinephrine nasal spray) product information, revised by ARS Pharmaceuticals Operations, Inc. 03-2025. Available at DailyMed http://dailymed.nlm.nih.gov. June 27, 2025.

Campbell RL, Kelso JM. Anaphylaxis: Emergency treatment. In: UpToDate, Walls RM, Randolph AG, Feldweg AM, Ganetsky M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2025. Topic last updated August 12, 2025. Accessed September 29, 2025.

Sicherer SH. Prescribing epinephrine for anaphylaxis self-treatment. In: UpToDate, Kelso JM, TePas E (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2025. Topic last updated June 12, 2025. Accessed September 29, 2025.

Turner P. Long-term management of patients with anaphylaxis. In: UpToDate, Kelso JM, Feldweg AM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2025. Topic last updated November 05, 2024. Accessed September 29, 2025.

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