VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/17/2021

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 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.

Clinical Efficacy

The Palforzia pivotal study, PALISADE (published) [n = 551 {n = 496 patients 4 to 17 years of age in the intent-to-treat (ITT) analysis}], included patients were required to have a diagnosis of peanut allergy supported by either a serum peanut-specific immunoglobulin E (psIgE) 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 (SPT) for peanut.[2] Additionally, to be eligible for randomization, patients had to have an allergic reaction (with dose-limiting symptoms) to a dose of 100 mg or less of peanut protein (equivalent to approximately one-third of a peanut kernel) during a double-blind, placebo-controlled food challenge (DBPCFC) at screening. Eligible patients were randomized (3:1) to receive either Palforzia or matching placebo administered once daily (QD). Following Initial dose Escalation, Up-Dosing, and 24 weeks of Maintenance Dosing, patients underwent an exit DBPCFC to assess their tolerance to peanut protein. In patients 4 to 17 years of age, 67.2% of patients receiving Palforzia (n = 250/372) were able to tolerate the single dose of 600 mg of peanut protein or more during the exit DBPCFC, compared with 4.0% (n = 5/124) with placebo (treatment difference: 63.2%; $P < 0.001$).

Guidelines

According to guidelines for the Diagnosis and Management of Food Allergy in the US from the National Institute of Allergy and Infectious Diseases (NIAID) expert panel (2010; 2017 addendum for the prevention of peanut allergy), medical history and a physical examination should guide the diagnosis, but parent and patient reports of food allergy must be confirmed, as 50% to 90% of patient-reported food allergies are not IgE-mediated food allergies.[4] An SPT and allergen-specific IgE testing are each recommended as a method to identify food that provoke allergic reactions. However, each test alone cannot be considered to be diagnostic for food allergy. The NIAID guidelines[3,4], as well as a Joint Task Force practice parameter on food allergy from the American Academy of Allergy, Asthma & Immunology (AAAAI) and the American College of Allergy, Asthma & Immunology (ACAAI)[5] and food allergy and anaphylaxis guidelines from the European Academy of Allergy and Immunology (EAACI) [2014][6] all recommend strict avoidance of peanut as the primary treatment for peanut allergy; anaphylaxis should be managed with epinephrine. These guidelines were published prior to the approval of Palforzia.

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 criteria (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 has a positive skin prick test (SPT) response to peanut with a wheal diameter ≥ 3 mm larger than the negative control; AND
   - **D)** Patient has a positive *in vitro* test (i.e., a blood test) for peanut-specific IgE (psIgE) with a level ≥ 0.35 kU_A/L; AND
   - **E)** Per the prescriber, Palforzia will be used in conjunction with a peanut-avoidant diet; 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]. Brisbane, CA: Aimmune Therapeutics; January 2020.
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. Boyce JA, Assa'ad A, Burks AW, et al. on behalf of the NIAID-sponsored expert panel. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J Allergy Clin Immunol*. 2010;126(6 Suppl):S1-S58.
4. 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 Clinc Immunol*. 2017;139(1):29-44.
5. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update – 2014. *J Allergy Clin Immunol*. 2014;134(5):1016-1025.
6. Muraro A, Werfel T, Hoffmann-Sommergruber K, et al. EAACI food allergy and anaphylaxis guidelines: diagnosis and management of food allergy. *Allergy*. 2014;69(8):1008-1025.
7. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol*. 2011;127(1 Suppl):S1-S55.
8. Pajno GB, Fernandez-Rivas M, Arasi S, et al. EAACI guidelines on allergen immunotherapy: IgE-mediated food allergy. *Allergy*. 2018;73(4):799-815.