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

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Palforzia is recommended in those who meet the following criteria:

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 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 RECOMMENDED FOR APPROVAL

Coverage of Palforzia is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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.