Oscar Clinical Guideline: Neffy (epinephrine nasal spray) (PG243, Ver. 1)

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.

Summary

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.

Neffy (epinephrine nasal spray) is an intranasal formulation of epinephrine approved by the FDA for the emergency treatment of allergic reactions, including anaphylaxis, in patients 30 kg or greater. It provides a non-injectable option for administration of epinephrine.

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.

Medical Necessity Criteria for Authorization

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

1. The member weighs (≥) 30 kg or greater; ***AND***
2. 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***
3. Neffy is being prescribed for the acute treatment of allergic reactions, including anaphylaxis; ***AND***
4. Clinical documentation indicating the member meets **ONE** 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***
5. The member does **NOT** have underlying structural or anatomical nasal conditions (e.g. nasal polyps, history of nasal fractures/injuries/surgery) that may affect absorption of Neffy.

If the above prior authorization criteria are met, the requested product will be authorized for 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 30 kg.
- Use for the prevention of anaphylaxis or allergic reactions.
- Use for any non-FDA approved indications.

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