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 peanuts. The mechanism of action is unknown at this time.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
peanut allergen powder-dnfp (Palforzia)	Peanut allergy	0.5 mg – 6 mg capsule sprinkle	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

Initial Evaluation

I. **Peanut allergen powder-dnfp (Palforzia)** may be considered medically necessary when the following criteria are met:
   A. Member is one to 17 years of age and request is for initial dose escalation; **OR**
      1. Member is one 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 a 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 or other eosinophilic gastrointestinal disease.

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 one to 17 years of age; **OR**
   A. Member is one year of age or older and is up-dosing or using as maintenance; **AND**
IV. Member must have a current prescription for epinephrine; **AND**
V. Medication must be 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 or other eosinophilic gastrointestinal disease; **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. FDA approval of peanut allergen powder-dnfp (Palforzia) in patients aged 1 to <4 years old was demonstrated in the pivotal Phase 3 double-blind, placebo-controlled trial (POSEIDON) in July 2024. A total of 146 subjects aged 1 to <4 years old with peanut allergy were included in the trial. In the POSEIDON trial, the prespecified primary efficacy population consisted of 98 subjects aged 1 to <4 years who received at least one dose of Palforzia, while 48 participants received placebo. The primary endpoint was the ability to tolerate a single dose of ≥600 mg of peanut protein with no more than mild allergic symptoms, defined by pruritus, swelling or rash, abdominal discomfort, or other transient or mild discomforts (<48 hours), and no or minimal medical intervention/therapy required. Most adverse events in the Palforzia group were mild to moderate in severity, primarily consisting of gastrointestinal symptoms. A total of 86.7% of participants in the Palforzia group were able to tolerate the single 600 mg dose of peanut protein during the exit double-blind placebo-controlled food challenge (DBPCFC), compared to 6.7% in the placebo group. This reflects a treatment difference of 80.1% and indicates a statistically and clinically significant improvement in desensitization in this age group.

III. In the PALISADE and POSEIDON trial, subjects had confirmed peanut allergy diagnosis consisting of a clinical history of peanut allergy and an elevated IgE test (≥ 0.35 kUA/L) or positive skin test (mean wheal diameter ≥ 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 (roughly 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.

IV. 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".

V. The peanut allergen powder-dnfp (Palforzia) package insert and Risk Evaluation and Mitigation Strategy (REMS) program requires peanut allergen powder-dnfp (Palforzia) to 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.

VI. 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, abdominal pain in children; and dysphagia and esophageal food impactions in adolescents and adults. Eosinophilic esophagitis is a known complication of oral immunotherapy.

VII. 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.

VIII. 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.

IX. 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 (and subsequently in subjects aged 1 to <4 years old in the POSEIDON trial) 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 1 through 17 years, although Up-Dosing and Maintenance may be continued in patients 1 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

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Policy Implementation/Update:

Action and Summary of Changes	Date
Updated criteria to allow treatment of peanut allergy in patients 1 to <4 years of age given age expansion. Updated supporting evidence and E/I age limits.	06/2025
Policy created	05/2020