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 \( \geq 0.35 \text{kUA/L} \)
   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.