

PALFORZIA
[Peanut (*Arachis hypoqaea*) Allergen Powder-dnfp]

RATIONALE FOR INCLUSION IN PA PROGRAM**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).

(1).

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



**BlueCross
BlueShield**

Federal Employee Program.

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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).

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.