

Pharmacy Policy Bulletin

Title: Peanut Immunotherapy (Palforzia®)

Policy #: Rx.01.224

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Peanut Immunotherapy (Palforzia®)** as provided under the member's prescription drug benefit.

Description:

In the United States, the prevalence rate of peanut allergy is about 1 to 2 percent. Nine major and minor allergenic proteins in peanut, designated Ara h 1 to 9, have been identified that are responsible for IgE-mediated reactions. The risk factors for the development of peanut allergy include a family or personal history of atopic disease, severe atopic dermatitis and/or egg allergy in young infants, and a family history of peanut allergy. The majority of allergic reactions to peanut are systemic. Symptoms can be isolated to a single organ system, most commonly the skin (e.g. urticaria, angioedema), or involved multiple organ systems (anaphylaxis).

Palforzia® is an oral immunotherapy indicated 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 7 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older. Palforzia® is to be used in conjunction with a peanut-avoidant diet. The mechanism of action of Palforzia® has not been established.

Policy:

INITIAL CRITERIA Peanut immunotherapy (Palforzia®) is approved when ALL of the following are met:

1. Diagnosis of peanut allergy as documented by all of the following:
 - a. Serum peanut-specific IgE level of greater than or equal to 0.35kUA/L; and
 - b. Mean wheal diameter that is at least 3mm larger than the negative control on skin-prick testing for peanut; and
2. Member does not have any of the following:
 - a. History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease; or
 - b. History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months; or
 - c. Severe or poorly controlled asthma; and
3. One of the following:
 - a. Member is 4 to 17 years of age and in the initial dose escalation phase of therapy; or
 - b. Member is 4 years of age or older and in the up-dosing or maintenance phase of therapy; and
4. Prescribed by or in consultation with an allergist/immunologist

Initial authorization duration: 12 months

REAUTHORIZATION CRITERIA Peanut immunotherapy (Palforzia®) is re-approved when prescribed by or in consultation with allergist/immunologist.

Reauthorization duration: 12 months

Black Box Warning as shown in the drug Prescribing Information:

ANAPHYLAXIS

Palforzia® can cause anaphylaxis, which may be life-threatening and can occur at any time during Palforzia® therapy.

Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.

Do not administer Palforzia® to patients with uncontrolled asthma

Dose modifications may be necessary following an anaphylactic reaction

Observe patients during and after administration of the Initial Dose Escalation and the first does of each Up-Dosing level, for at least 60 minutes

Palforzia® is available only through a restricted program called the Palforzia® REMS.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Palforzia® (peanut immunotherapy) [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc. January 2020. Available at: https://www.palforzia.com/static/pi_palforzia.pdf. Accessed January 11, 2022.

Wang, Julie MD. Peanut, tree nut, and seed allergy: Clinical Features. UpToDate. November 2019. Accessed January 11, 2022

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Peanut Immunotherapy (Palforzia®)

Cross References:

Off-Label Use policy Rx.01.33

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| Policy Version Number: | 4.00 |
| P&T Approval Date: | December 09, 2021 |
| Policy Effective Date: | April 01, 2022 |
| Next Required Review Date: | December 09, 2022 |

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If

you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

