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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Biologicals	**Original Policy Date:**	March 6, 2020
Subject:	Palforzia	**Page:**	1 of 5

Last Review Date: March 7, 2025

Palforzia

Description

Palforzia [Peanut (Arachis hypoqaea) Allergen Powder-dnfp]

Background
Palforzia is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients with a confirmed diagnosis of peanut allergy. Palforzia is a powder for oral administration containing peanut protein and manufactured from defatted peanut flour. The mechanism of action of Palforzia has not been established (1).

Regulatory Status
FDA-approved indication: 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 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age and older (1).

Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis (1).

Palforzia should be used in conjunction with a peanut-avoidant diet (1).

Palforzia has a boxed warning that it may cause anaphylaxis. Patients should be educated to recognize the signs and symptoms of anaphylaxis. Patients should be prescribed injectable

epinephrine, instructed and trained on its appropriate use, and instructed to seek immediate medical care upon its use (1).

Palforzia is contraindicated in patients with uncontrolled asthma and a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease. Palforzia should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Palforzia should be discontinued and a diagnosis of eosinophilic esophagitis considered in patients who experience severe or persistent gastrointestinal symptoms (1).

Palforzia is available only through a restricted program called the Palforzia REMS (1).

In the clinical studies, subjects were primarily (79%) white and so Palforzia's safety and efficacy in other races may be limited (1).

The safety and effectiveness of Palforzia in patients less than 1 year of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Palforzia may be considered **medically necessary** if the conditions indicated below are met.

Palforzia may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 1 year of age or older

Diagnosis

Patient must have the following:

Peanut allergy

AND ALL of the following:

1. Patient has received, or will receive, **Initial Dose Escalation while age 1 through 17**
2. Used for the mitigation of allergic reactions that may occur with accidental exposure to peanut use
3. The diagnosis of peanut allergy has been confirmed with an IgE ≥ 0.35 kUA/L or skin-prick test ≥ 3mm compared to control
4. Used in conjunction with a peanut-avoidant diet
5. The first dose of each new Up-Dosing level must be administered under the supervision of a health care professional in a health care setting
6. Patient has been prescribed injectable epinephrine **AND** patient and/or caregiver has been instructed and trained on its appropriate use
7. Prescribed by or recommended by an allergist or immunology specialist
8. Health care provider, health care setting, and the patient are enrolled in the Palforzia REMS program
9. **NOT** for emergency treatment of allergic reactions, including anaphylaxis
10. **NO** uncontrolled asthma
11. **NO** history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease

Prior–Approval *Renewal* Requirements

Age 1 years of age or older

Diagnosis

Patient must have the following:

Peanut allergy

AND ALL of the following:

1. Patient received **Initial Dose Escalation while age 1 through 17**
2. Used for the mitigation of allergic reactions that may occur with accidental exposure to peanut use
3. Used in conjunction with a peanut-avoidant diet

4. Patient has been prescribed injectable epinephrine **AND** patient and/or caregiver has been instructed and trained on its appropriate use
5. **NOT** for emergency treatment of allergic reactions, including anaphylaxis
6. **NO** uncontrolled asthma
7. **NO** history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Palforzia is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients with a confirmed diagnosis of peanut allergy. Palforzia is a powder for oral administration containing peanut protein and manufactured from defatted peanut flour. The mechanism of action of Palforzia has not been established. The safety and effectiveness of Palforzia in patients less than 1 year of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Palforzia while maintaining optimal therapeutic outcomes.

References

1. Palforzia [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc.; July 2024.

Policy History

Date	Action
March 2020	Addition to PA
June 2020	Annual review. Revised regulatory status and added that Palforzia can be prescribed or recommended by an immunology specialist per SME. Also added requirement “The diagnosis of peanut allergy has been confirmed with an IgE ≥ 0.35 kUA/L or skin-prick test ≥ 3mm compared to control” per SME. Also added statement to regulatory status about how the clinical study population was primarily white per SME
September 2021	Annual review
September 2022	Annual review
March 2023	Annual review. Per SME, added requirement of no history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
March 2024	Annual review and reference update. Per SME, added percentage of white participants in study population to regulatory section
March 2025	Annual editorial review and reference update. Changed age requirement to 1 and older

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.