Pharmacy Management Drug Policy

SUBJECT: Palforzia® (peanut [Arachis hypogaea] allergen powder-dnfp)
POLICY NUMBER: PHARMACY-88
EFFECTIVE DATE: 02/24/2020
LAST REVIEW DATE: 03/05/2024

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Palforzia® (peanut [Arachis hypogaea] allergen powder-dnfp), a peanut protein that is manufactured from defatted peanut flour, is the first FDA-approved therapy for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is given in three different treatment phases: Initial Dose Escalation, Up-Dosing, and Maintenance. The Initial Dose Escalation and the first dose of each Up-Dosing level of Palforzia are only dispensed and distributed to certified healthcare settings and only administered to patients in certified healthcare settings in accordance with the Palforzia REMS program.

In the United States, it is estimated that 2.2% of children and adolescents (1.25 million) have an allergy to peanuts. The current standard of care for management of peanut allergy is strict avoidance of peanuts and treatment with epinephrine for accidental exposures. Palforzia is not addressed in the current guidelines.

Palforzia is thought to cause a desensitization to peanut by reducing peanut specific IgE levels overtime. A rise in peanut-specific IgE from baseline occurs within the first 6 months of treatment (during the Initial Dose Escalation and Up-Dosing phases). Once at the therapeutic dose (maintenance phase), peanut specific IgE levels gradually decline with continued immunomodulation.

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Palforzia® (peanut [Arachis hypogaea] allergen powder-dnfp)

POLICY:

Palforzia (peanut [Arachis hypogaea] allergen powder-dnfp)
1. Must be prescribed and administered by an allergist or immunologist 2. Must be used for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts in conjunction with a peanut-avoidant diet 3. Patients being started on the Initial Dose Escalation phase of Palforzia must be between the ages of 4-17 years a. The Up-Dosing and Maintenance phase may be continued in patients 4 years of age and older 4. The patient must have a history of an allergic reaction to peanuts. The allergic reaction must have caused a systemic, IgE-mediated, reaction (systemic hives, facial/lip edema, wheezing/coughing, difficulty breathing, hypotension, gastrointestinal side-effects) **AND** must have required the patient to have a prescription for an injectable epinephrine product. 5. The patient must have **ONE** of the following to confirm an allergy to peanuts: a. A serum immunoglobulin E (IgE) to peanut of ≥ 0.35 kUA/L (kilos of allergen-specific units per liter) b. A skin prick test (SPT) to peanut of ≥ 3 mm compared to control 6. The prescriber must attest that the healthcare setting (where Palforzia will be administered), the prescriber, and the pharmacy are *certified* in the Palforzia REMS program. In addition, the provider must attest that the patient is *enrolled* in the Palforzia REMS program. 7. Initial approval will be for 6 months to allow for the first 2 phases of treatment. Consideration for an additional 6-month approval to allow for completion of the first 2 phases of treatment will be reviewed on a case-by-case basis for patients who required temporary dose modification (see number 7 of Policy Guidelines below). Initial approval of the maintenance phase will be 6 months and will require documentation that the patient successfully completed Phase 1 and Phase 2 of treatment. Ongoing recertification of maintenance dosing will require documentation that the patient has not experienced moderate-to-severe side-effects to treatment with Palforzia **AND** the provider must attest to the benefit of ongoing therapy and will be approved for 1 year. 8. Coadministration of Palforzia with a monoclonal antibody [e.g., Xolair (omalizumab) or dupilumab] for mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut OR for purposes of improving tolerability of Palforzia has not been studied and will be considered experimental/investigational and will not be authorized.

POLICY GUIDELINES:

1. Non-FDA approved indications for Palforzia will not be approved.
   a. The safety and effectiveness of Palforzia have not been established in persons younger than 4 years of age.
   b. The safety and effectiveness of initiating the Initial Dose Escalation phase of Palforzia have not been established in persons older than 17.
2. Treatment with Palforzia can be continued after the age of 17 so long as the patient began treatment (completed the Initial Dose Escalation Phase) before 18 years of age (≤ 17 years of age).
3. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
4. If the patient is unable to begin the Up-Dosing phase within 4 days, then the Initial Dose Escalation phase must be repeated.
5. Patients who are unable to tolerate doses up to and including the 3 mg dose during Initial Dose Escalation should discontinue treatment with Palforzia.

