

## Neffy (epinephrine nasal spray)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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### Summary

Type 1 allergic reactions are known as immediate hypersensitivity reactions and include anaphylaxis. Anaphylaxis is a serious, life-threatening allergic reaction that can occur within seconds or minutes of exposure to an allergen. It can be triggered by IgE-mediated reactions to allergens such as foods, drugs, insect stings, and latex. Epinephrine is the first-line treatment for anaphylaxis. Current clinical guidelines

recommend all patients at risk of anaphylaxis be prescribed epinephrine and trained on proper administration.

Epinephrine helps alleviate bronchospasm, wheezing and dyspnea that may occur during anaphylaxis. Epinephrine also alleviates pruritus (itching), urticaria (hives), and angioedema (rapid swelling, typically in the face, lips, tongue and throat). It may also relieve gastrointestinal and genitourinary symptoms associated with anaphylaxis.

Neffy (epinephrine nasal spray) is an intranasal formulation of epinephrine approved by the FDA for the emergency treatment of allergic reactions, including anaphylaxis, in those 4 years of age and older who weigh 15 kg or greater. It provides a non-injectable option for administration of epinephrine. Neffy (epinephrine nasal spray) is administered as a single spray into one nostril. In absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose of Neffy (epinephrine nasal spray) in the same nostril with a new nasal spray starting 5 minutes after the first dose. As such, it is recommended that individuals are prescribed and have immediate access to two Neffy (epinephrine nasal spray) nasal sprays at all times.

## Definitions

"Anaphylaxis" refers to a serious, potentially life-threatening allergic reaction that can occur within seconds or minutes of exposure to an allergen and requires immediate treatment with epinephrine.

"Epinephrine" refers to a medication that acts on alpha and beta-adrenergic receptors to quickly reverse the symptoms of anaphylaxis such as airway swelling, hypotension, and wheezing.

"Epinephrine auto-injector" is a medical device used for the automatic injection of a measured dose of epinephrine, most commonly for the treatment of anaphylaxis. Examples include EpiPen, Auvi-Q, generic versions.

"Needle phobia" is an extreme fear of medical procedures involving injections or hypodermic needles, which can lead to avoidance of medically necessary treatment.

## Clinical Indications

### Medical Necessity Criteria for Clinical Review

#### Indication-Specific Criteria

##### Type I Allergic Reactions

The Plan considers Neffy (epinephrine nasal spray) medically necessary when ALL of the following criteria are met:

1. The member is 4 years of age and older; *AND*

*NOTE: Clinical rationale is provided to support the use of Neffy (epinephrine nasal spray) in pediatric members younger than 4 years of age.*

2. The member weighs ( $\geq$ ) 15 kg or greater; *AND*
3. The member has a documented diagnosis of an allergy that may require emergency epinephrine treatment (e.g., food allergy, insect venom allergy, exercise-induced anaphylaxis, idiopathic anaphylaxis); *AND*
4. Neffy (epinephrine nasal spray) is being prescribed for the acute treatment of allergic reactions, including anaphylaxis; *AND*
5. Clinical documentation indicating the member meets **ONE (1)** of the following:
  - a. Has experienced an inadequate response, intolerance, or contraindication to an epinephrine auto-injector product (e.g., EpiPen, generic epinephrine auto-injector); *or*
  - b. Is unable to appropriately use an epinephrine auto-injector due to a clinically valid reason (e.g., needle phobia, lack of dexterity, visual impairment, arthritis); *AND*
6. No evidence of severe obstructive pathology that would reasonably impair drug delivery; *AND*
7. Neffy (epinephrine nasal spray) is being prescribed at a dose and frequency that is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication (see [Appendix A](#), Table 1 below).

*The requested medication is being used within the Plan's Quantity Limit of:*

- Neffy solution nasal spray 1 mg/0.1 ml: 4 devices per 28 days
- Neffy solution nasal spray 2 mg/0.1 ml: 4 devices per 28 days

*NOTE: It is recommended that individuals are prescribed and have immediate access to two Neffy (epinephrine nasal sprays) at all times.*

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.

#### [Experimental or Investigational / Not Medically Necessary](#)

Neffy (epinephrine nasal spray) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Use in members less than 15 kg. The safety and efficacy of Neffy (epinephrine nasal spray) had not been studied in this population.
- Use for the prevention of anaphylaxis or allergic reactions. Epinephrine is not intended to be used to prevent an allergic or anaphylactic reaction.
- Use for any non-FDA approved indications.

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## Appendix A

Table 1: Recommended Dosage of Neffy (epinephrine nasal spray) for those 4 Years of Age and Older

Member's Weight	Dosage
30 kg or Greater	One spray of Neffy 2 mg
15 kg to less than 30 kg	One spray of Neffy 1 mg

Each Neffy (epinephrine nasal spray) nasal spray is for single use and delivers the entire dose upon activation.

In absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose of Neffy (epinephrine nasal spray) in the same nostril with a new nasal spray starting 5 minutes after the first dose. As such, it is recommended that individuals are prescribed and have immediate access to two Neffy (epinephrine nasal spray) nasal sprays at all times.

## Clinical Guideline Revision / History Information

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