Medical Coverage Policy | Desensitization Treatment for Peanut Allergies

EFFECTIVE DATE: 04|01|2021
POLICY LAST UPDATED: 08|03|2022

OVERVIEW
While peanut allergy is the most common cause of food allergy among children in the United States, deaths from accidental peanut exposure are rare. Approximately 80% of individuals who develop peanut allergy early in childhood do not outgrow their allergy and over half of them suffer from additional food allergies. Diagnosis of peanut allergy is made with an unequivocal history of an immediate allergic reaction following peanut ingestion, use of skin prick test and peanut specific IgE levels. Strict allergen avoidance is the standard of care. Peanut (Arachis hypogaea) allergen powder-dnfp is a defatted, slightly roasted peanut flour with a characterized peanut allergen profile and gradually increasing doses are given orally to desensitize patients.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of peanut (Arachis hypogaea) allergen powder-dnfp is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
The use of peanut (Arachis hypogaea) allergen powder-dnfp is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
Peanut allergy is the most common food allergy in the United States (U.S.) with an estimated 1.6 million children and teens affected. It is also the most common allergen implicated in cases of death due to food allergy among teens. However, death from accidental peanut exposure is rare; estimated rates of fatal anaphylaxis due to accidental peanut exposure range from 0.73 to 4.25 deaths per 1,000,000 patient years, depending on community prevalence. Data from National Food Allergy Death Registry reports less than four deaths per year over the past ten years in the U.S. among children and adolescents.

Diagnosis
Double-blind, placebo-controlled, oral food challenges are the gold standard for the diagnosis of food allergy including peanut. However, food challenge tests for peanut allergy are not performed routinely in a clinical setting due to high-risk of precipitating severe symptoms including anaphylaxis. The diagnosis and management of peanut allergy in clinical practice rely on an unequivocal history of an immediate reaction consisting of typical allergic symptoms following the isolated ingestion of a peanut. After establishing the pretest probability of the diagnosis based on positive clinical history, clinicians measure allergen sensitization

with a skin prick test, allergen specific IgE, or both to establish the post-test probability of peanut allergy. The predictive power of such tests to confirm clinical history has been based on observational studies. Food challenge tests may be required if the history and IgE test results do not clearly indicate an allergy.

Current Treatment

The current standard of care is strict avoidance of peanut-containing food products and timely administration of epinephrine, antihistamines, beta-blockers, and steroids in case of an allergic reaction upon accidental exposure. Up to 4 out of 10 individuals with a peanut allergy may experience an accidental exposure with an annual incidence ranging from 5% to 20%. Neuman-Sunshine et al (2012) retrospectively analyzed records of 572 individuals with peanut allergy. The median age at initial observation was 1.4 years; the median duration of follow-up was 5.3 years. The rate of post-diagnosis peanut exposure was 4.7%/year; the rate of severe reactions was 1.6%/year and the use of epinephrine was 1.1%/year. Of the 685 exposures analyzed, 75.9% were due to ingestion, 13.6% due to contact and 4.5% were airborne. Patients and patient representatives report that strict avoidance of allergen results in an increased burden of day-to-day living, limitation on social activity and independence, missed time from work, negative impact on the quality of life and negative emotional impact. Further, affected persons and their family lifestyles are heavily impacted by fear and anxiety, and an important goal for patients is to be able to live and eat more freely.

Oral immunotherapy (OIT) is practiced in the U.S. either under clinical trial protocols at tertiary centers or at unregulated private clinics. The extent of their use is not known and non-reimbursable. According to the Institute for Clinical and Economic Review, the majority of allergists do not offer oral immunotherapy. As a result, patients who pursue it often pay out of pocket, which can limit access to those who can afford it. There have been many studies of oral immunotherapy for peanut allergy using different peanut preparations, different dose escalation strategies, different maintenance doses (125 mg to 5000 mg peanut protein per day), different primary outcomes and different target populations.

Allergic reactions can range from mild cutaneous symptoms to gastrointestinal symptoms such as abdominal pain, nausea, vomiting, and diarrhea and severe reactions such as anaphylaxis. Approximately 80% of individuals who develop peanut allergy early in childhood do not outgrow their food allergy in adulthood and over half of them suffer from additional food allergies.

For individuals who are peanut-allergic children and adolescents ages 4 to 17 who receive peanut (Arachis hypogaea) allergen powder-dnfp, the evidence includes 2 pivotal double-blind, randomized, placebo-controlled trials (PALISADE and ARTEMIS), and an open-label extension study of the PALISADE trial. Relevant outcomes are symptoms, quality of life, hospitalizations, medication use, and treatment-related mortality and morbidity. In the PALISADE trial, 555 patients aged4 to 55 years were randomized to peanut (Arachis hypogaea) allergen powder-dnfp (n=416) or placebo (n=139). A subset of 499 patients aged 4 to 17 years old were used for the primary analysis. The primary outcome was the difference in the proportion of participants who could ingest 600 mg or more of peanut protein without dose-limiting symptoms in a food challenge after approximately 1-year follow-up between the treatment and placebo arm. The percentage of patients who met the primary endpoint at exit food challenge test was 67.2% versus 4.0% (difference 63.2%, 95% confidence interval [CI]: 53.0 to 73.3, $p<.001$) in the treatment arm versus placebo, respectively. Adverse events occurred with greater frequency and severity in peanut (Arachis hypogaea) allergen powder-dnfp treated individuals versus placebo: serious adverse events (2.2% vs. 0.8%), systemic allergic reactions (14.2% vs. 3.2%), use of epinephrine outside of the food challenge test (14.0% vs. 6.5%), withdrawal due to adverse events (11.6% vs. 2.4%), and overall withdrawal rate (21.0% vs. 7.3%). In the ARTEMIS trial, similar results revealed that peanut (Arachis hypogaea) allergen powder-dnfp significantly increased the percentage of patients who could tolerate an even higher dose of peanut protein of 1000 mg as compared to placebo (58% vs. 2%, $p<.0001$). Additionally, 99% of patients in the peanut (Arachis hypogaea) allergen powder-dnfp group and 98% of patients in the placebo group experienced 1 or more treatment-emergent adverse events, with the majority of events being mild or moderate in severity. Gastrointestinal disorders occurred more frequently among the peanut (Arachis hypogaea) allergen powder-dnfp participants as compared to placebo (91% vs.

77%). Additionally, certain subjects in the peanut (Arachis hypogaea) allergen powder-dnfp group reported quality of life improvements that exceeded the minimum clinically important difference between the 2 groups across various domains. Notable study relevance limitations included the intended use for the population was unclear, key health outcomes were not addressed, insufficient assessment of harms, and the existence of an insufficient duration for the evaluation of benefits and harms. Key limitations in study design and conduct included the potential for partial unblinding due to adverse events (outcome assessed by treating physician). There is need for more data to demonstrate that desensitization leads to reduced reactions to accidental exposure to peanuts and improved quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Regulatory Status
On January 31, 2020, Palforzia® [Peanut (Arachis hypogaea) Allergen Powder-dnfp] was approved by the U.S. Food and Drug Administration for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4years of age and older. Palforzia is to be used in conjunction with a peanut-avoidant diet.

CODING

Medicare Advantage Plans and Commercial Products
There is no specific CPT code for treatment using Palforzia (Peanut [Arachis hypogaea] Allergen Powder-dnfp). Claims should be filed using the unlisted HCPCS code:

J8499 Prescription drug, oral, non chemotherapeutic, NOS

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, October 2022
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