Pharmacy Policy Bulletin: J-0246 Palforzia [peanut (*Arachis hypogaea*) allergen powder-dnfp] – Commercial and Healthcare Reform	
Number: J-0246	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0246-009	**Original Date:** 03/02/2020
Effective Date: 04/25/2025	**Review Date:** 01/29/2025

Drugs Product(s):	• Palforzia [peanut (*Arachis hypogaea*) allergen powder-dnfp]
FDA-Approved Indication(s):	• Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients with a confirmed diagnosis of peanut allergy.

Background:	• Palforzia is the first agent approved by the FDA to mitigate allergic reactions that may occur with accidental exposure to peanut. Palforzia is manufactured from peanuts, however, the mechanism of action has not been established.
	• Palforzia is initially a healthcare-administered and then a self-administered oral immunotherapy (OIT). Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Palforzia is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
	  ○ 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.
	• Palforzia is an OIT, which is a form of desensitization that consists of daily ingestion of a specific amount of food allergen following a schedule starting with minimal quantities and slowly increasing the exposure over weeks to months.
	  ○ Treatment is started in a controlled setting under physician supervision.
	  ○ Once therapeutic dosage is achieved, the dose of the food allergen can be self-administered and must continue to be ingested on a regular basis to maintain desensitization.
	• Current management standards involve allergen avoidance, patient education, and provision of emergency medicine (e.g. epinephrine) for use in allergic reactions.
	• Prescribing Considerations
	  ○ Palforzia is contraindicated in patients with uncontrolled asthma, history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease.

	○ Palforzia has a black box warning for 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 dose of each Up-Dosing level for at least 60 minutes. ○ Palforzia is not indicated for the emergency treatment of allergic reactions, including anaphylaxis. ○ Wash hands immediately after handling Palforzia. ○ Each dose should be consumed with a meal, at approximately the same time each day, preferably in the evening. Open capsule(s) or sachet and empty onto refrigerated or room temperature semisolid food. Mix well and consume entire volume. Do not swallow capsule or inhale powder. ○ Observe the patient for at least 60 minutes after administering Palforzia for any signs of intolerability. ○ Patient should delay consuming Palforzia after strenuous exercise until signs of a hypermetabolic state (e.g., flushing, sweating, rapid breathing, rapid heart rate) have subsided. ○ Avoid taking hot showers or baths immediately prior to or within 3 hours after consuming Palforzia. ○ Refrigerate or store at room temperate and do not freeze. Store in original packaging until use. ○ Palforzia is available only through a Risk Evaluation and Mitigation Strategy (REMS) with the following requirements: ▪ The prescribing physician and patient must be enrolled in the REMS prior to initiation of treatment. ▪ The initial dose escalation and the first dose of each up-dosing level must be administered in a certified healthcare setting. ▪ Epinephrine must always be immediately available to patients. ○ Palforzia is to be used in combination with a peanut-avoidant diet.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Palforzia may be approved when all of the following criteria are met **(A. through H.)**:

A. The medication is being prescribed by or consultation with an allergist or immunologist.

B. The member meets one (1) of the following **(1. or 2.)**:
- **1.** The member is between 1 and 17 years of age for initial dose escalation.
- **2.** The member is 1 year of age and older for up-dosing and maintenance.

C. The prescriber submits clinical documentation of a confirmed diagnosis of peanut allergy (ICD10: Z91.010) confirmed by one (1) of the following **(1. or 2.)**:
- **1.** Peanut-specific skin prick test (SPT).
- **2.** Peanut-specific IgE (sIgE) antibodies.

D. The member experienced an allergic reaction to peanut.

E. The member will be on a peanut-avoidant diet while on Palforzia therapy.

F. The member does not have uncontrolled asthma.

G. The member does not have eosinophilic esophagitis or eosinophilic gastrointestinal disease.

H. The member has a documented prescription for epinephrine.

II. Reauthorization

When a benefit, reauthorization of Palforzia may be approved when all of the following criteria are met **(A. through D.)**:

- **A.** The member has experienced a positive clinical response to therapy.
- **B.** The member requires continuation of therapy.
- **C.** The member has not missed three (3) or more consecutive days of therapy as evidenced by claims.
- **D.** The member will continue a peanut-avoidant diet while on Palforzia therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial and HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial or HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Palforzia [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc.; July 2024.
2. PALISADE Group of Clinical Investigators, Vickery BP, Vereda A, et al. AR101 Oral Immunotherapy for Peanut Allergy. *N Engl J Med*. 2018 Nov 22;379(21):1991-2001.
3. Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the National Institute of Allergy and Infectious Diseases (NIAID)-sponsored expert panel. *J Allergy Clin Immunol* 2010; 126: Suppl: S1-S58.
4. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update. *J Allergy Clin Immunol* 2014; 134(5): 1016-25.e43.
5. Togias A, Cooper SF. Acebal M, et al. Addendum guidelines for the prevention of peanut allergy in the United States: report of the National Institute of Allergy and Infectious Diseases (NIAID)-sponsored expert panel. *J Pediatr Nurs*. 2017;32:91-98.
6. Muraro A, Werfel T, Hoffmann-Sommergruber K, et al. EAACI food allergy and anaphylaxis guidelines: diagnosis and management of food allergy. *Allergy* 2014; 69: 1008-25.
7. Approved Risk Evaluation and Mitigation Strategies (REMS). U.S. Food & Drug Administration. Available at: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=398. Accessed February 13, 2025.
8. Greenhawt M, Shaker M, Wang J, et al. Peanut allergy diagnosis: A 2020 practice parameter update, systematic review, and GRADE analysis. *J Allergy Clin Immunol.* 2020;146 (6):1302-1334.