peanut allergen powder-dnfp (Palforzia™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO183

Description

Peanut allergen powder-dnfp (Palforzia) is an oral immunotherapy FDA-approved for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. The mechanism of action is unknown at this time.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
peanut allergen powder-dnfp (Palforzia)	0.5 mg – 6 mg capsule sprinkle	Peanut allergy	13 capsule sprinkles/1 day
	3 mg daily dose capsule sprinkle		45 capsule sprinkles/15 days
	6 mg daily dose capsule sprinkle		90 capsule sprinkles/15 days
	12 mg daily dose capsule sprinkle		45 capsule sprinkles/15 days
	20 mg daily dose capsule sprinkle		15 capsule sprinkles/15 days
	40 mg daily dose capsule sprinkle		30 capsule sprinkles/15 days
	80 mg daily dose capsule sprinkle		60 capsule sprinkles/15 days
	120 mg daily dose capsule sprinkle		30 capsule sprinkles/15 days
	160 mg daily dose capsule sprinkle		60 capsule sprinkles/15 days
	200 mg daily dose capsule sprinkle		30 capsule sprinkles/15 days
	240 mg daily dose capsule sprinkle		60 capsule sprinkles/15 days
	300 mg titration powder pack		15 capsule sprinkles/15 days
	300 mg maintenance capsule sprinkle powder pack		30 capsule sprinkles/30 days

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Initial Evaluation

I. Peanut allergen powder-dnfp (Palforzia) may be considered medically necessary when the following criteria are met:
   A. Member is four to 17 years of age and request is for initial dose escalation; **OR**
      1. Member is four years of age or older and is up-dosing; **AND**
   B. Medication is prescribed by, or in consultation with an allergist or immunologist; **AND**
   C. The medication will not used in combination with Viaskin™ Peanut patch or other peanut desensitization therapy; **AND**
   D. A diagnosis of **peanut allergy** when the following are met:
      1. Documented medical history of severe peanut allergy, with reactions that cannot be managed with conventional therapies such as antihistamines (e.g., reaction causes anaphylaxis, requires epinephrine use, allergy that can be triggered by smell); **AND**
      2. Must have current prescription for epinephrine; **AND**
      3. Medication used in conjunction with peanut-avoidant diet; **AND**
      4. Member does not have severe or uncontrolled asthma; **AND**
      5. Member does not have eosinophilic esophagitis

II. Peanut allergen powder-dnfp (Palforzia) is considered investigational when used for all other conditions, including but not limited to:
   A. Initial dose escalation in members 18 years of age and older

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Member is four to 17 years of age; **OR**
   A. Member is four years of age or older and is up-dosing or in maintenance; **AND**
IV. Must have current prescription for epinephrine; **AND**
V. Medication used in conjunction with peanut-avoidant diet; **AND**
VI. Member does not have severe or uncontrolled asthma; **AND**
VII. Member does not have eosinophilic esophagitis; **AND**
VIII. The medication will not used in combination with Viaskin™ Peanut patch or other peanut desensitization therapy

Supporting Evidence

I. The pivotal Phase 3 double-blind, placebo-controlled trial (PALISADE) leading to FDA-approval of peanut allergen powder-dnfp (Palforzia) consisted of 551 subjects aged 4 through 55 years with peanut allergy. However, the primary efficacy analysis population included only those aged 4-17 years as there were very few patients 18 years and older in the trial. Thus, FDA-approval is specific to patients aged 4 through 17 years, although Up-Dosing and Maintenance may be continued in patients 4 years of age and older. To date, there is insufficient evidence to support the initiation of peanut allergen powder-dnfp (Palforzia) therapy past the age of 17 years. Studies in adults are on-going.

II. In the PALISADE trial subjects had confirmed peanut allergy diagnosis consisting of a clinical history of peanut allergy and an elevated IgE test ($\geq$ 0.35 kUA/L) or positive skin test (mean wheal diameter $\geq$ 3 mm larger than negative control). To be included in the trial subjects must have also had a reaction to an oral food challenge with dose limiting symptoms to no more than 100 mg of peanut protein (~ one third of a peanut kernel). Oral food challenges are not routinely done in practice but may be needed if the patient's clinical history and IgE test results do not clearly indicate an allergy.

