Drug Coverage Policy

Effective Date..... 08/15/2024
Coverage Policy Number..... IP0141
Policy Title..... Palforzia

Allergen Immunotherapy – Palforzia

- Palforzia® (peanut [Arachis hypogaea] allergen powder-dnfp for oral administration – Aimmune)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW
Palforzia, an oral immunotherapy, is indicated for the mitigation of **allergic reactions**, including anaphylaxis, that may occur with accidental exposure to peanut.[1] It is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients 4 through 17 years of age; up-dosing and maintenance may be continued in patients ≥ 4 years of age. Palforzia is labeled to be used in conjunction with a peanut-avoidant diet. It is not indicated for the emergency treatment of allergic reactions, including anaphylaxis. Prior to initiation, the prescriber should verify that the patient has injectable epinephrine and has been instructed on its appropriate use. Palforzia is contraindicated in patients with uncontrolled asthma and patients with a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.

Clinical Efficacy
The Palforzia pivotal study, PALISADE, included patients who were required to have a diagnosis of peanut allergy supported by either a serum peanut-specific immunoglobulin E (IgE) level of ≥ 0.35 allergen-specific unit per liter (kU_A/L) or a mean wheal diameter of at least 3 mm larger than the negative control to a skin-prick test for peanut.[2] Additionally, to be eligible for randomization, patients had to have an allergic reaction (with dose-limiting symptoms) to a prespecified dose of peanut protein during a double-blind, placebo-controlled food challenge at screening. One of the key safety studies supporting the approval of Palfozia used slightly different enrollment criteria.[1] Patients were required to have peanut allergy characterized by allergic signs and symptoms observed within 2 hours of known oral peanut exposure, along with a serum peanut-specific IgE ≥ 14 Ku_A/L and a mean wheal diameter on skin prick test at least 8 mm larger than the negative control.[1]

Guidelines
Current guidelines regarding diagnosis and management of food allergy state that parent and patient reports of food allergy must be confirmed.[3] An SPT and allergen-specific IgE testing are each recommended as a method to identify foods that provoke allergic reactions. However, each test alone cannot be considered to be diagnostic for food allergy.

Medical Necessity Criteria

Palforzia is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Peanut Allergy.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is 4 to 17 years of age; OR
     - **ii.** Patient is ≥ 18 years of age AND has been previously started on therapy with Palforzia prior to becoming 18 years of age; AND
   - **B)** Per the prescriber, the patient has a history of an allergic reaction to peanut that met each of the following (i, ii, and iii):
     - **i.** Patient demonstrated signs and symptoms of a significant systemic allergic reaction; AND
       Note: Signs and symptoms of a significant systemic allergic reaction include hives, swelling, wheezing, hypotension, and gastrointestinal symptoms.
     - **ii.** This reaction occurred within a short period of time following a known ingestion of peanut or peanut-containing food; AND
     - **iii.** The prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector; AND
       Note: Examples of epinephrine auto-injectors include EpiPen, EpiPen Jr., Auvi-Q, and generic epinephrine auto-injectors.
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets BOTH of the following (1 and 2):
       - **(1)** Patient has a positive skin prick test response to peanut with a wheal diameter ≥ 3 mm larger than the negative control; AND
       - **(2)** Patient has a positive *in vitro* test (i.e., a blood test) for peanut-specific IgE with a level ≥ 0.35 kU_A/L; OR
     - **ii.** Patient meets ONE of the following (1 or 2):
       - **(1)** Patient has a positive skin prick test response to peanut with a wheal diameter ≥ 8 mm larger than the negative control; OR

(2) Patient has a positive in vitro test (i.e., a blood test) for peanut-specific IgE with a level ≥ 14 kU_A/L; AND

D) Per the prescriber, Palforzia will be used in conjunction with a peanut-avoidant diet; AND

E) Patient does NOT have uncontrolled asthma; AND

F) The medication is prescribed by or in consultation with an allergist or immunologist.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Palforzia® allergen powder [prescribing information]. Brisbane, CA: Aimmune; March 2023.
2. Vickery BP, Vereda A, Casale TB, et al. for the PALISADE group of clinical investigators. AR101 oral immunotherapy for peanut allergy. *N Engl J Med*. 2018;379(21):1991-2001.
3. Togias A, Cooper SF, Acebal ML, et al. Addendum guidelines for the prevention of peanut allergy in the United States: report of the National Institute of Allergy and Infectious Diseases-sponsored expert panel. *J Allergy Clin Immunol*. 2017;139(1):29-44.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Name Change: Updated** Policy Name from "Peanut (Arachis hypogaea) Allergen Powder-dnfp" to "Allergen Immunotherapy – Palforzia." **Peanut Allergy: Removed** the note stating that a positive food challenge result, at or before the 100 mg challenge dose of peanut protein, would be an acceptable alternative for SPT or psIgE testing requirements. **Removed** the requirement that the individual must not have either eosinophilic esophagitis or other eosinophilic gastrointestinal condition. **Conditions Not Covered: Removed** the criterion regarding emergency treatment of allergic reactions, including anaphylaxis.	08/15/2024

The policy effective date is in force until updated or retired.