6. Management of missed doses per the prescribing information:" Following 1 to 2 consecutive days of missed doses, patients may resume Palforzia at the same dose level. Data are insufficient to inform resumption of Palforzia following 3 or more consecutive days of missed doses. Patients who miss 3 or more consecutive days of Palforzia should consult their healthcare providers; resumption of Palforzia should be done under medical supervision.
7. Per the Palforzia prescribing information: "Temporary dose modification of Palforzia may be required for patients who experience allergic reactions during Up-Dosing or Maintenance, for patients who miss doses, or for practical reasons of patient management. Allergic reactions, including gastrointestinal reactions, that are severe, recurrent, bothersome, or last longer than 90 minutes during Up-Dosing or Maintenance should be actively managed with dose modifications. Use clinical judgment to determine the best course of action, which can include maintaining the dose level for longer than 2 weeks, reducing, withholding, or discontinuing Palforzia doses."
8. Palforzia is contraindicated in patients with uncontrolled asthma and/or a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.
9. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
10. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
11. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approved language being added to the policy.
12. Quantity Limit:

Phase-Level	Dose	Quantity Limit	Day Supply	NDC
IDE – A - E	--	13 capsules	1	71881-0113-13
UD – Level 1	3 mg (3-1 mg capsules)	45 capsules	14	71881-0101-45
UD – Level 2	6 mg (6-1 mg capsules)	90 capsules	14	71881-0102-90
UD – Level 3	12 mg (2-1 mg capsules; 1-10 mg capsule)	45 capsules	14	71881-0103-45
UD – Level 4	20 mg (1-20mg capsule)	15 capsules	14	71881-0104-15
UD – Level 5	40 mg (2-20 mg capsules)	30 capsules	14	71881-0105-30
UD – Level 6	80 mg (4-20 mg capsules)	60 capsules	14	71881-0106-60
UD – Level 7	120 mg (1-20 mg capsule; 1-100 mg capsule)	30 capsules	14	71881-0107-30
UD – Level 8	160 mg (3-20 mg capsules; 1-100 mg capsule)	60 capsules	14	71881-0108-60
UD – Level 9	200 mg (2-100 mg capsules)	30 capsules	14	71881-0109-30
UD – Level 10	240 mg (2-20 mg capsules; 2-100 mg capsules)	60 capsules	14	71881-0110-60
UD – Level 11	300 mg (1-300 mg sachet)	15 sachets	14	71881-0111-15
Maintenance	300 mg (1-300 mg sachet)	30 sachets	30	71881-0111-30
IDE = Initial Dose Escalation (Phase 1); UD = Up Dosing (Phase 2); NDC = National Drug Code				

13. Dose Summary:
    a. Initial Dose Escalation (IDE): Given on Day 1, increasing doses of Palforzia (0.5, 1, 1.5, 3, and 6 mg) are administered 20 to 30 minutes apart under the supervision of a healthcare professional in a healthcare setting with the ability to manage possibly severe allergic reactions. Palforzia should be discontinued if symptoms requiring medical intervention (e.g., use of epinephrine) occur with any dose during Initial Dose Escalation. Patients who tolerate at least the 3 mg dose should return to the healthcare setting within 4 days to begin Up-Dosing.
    b. Up-Dosing (UD): Initiated at 3 mg once daily (UD-Level 1) and is slowly increased every 2 weeks through 11 different dose levels up to 300 mg once daily (UD-Level 11). The first dose of each new dose level is given in the healthcare setting; if the first administration is tolerated, the patient may complete the remainder of the doses at that level at home.

c. Maintenance: After successful completion of Up-Dosing, the maintenance dose of Palforzia is 300 mg once daily. Continued daily dosing is required to maintain Palforzia's effect.

14. Providers should follow AAAI and ACAAI recommendations for coding and billing of the in-office initial dose escalation and up-dosing.

    The following references are available to provide additional guidance for coding and billing:
    a. Palforzia Coding and Billing Overview: https://www.palforziapro.com/coding_billing.pdf?v=20210208
    b. Optimal Coding for Oral Immunotherapy (OIT) for Peanut Desensitization: https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Coding/OIT-Guidance-Revised-3-16-21.pdf

UPDATES:

Date	Revision
03/05/2024	Revised
12/06/2023	Revised
05/11/2023	Reviewed / P&T Committee Approval
05/2022	P&T Committee Approval
04/2022	Revised
05/2021	P&T Committee Approval
04/2021	Reviewed
05/2020	P&T Committee Approval
02/2020	Created

REFERENCES:

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2. Vickery BP, Vereda A, Casale TB, et al for the PALISADE group of clinical investigators. AR101 oral immunotherapy for peanut allergy. N Engl J Med. 2018;379(21):1991-2001.
3. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update – 2014. J Allergy Clin Immunol. 2014;134(5):1016-1025.
4. Togias A, Cooper SF, Acebal ML, et al. Addendum guidelines for the prevention of peanut allergy in the United States: report of the National Institute of Allergy and Infectious Diseases-sponsored expert panel. J Allergy Clinc Immunol. 2017;139(1):29-44.