JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS124
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	Subject **Palforzia**	*Revision Date*	12/08/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Palforzia

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I. POLICY

Palforzia (Peanut [Arachis hypogaea] Allergen Powder-dnfp) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Palforzia** may be approved for patients meeting ALL the following:
   1. Patient is one of the following:
      a. between 4 and 17 years of age and the request is for initiation of therapy
      b. 4 year of age or older and the request is for up-dosing or maintenance therapy
   2. Documentation has been submitted confirming diagnosis of peanut allergy, including both of the following:
      a. Serum immunoglobulin E (IgE) level response to peanut showing greater than or equal to 0.35 kUA/L (kilos of allergen-specific units per liter)
      b. Skin-prick test with peanut showing a mean wheal diameter that is at least 3mm larger than the negative control
   3. Documentation has been submitted showing the following:
      1. Patient's clinical history of allergic reaction to peanut, evidenced by:
         a. Previous signs and symptoms of systemic reaction after peanut or peanut-containing food ingestion (hives, swelling, wheezing, gastrointestinal disturbances) that necessitated the need for injectable epinephrine prescription
      2. Patient will be on a peanut-avoidant diet
      3. Patient has been prescribed injectable epinephrine and patient or caregiver has been educated on appropriate use
   4. Prescriber is, or has consulted with, an allergist or immunologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing the following:
    1. Patient is having a beneficial response to treatment, evidenced by increased tolerance of peanut protein with possibly only mild allergic symptoms
    2. Patient has been prescribed injectable epinephrine

IV. EXCLUSIONS

A. Palforzia will not be approved for the following:
    1. Emergency treatment of allergic reactions, including anaphylaxis
    2. Patients with any of the following:
        1. Uncontrolled, or severe Asthma
        2. History of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
        3. History of cardiovascular disease, including uncontrolled or inadequately controlled hypertension
        4. History of a mast cell disorder, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema
    3. Patients that are younger than 4 years of age
    4. Concurrent use with a monoclonal antibody agent
    5. Any indications or usages that are not FDA-approved, or guideline-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Palforzia [Prescribing Information]. Brisbane, CA: Aimmune Therapeutics, Inc.; January 2020
2. 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.
3. PALISADE Group of Clinical Investigators, et. al. AR101 Oral Immunotherapy for Peanut Allergy. N Engl J Med. 2018 Nov 22;379(21):1991-2001.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/15/2020	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples

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