MEDICAL MUTUAL®

Drug Policy

Policy: SD	Palforzia (Peanut [Arachis hypogaea] Allergen Powder-dnfp)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

OVERVIEW

Palforzia, an oral immunotherapy, is indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut.[1] It is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients 1 through 17 years of age; Up-Dosing and Maintenance may be continued in patients ≥ 1 years of age. Palforzia is to be used in conjunction with a peanut-avoidant diet. It is not indicated for the emergency treatment of allergic reactions, including anaphylaxis. Prior to initiation, the prescriber should verify that the patient has injectable epinephrine and has been instructed on its appropriate use. Palforzia is contraindicated in patients with uncontrolled asthma and patients with a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.

POLICY STATEMENT

This policy involves the use of Palforzia. Prior authorization is recommended for pharmacy benefit coverage of Palforzia. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Palforzia as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Palforzia be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Palforzia is recommended in those who meet the following criteria:

1. <u>Peanut Allergy- initial therapy</u>

Criteria. *Patient must meet the following criteria (A, B, C, D, E, <u>and</u> F):*

A) The patient meets ONE of the following (i or ii):
- **i.** Patient is 1 to 17 years of age; OR
- **ii.** Patient is ≥ 18 years of age AND has been previously started on therapy with Palforzia prior to becoming 18 years of age; AND

B) The medication is prescribed by or in consultation with an allergist or immunologist; AND

C) Per the prescriber, the patient has a history of an allergic reaction to peanut that met each of the following (i, ii, and iii):
- **i.** The patient demonstrated signs and symptoms of a significant systemic allergic reaction; AND
  Note: Signs and symptoms of a significant systemic allergic reaction include hives, swelling, wheezing, hypotension, and gastrointestinal symptoms.
- **ii.** This reaction occurred within a short period of time following a known ingestion of peanut or peanut-containing food; AND
- **iii.** The prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector; AND
  Note: Examples of epinephrine auto-injectors include EpiPen, EpiPen Jr., Auvi-Q, and generic epinephrine auto-injectors.

D) Patient meets ONE of the following (i or ii):
- **i.** Patient meets BOTH of the following (1 and 2):
  - i. Patient has a positive skin prick test response to peanut with a wheal diameter ≥ 3 mm larger than the negative control; AND
  - ii. Patient has a positive *in vitro* test (i.e., a blood test) for peanut-specific immunoglobulin E (IgE) with a level ≥ 0.35 kU_A/L; OR
- **ii.** Patient meets ONE of the following (1 or 2):
  - i. Patient has a positive skin prick test response to peanut with a wheal diameter ≥ 8 mm larger than the negative control; OR
  - ii. Patient has a positive *in vitro* test (i.e., a blood test) for peanut-specific IgE with a level ≥ 14 kU_A/L; AND

E) Per the prescriber, Palforzia will be used in conjunction with a peanut-avoidant diet; AND

F) Patient does NOT have uncontrolled asthma.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Palforzia has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a

pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Boyce JA, Assa'ad A, Burks AW, et al. on behalf of the NIAID-sponsored expert panel. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J Allergy Clin Immunol*. 2010;126(6 Suppl):S1-S58.
2. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update – 2014. *J Allergy Clin Immunol*. 2014;134(5):1016-1025.
3. Muraro A, Werfel T, Hoffmann-Sommergruber K, et al. EAACI food allergy and anaphylaxis guidelines: diagnosis and management of food allergy. *Allergy*. 2014;69(8):1008-1025.
4. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol*. 2011;127(1 Suppl):S1-S55.
5. Pajno GB, Fernandez-Rivas M, Arasi S, et al. EAACI guidelines on allergen immunotherapy: IgE-mediated food allergy. *Allergy*. 2018;73(4):799-815.
6. Palforzia® allergen powder [prescribing information]. Bridgewater, NJ: Aimmune; July 2024.
7. 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.
8. 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 Clin Immunol. 2017;139(1):29-44.
9. Jones SM, Kim EH, Nadeau KC, et al. Efficacy and safety of oral immunotherapy in children aged 1 to 3 years with peanut allergy (the Immune Tolerance Network IMPACT trial): a randomized placebo-controlled study. Lancet. 2022;399(10322):359-371.