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Coverage Policy Number IP0141

Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

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Related Coverage Resources

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.

Overview

This policy supports medical necessity review for peanut (*Arachis hypogaea*) allergen powder-dnfp (Palforzia®).

Medical Necessity Criteria

Peanut (*Arachis hypogaea*) allergen powder-dnfp (Palforzia) is considered medically necessary when the following are met:

1. **Peanut Allergy.** Individual meets **ALL** of the following criteria (A, B, C, D, E, and F):
    A. **ONE** of the following (i or ii):
        i. Individual is 4 to 17 years of age
        ii. Individual is 18 years of age or older **AND** has been previously started on therapy with Palforzia prior to becoming 18 years of age
    B. Documented diagnosis of peanut allergy confirmed by **EITHER** of the following within the past 12 months (i or ii):
        i. **BOTH** of the following (1 and 2):

(1) Documented positive skin prick test (SPT) response to peanut with a wheal diameter greater than or equal to 3 mm larger than the negative control
(2) Documented positive *in vitro* test (for example, a blood test) for peanut-specific IgE (psIgE) with a level greater than or equal to 0.35 kUA/L

Note: A positive food challenge result, at or before the 100 mg challenge dose of peanut protein, would be an acceptable alternative for one of the above testing requirements (SPT or psIgE)

ii. **EITHER** of the following (1 or 2):
(1) Documented positive skin prick test (SPT) response to peanut with a wheal diameter greater than or equal to 8 mm larger than the negative control
(2) Documented positive *in vitro* test (for example, a blood test) for peanut-specific IgE (psIgE) with a level greater than or equal to 14 kUA/L

C. History of an allergic reaction to peanut that met **ALL** of the following (i, ii and iii.):
i. Demonstrated signs and symptoms of a significant systemic allergic reaction (for example, hives, swelling, wheezing, hypotension, gastrointestinal symptoms)
ii. Reaction occurred within several hours following a known ingestion of peanut or peanut-containing food
iii. Prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector
D. Individual does NOT have **ANY** of the following (i, ii or iii):
i. Eosinophilic esophagitis
ii. Other eosinophilic gastrointestinal condition
iii. Uncontrolled asthma
E. Palforzia will be used in conjunction with a peanut-avoidant diet
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.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Peanut (*Arachis hypogaea*) allergen powder-dnfp (Palforzia) is considered medically necessary for continued use when **ALL** of the following criteria are met:
1. Individual met pre-treatment criteria
2. Documentation of beneficial response
3. Individual continues to tolerate 300 mg daily of Palforzia
4. Individual continues peanut-avoidance diet
5. The medication continues to be prescribed by or in consultation with an allergist or immunologist

Authorization Duration

Initial approval duration is up to 12 months.

Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Peanut (*Arachis hypogaea*) allergen powder-dnfp (Palforzia) is considered experimental, investigational, or unproven for **ANY** other use including the following (this list may not be all inclusive):

1. **Emergency treatment of allergic reactions, including anaphylaxis**

Background

OVERVIEW

Palforzia, an oral immunotherapy, is indicated for the mitigation of **allergic reactions**, including anaphylaxis, which 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.

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