Clinical Policy: Peanut Allergen Powder-dnfp (Palforzia)

Reference Number: PA.CP.PMN.220
Effective Date: 01/2023
Last Review Date: 01/2023

Revision Log

Description

Peanut *(Arachis hypogaea*) allergen powder-dnfp (Palforzia™) is an oral immunotherapy.

FDA Approved Indication(s)

Palforzia is 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 17 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.

Limitation(s) of use: Palforzia is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Palforzia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Peanut Allergy (must meet all)**:**

1. Diagnosis of peanut allergy;
2. Prescribed by an allergist or immunologist;
3. Age ≥ 4 years and ≤ 17 years at therapy initiation;
4. Confirmation of positive skin test or peanut-specific serum IgE ≥ 0.35 kUA/L;
5. Palforzia is prescribed concurrently with injectable epinephrine;
6. Member has a history of at least 1 systemic allergic reaction to peanuts requiring hospitalization, an ER visit, or use of injectable epinephrine;
7. Must use Palforzia in combination with a peanut avoidant diet;
8. Dose does not exceed 300 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Peanut Allergy (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. For members who required use of injectable epinephrine while on Palforzia therapy, medical justification supports the need for continued therapy with Palforzia;
3. If age ≥ 18 years, medical justification supports continued necessity for oral immunotherapy despite peanut avoidance;
4. If request is for a dose increase, new dose does not exceed 300 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
ICER: Institute for Clinical and Economic Review
REMS: Risk Evaluation and Mitigation Strategy

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): uncontrolled asthma, history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
- Boxed warning(s): anaphylaxis; Palforzia has a Risk Evaluation and Mitigation Strategy (REMS) program with the following requirements:
  - Health care providers who prescribe Palforzia must be certified with the program by enrolling.
  - Health care settings must be certified in the program, have on-site access to equipment and personnel trained to manage anaphylaxis, and establish policies and procedures to verify that patients are monitored during and after the Initial Dose Escalation and first dose of each Up-Dosing level.
  - Patients must be enrolled in the program prior to initiation of Palforzia treatment and must be informed of the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose

of each Up-Dosing level, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis.
  - Pharmacies must be certified with the program and must only dispense Palforzia to health care settings that are certified or to patients who are enrolled depending on the treatment phase.

Appendix D: General Information

- In the pivotal study for approval, there was no significant difference between Palforzia and placebo in adult patients (treatment difference 27.2% [95% CI: -1.7, 56]; p = 0.064) on the primary efficacy endpoint. The study evaluated the proportion of patients able to tolerate ≥ 600 mg of peanut protein with no more than mild symptoms at the end of the trial, with success being demonstrated if the lower bound of the 95% CI was greater than 15%.
- In an evidence report published July 2019, the Institute for Clinical and Economic Review (ICER) states that there is moderate certainty of a comparable, small, or substantial net health benefit and a small (but non-zero) likelihood of a negative net health benefit for Palforzia compared with strict avoidance and rapid use of epinephrine (P/I, promising, but inconclusive). This is because the significant response rate observed with Palforzia comes with an increase in adverse effects such as systemic allergic reactions, treatment-related anaphylaxis, and increased utilization of injectable epinephrine.
- Systemic allergic reaction refers to events coded to anaphylactic reaction of any severity, including anaphylaxis (severe anaphylactic reaction).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Peanut allergy	• Initial dose escalation: 0.5 to 6 mg PO over 1 day • Up-dosing: 3 mg PO with up-dosing every 2 weeks as tolerated until the maintenance dose is reached (refer to prescribing information for details) • Maintenance dose: 300 mg PO daily The initial dose escalation and first dose of each new level in the up-dosing schedule must be administered under supervision of a healthcare professional with the ability to manage severe allergic reactions, including anaphylaxis.	300 mg/day

VI. Product Availability

- Pull-apart capsules: 0.5 mg, 1 mg, 10 mg, 20 mg, 100 mg
- Sachet: 300 mg

VII. References

1. Palforzia Prescribing Information. Brisbane, CA: Aimmune Therapeutics, Inc; January 2020. Available at: www.palforzia.com. Accessed November 3, 2022.

2. FDA Briefing Document: Palforzia. Prepared for meeting on September 13, 2019. Available at: https://www.fda.gov/media/130653/download. Accessed November 3, 2022.
3. Sponsor Briefing Document: Palforzia. Prepared for meeting on September 13, 2019. Available at: https://www.fda.gov/media/130654/download. Accessed November 3, 2022.
4. IPD Analytics. Palforzia Review – FDA Allergenic Products Advisory Committee. Published September 19, 2019.
5. Institute for Clinical and Economic Review. Oral immunotherapy and Viaskin peanut for peanut allergy: Effectiveness and value. Published July 20, 2019. Available at: https://icer.org/assessment/peanut-allergy-2019. Accessed November 3, 2022

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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