

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 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.

Criteria:

- **Criteria for initial therapy:** Neffy (epinephrine nasal spray) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met:

1. Individual is 8 years of age or older weighing at least 30 kg
2. Individual has a confirmed diagnosis of type I allergic reaction(s), including anaphylaxis to be used for emergency treatment
3. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))

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

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4. Individual meets **ONE** of the following:
 - a. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for epinephrine auto-injection
 - b. Individual meets **ONE** of the following:
 - i. Individual has diagnosis of phobia preventing self-administration (documentation from a psychiatric evaluation is required ([see Definitions section](#)))
 - ii. Unable to successfully self-administer medication using proper technique due to physical or mental impairment
5. Individual does **NOT** have a caregiver or family member willing or able to assist with home administration of epinephrine auto-injection
6. Individual does not have any underlying structural and anatomical nasal conditions (e.g., polyps, history nasal fracture or injuries, or history nasal surgery)

Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Neffy (epinephrine nasal spray) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual is 8 years of age or older weighing at least 30 kg
2. Individual has a confirmed diagnosis of type I allergic reaction(s), including anaphylaxis to be used for emergency treatment
3. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
4. Individual does not have any underlying structural and anatomical nasal conditions (e.g., polyps, history nasal fracture or injuries, or history nasal surgery)

Renewal duration: 12 months

- 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**

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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.
- 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)

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Resources:

Neffy (epinephrine nasal spray) product information, revised by ARS Pharmaceuticals Operations, Inc. 08-2024. Available at DailyMed <http://dailymed.nlm.nih.gov>. August 21, 2024.

Campbell RL, Kelso JM. Anaphylaxis: Acute diagnosis. In: UpToDate, Walls RM, Feldweg AM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2024. Topic last updated May 14, 2024. Accessed August 24, 2024.

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Sicherer SH. Prescribing epinephrine for anaphylaxis self-treatment. In: UpToDate, Kelso JM, Feldweg AM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2024. Topic last updated August 20, 2024. Accessed August 24, 2024.

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 July 2024. Topic last updated December 14, 2023. Accessed August 24, 2024.

Kemp SK. Pathophysiology of anaphylaxis. In: UpToDate, Kelso JM, Feldweg AM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2024. Topic last updated May 06, 2024. Accessed August 24, 2024.

Block SA. Fatal anaphylaxis. In: UpToDate, Kelso JM, Feldweg AM (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through July 2024. Topic last updated April 27, 2024. Accessed August 24, 2024.

Schneier FR. Social anxiety disorder in adults: Epidemiology, clinical features, assessment, and diagnosis. In: UpToDate, Stein MB, Friedman M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through August 2024. Topic last updated September 14, 2023. Accessed September 05, 2024.