Palforzia [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp]

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 1 year Continuation requests: 1 year

Medications	Quantity Limit
Palforzia Initial Dose Escalation Kit	1 kit per fill; one time fill (starting dose, 1 day supply.
Palforzia Up-Dosing Kits (Levels 1-11)	1 kit per fill
Palforzia 300 mg sachets	1 sachet per day

APPROVAL CRITERIA

Initial requests for Palforzia [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] may be approved if the following criteria are met:

I. Individual is 4 to 17 years of age at initiation of therapy; **AND**
II. Individual is using in conjunction to peanut allergen avoidance to reduce the risk of anaphylaxis due to accidental exposure; **AND**
III. Individual has a confirmed prescription for an auto-injectable epinephrine agent; **AND**
IV. Individual has a clinical history of allergy to peanuts or peanut-containing foods;

AND

V. If individual has had a positive clinician-supervised oral food challenge, peanut allergy is confirmed by the following (Vickery 2018):
    A. Positive skin prick test to peanut ≥3 mm compared to control; **OR**
    B. Serum IgE to peanut ≥0.35 kUA/L;

OR

VI. In the absence of positive clinician-supervised food challenge, peanut allergy is confirmed by the following (NCT03126227):
    A. Positive skin prick test to peanut ≥8 mm compared to control [unless skin testing is contraindicated]; **AND**
    B. Serum IgE to peanut ≥14 kUA/L.

Continuation requests for Palforzia [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] may be approved if the following criteria are met:

I. Individual is using in conjunction to peanut allergen avoidance to reduce the risk of anaphylaxis due to accidental exposure; **AND**
II. Individual has a confirmed prescription for an auto-injectable epinephrine agent; **AND**
III. There is confirmation of positive clinical response to Palforzia as evidenced by the ability to tolerate and comply with maintenance therapy.

Requests for Palforzia [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] may not be approved for the following:

I. If initiating therapy, individual has had severe or life-threatening anaphylaxis within 60 days prior to initiating therapy; **OR**
II. Individual has a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease, or has had suspected eosinophilic esophagitis while on treatment; **OR**
III. Individual has severe, unstable or uncontrolled asthma; **OR**
IV. Individual has a history of cardiovascular disease, including uncontrolled or inadequately controlled hypertension (Vickery 2018); **OR**
V. Individual has a history of mast cell disorder, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema (Vickery 2018); **OR**
VI. Individual is in "build-up phase" of immunotherapy to another allergen (i.e. has not reached maintenance dosing) (Vickery 2018).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 5, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Protocol for Vickery BP, Vereda A, Casale TB, et al (The PALISADE Group of Clinical Investigators). AR101 oral immunotherapy for peanut allergy. N Engl J Med 2018;379:1991-2001. DOI: 10.1056/NEJMoa1812856.
6. Vickery BP, Vereda A, Casale TB, et al (The PALISADE Group of Clinical Investigators). AR101 Oral Immunotherapy for Peanut Allergy. N Engl J Med 2018; 379:1991-2001.
7. Clinicaltrials.gov [Internet]. Bethesda, MD: National Library of Medicine (US) 2000 Feb 29- . Identifier NCT03126227. Real-World AR101 Market-Supporting Experience Study in Peanut-Allergic Children: 2018 Sept 23 [cited 2020 Feb 04]. Available from: https://clinicaltrials.gov/ct2/show/NCT03126227. Accessed on October 5, 2021.