Cigna National Formulary Coverage Policy

Effective Date..... 4/1/2023
Next Review Date..... 4/1/2024

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

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108681

Effective 2/7/23: 62115

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. 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.

National Formulary Medical Necessity

Cigna covers peanut [*Arachis hypogaea*] allergen powder (Palforzia®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

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 individuals 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.

FDA Indication(s)

1. **Peanut Allergy.** Approve for 1 year if the individual meets ALL of the following criteria (A, B, C, D, E, and F):
   A) Individual meets ONE of the following (i or ii):

i. Individual is 4 to 17 years of age; OR
ii. Individual 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 individual has a history of an allergic reaction to peanut that met each of the following (i, ii, and iii):
i. Individual 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) Individual has a positive skin prick test (SPT) response to peanut with a wheal diameter ≥ 3 mm larger than the negative control; AND

D) Individual 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 Covered

Peanut [*Arachis hypogaea*] allergen powder (Palforzia®) is considered experimental, investigational or unproven for ANY other use.

Background

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.

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 (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 prespecified dose of peanut protein during a double-blind, placebo-controlled food challenge at screening.

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.

References

1. Palforzia® allergen powder [prescribing information]. Brisbane, CA: Aimmune; 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. 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 History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	3/1/2023