Clinical Policy: Peanut Allergen Powder-dnfp (Palforzia)

Reference Number: CP.PMN.220
Effective Date: 03.01.20
Last Review Date: 02.22
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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. Medical justification supports necessity for oral immunotherapy despite peanut avoidance (e.g., member lacks sufficient mental capacity to effectively avoid peanuts);
8. Dose does not exceed 300 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Peanut Allergy (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

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 September 13, 2021.
2. FDA Briefing Document: Palforzia. Prepared for meeting on September 13, 2019. Available at: https://www.fda.gov/media/130653/download. Accessed September 13, 2021.
3. Sponsor Briefing Document: Palforzia. Prepared for meeting on September 13, 2019. Available at: https://www.fda.gov/media/130654/download. Accessed September 13, 2021.
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 September 13, 2021

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively.	11.26.19	02.20
Modified prescriber restriction to indicate that Palforzia must be prescribed by an allergist or immunologist (removed "or in consultation with") due to significant safety concerns for anaphylaxis and requirements for up-dosing to be administered under supervision of a healthcare professional.	02.11.20	02.20 (ad-hoc)
Drug is now FDA approved - criteria updated per FDA labeling: modified I.A.3 to specify that age must be between 4-17 years at therapy initiation; added that peanut IgE should be ≥ 0.35 kUA/L; added requirement for history of at least 1 systemic allergic reaction requiring hospitalization, ER visit, or injectable epinephrine usage; modified II.A.2 to remove "exceeding health plan quantity limit" to accommodate potential buy & bill; modified II.A.3 from age ≤ 17 years to require medical justification if age is ≥ 18 years; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	03.03.20	05.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.20.20	02.21
1Q 2022 annual review: no significant changes; modified example of medical justification; references reviewed and updated.	09.13.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.06.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.