Drug Coverage Policy

Effective Date.....10/15/2025
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 where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

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 1 through 17 years of age; up-dosing and maintenance may be continued in patients ≥ 1 year 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 in patients 4 to 17 years of age, PALISADE, included patients who were required to have a diagnosis of peanut allergy supported by either a positive serum peanut-specific immunoglobulin E (IgE) test or a positive 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 Palforzia in patients 4 to 17 years of age required patients to have peanut allergy characterized by allergic signs and symptoms observed within 2 hours of known oral peanut exposure. In the Palforzia pivotal study in patients 1 to 3 years of age, eligible patients had a documented history of a physician-diagnosed IgE-mediated peanut allergy or no known history of peanut ingestion and a peanut-specific IgE level indicative of peanut allergy within 12 months prior to randomization.[3] The physician-diagnosis of peanut allergy was required to include clinical signs and/or symptoms of allergy within 2 hours of peanut exposure and either a positive skin prick test or aa psIgE level indicative of peanut allergy within 12 months prior to randomization.[4]

Guidelines
Current guidelines regarding diagnosis and management of food allergy state that parent and patient reports of food allergy must be confirmed.[3,5] A skin prick test and allergen-specific IgE testing are each recommended as a method to identify foods that provoke allergic reactions. In children and adolescents with a confirmed IgE-mediated peanut allergy, peanut oral immunotherapy (e.g., Palforzia) is recommended to achieve desensitization (high certainty of evidence; strong recommendation).[6]

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Policy Statement
Prior Authorization is required for benefit coverage of Palforzia. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Palforzia as well as the monitoring required for adverse events and long-term efficacy, approval requires Palforzia to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. In subsequent coverage reviews for a patient who has previously met the documentation requirements and related criteria in the *Allergen Immunotherapy – Palforzia* through the Coverage Review Department, and who is requesting reauthorization, the criteria utilized do NOT require resubmission of documentation for reauthorization, except for the criterion requiring documentation of response or benefit to Palforzia therapy.

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 1 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)** According to the prescriber, the patient has a history of an allergic reaction to peanuts 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 self-administered injectable or nasal product; AND
       Note: Examples of epinephrine self-administered injectable and nasal products include EpiPen, EpiPen Jr., Auvi-Q, generic epinephrine auto-injectors, and Neffy.
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has a positive skin prick test response to peanut **[documentation required]**; OR
     - **ii.** Patient has a positive *in vitro* test (i.e., a blood test) for immunoglobulin E (IgE) to peanut **[documentation required]**; AND
   - **D)** According to 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

Palforzia for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Palforzia® allergen powder [prescribing information]. Bridgewater, NJ: Aimmune; July 2024.
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.
4. Du Toit G, Brown KR, Vereda A, et al. Oral immunotherapy for peanut allergy in children 1 to less than 4 years of age. *NEJM Evid*. 2023;2(11): EVIDoa2300145.

5. Santos AF, Riggioni C, Agache I, et al. EAACI guidelines on the diagnosis of IgE-mediated food allergy. *Allergy*. 2023;78(12):3057-3076.
6. Santos AF, Riggioni C, Agache I, et al. EAACI guidelines on the management of IgE-mediated food allergy. *Allergy*. 2025;80(1):14-36.

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
Selected Revision	**Peanut allergy: The** age requirement was updated to approve if the patient is 1 to 17 years of age. Previously, this criterion approved if the patient is 4 to 17 years of age.	10/15/2024
Annual Revision	**Peanut allergy:** Criteria were updated to require a patient to have either a positive skin prick test response to peanut or a positive *in vitro* test (i.e., a blood test) for immunoglobulin E (IgE) to peanut. Previously, a patient was required either have a positive skin prick test response to peanut with a wheal diameter ≥ 3 mm larger than the negative control and a positive *in vitro* test (i.e., a blood test) for peanut-specific IgE with a level ≥ 0.35 kU_A/L; OR have either a positive skin prick test response to peanut with a wheal diameter ≥ 8 mm larger than the negative control or have a positive *in vitro* test (i.e., a blood test) for peanut-specific IgE with a level ≥ 14 kU_A/L. **Added** "documentation provided that" language to criterion 1C.	7/15/2025
Selected Revision	**Peanut allergy:** Throughout the criteria, references to "epinephrine auto-injectors" were updated to "epinephrine self-administered injectable or nasal products." Neffy was added as an example of an epinephrine self-administered injectable or nasal product. **Updated** "Per the prescriber" to "According to the prescriber" throughout the policy.	10/15/2025

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