III. A confirmed allergy diagnosis consisting of a clinical history of allergy along with confirmatory values (elevated IgE, positive skin test, or food challenge) is utilized as per guideline recommendations. The 2010 Guidelines for the Diagnosis and Management of Food Allergy in the United States indicate, "because individuals can develop allergic sensitization (as evidenced by the presence of allergen-specific IgE (sIgE)) to food allergens without having clinical symptoms on exposure to those foods, an sIgE-mediated food allergy requires both the presence of sensitization and the development of specific signs and symptoms on exposure to that food. Sensitization alone is not sufficient to define food allergy".

IV. The peanut allergen powder-dnfp (Palforzia) package insert and Risk Evaluation and Mitigation Strategy (REMS) program require peanut allergen powder-dnfp (Palforzia) be used in conjunction with a peanut-avoidant diet and prescribed with injectable epinephrine. Additionally, the package insert carries a black box warning for anaphylaxis that further states treatment should not be administered in patients with uncontrolled asthma.

V. Peanut allergen powder-dnfp (Palforzia) carries a warning and precaution for eosinophilic esophagitis as cases of eosinophilic esophagitis occurred in clinical trials (13.7% of patients during dose escalation). Use in patients with a history of eosinophilic esophagitis is contraindicated per the package insert. Eosinophilic esophagitis is inflammation and increased numbers of eosinophils in the esophagus. It can cause feeding disorders, vomiting, reflux symptoms, and abdominal pain in children; and dysphagia and esophageal food impactions in adolescents and adults. Eosinophilic esophagitis is a known complication of oral immunotherapy.

VI. Viaskin™ Peanut patch is a peanut desensitization therapy under review by the FDA. Safety and efficacy of combination use of peanut desensitization therapy is unknown.

VII. An evidence report by the Institute for Clinical and Economic Review (ICER) states there is only moderate certainty of a comparable, small, or substantial net health benefit and a small (but non-zero) likelihood of a negative net health benefit for peanut allergen powder-dnfp (Palforzia) compared with strict avoidance and rapid use of epinephrine (PI, promising, but inconclusive). This is due to net health benefit being driven by changes in quality of life and reductions in reactions to accidental exposure to peanuts, neither of which has been demonstrated. Additionally, the increase in patients treated who were able to tolerate 600 mg of peanut protein (~2 peanut kernels) during the exit food challenge in the trial compared with those treated with placebo (67.2% vs. 4.0%) is balanced by a significant increase in gastrointestinal symptoms, systemic allergic reactions, and epinephrine use.

VIII. Use of peanut allergen powder-dnfp (Palforzia) is reserved for members with a history of severe peanut allergy. Due to the safety risks noted above coupled with the unknown clinical significance and meaningfulness of improving tolerance of a single dose of 600 mg peanut protein. How tolerance of 600 mg of peanut protein relates to changes in quality of life and reductions in reactions to accidental exposure to peanuts was not evaluated in the clinical trial.

Investigational or Not Medically Necessary Uses

I. Peanut allergen powder-dnfp (Palforzia) has not been FDA-approved, or sufficiently studied for safety and efficacy for the conditions or settings listed below:
   A. Initial dose escalation in members 18 years of age and older
      i. Though the PALISADE trial included subjects aged 4-55 years, the prespecified primary analysis population consisted of the subjects aged 4-17 years who received at least one dose of study drug (n=496). Efficacy in those who were 18 and older (n=55) was evaluated as a secondary endpoint but did not show statistical significance.
      ii. FDA-approval is specific to patients aged 4 through 17 years, although Up-Dosing and Maintenance may be continued in patients 4 years of age and older. To date, there is insufficient evidence to support the initiation of peanut allergen powder-dnfp (Palforzia) therapy past the age of 17 years. Studies in adults are on-going.

References

1. Palforzia [Prescribing information]. Aimmune Therapeutics, Inc: Brisbane, CA. January 2020.
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7. Sampson HA, Gerth van wijk R, Bindslev-jensen C, et al. Standardizing double-blind, placebo-controlled oral food challenges: American Academy of Allergy, Asthma & Immunology-European Academy of Allergy and Clinical Immunology PRACTALL consensus report. J Allergy Clin Immunol. 2012;130(6):1260-74.
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Policy Implementation/Update:

Action and Summary of Changes	Date
Policy created	05/2020