



Prior Authorization Criteria

PALFORZIA® (*Peanut (Arachis hypogaea) Allergen Powder-dnfp*) PA Criteria

FDA Indication:

PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4 years of age and older. Palforzia is to be used in conjunction with a peanut-avoidant diet.

Initial authorization:

1. Palforzia will be approved based on **ALL** of the following criteria:
 - a. Diagnosis of peanut allergy
 - b. Beneficiary is between the ages of 4 and 17 years
 - c. Prescribed by an allergist or immunologist
 - d. Prescriber is certified/enrolled in the Palforzia REMS program
 - e. Confirmation of a positive skin test or a serum peanut-specific IgE level of \geq 0.35 kUA/L
 - f. Used in conjunction with a peanut-avoidant diet
 - g. Palforzia is prescribed concurrently with injectable epinephrine
 - h. Member has a history of at least 1 systemic allergic reaction to peanuts requiring hospitalization, an ER visit, or use of injectable epinephrine
 - i. Dose does not exceed 300 mg per day.

AND

2. Patient does not have any of the following:
 - a. History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
 - b. History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 60 days
 - c. Severe or poorly controlled asthma

- d. History of cardiovascular disease, including uncontrolled or inadequately controlled hypertension
- e. History of a mast cell disorder, including mastocytosis, urticaria pigmentosa, chronic idiopathic or chronic physical urticaria beyond simple dermatographism (e.g., cold urticaria, cholinergic urticaria) hereditary or idiopathic angioedema
- f. Beneficiary is not pregnant.

Authorization will be issued for 12 months.

Reauthorization:

1. Palforzia will be approved based on the following criteria:
 - a. Documentation of positive clinical response to Palforzia therapy
 - b. Used in conjunction with a peanut-avoidant diet
 - c. Prescribed by an allergist/immunologist
 - d. Prescriber is certified/enrolled in the Palforzia REMS Program
 - e. Beneficiary is not pregnant.

Authorization will be issued for 12 months.