PRIOR AUTHORIZATION POLICY

POLICY: Allergen Immunotherapy – Palforzia Prior Authorization Policy
- Palforzia® (peanut [*Arachis hypogaea*] allergen powder-dnfp for oral administration – Aimmune)

REVIEW DATE: 03/20/2024; selected revision 04/24/2024 and 08/28/2024

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 NATIONAL FORMULARY COVERAGE:

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 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 Palforzia in patients 4 to 17 years of age 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] In the Palforzia pivotal study in patients 1 to 3 years of age, patients were required to have peanut allergy confirmed by a peanut-specific IgE test and a skin prick test.[4]

Guidelines

Current guidelines regarding diagnosis and management of food allergy state that parent and patient reports of food allergy must be confirmed.[3] A skin prick test 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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Palforzia. All approvals are provided for the duration noted below. 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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 peanut that met ALL 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 immunoglobulin E (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) 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.

CONDITIONS NOT COVERED

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is(are) considered experimental, investigational or unproven for ANY other use(s); 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. Jones SM, Kim EH, Nadeau KC, et al. Efficacy and safety of oral immunotherapy in children aged 1 to 3 years with peanut allergy (the Immune Tolerance Network IMPACT trial): a randomized placebo-controlled study. *Lancet*. 2022;399(10322):359-371.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	No criteria changes.	03/01/2023
Annual Revision	No criteria changes.	03/20/2024
Selected Revision	**Peanut allergy:** Criteria were updated to require patients to meet both the existing peanut allergy testing parameters or have a positive skin prick test response to peanut with a wheal diameter ≥ 8 mm larger than the negative control or a positive in vitro test for peanut-specific IgE with a level ≥ 14 kU_A/L. Criteria were added to require the patient does not have uncontrolled asthma.	04/24/2024
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.	08/28/2024