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 0 -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 1 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 prescription for an auto-injectable epinephrine agent; **AND**
IV. Individual has a clinical history of allergy to peanuts or peanut-containing foods; **AND**
V. Individual has a positive peanut allergy verified by at least one of the following:
    A. Individual has a serum IgE to peanut of >0.35 kUA/L; **OR**
    B. Individual has a skin prick test to peanut of >3 mm compared to control;

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 chronic, recurrent, or severe gastroesophageal reflux disease (GERD), symptoms of dysphagia or recurrent gastrointestinal symptoms of undiagnosed etiology; **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); OR
VII. Individual will be using for the emergency treatment of allergic reactions, including anaphylaxis.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. 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.
5. Du Toit G, Brown KR, Vereda A, et al. Oral immunotherapy for peanut allergy in children 1 to less than 4 years of age. *NEJM Evid*. 2023;2(11):EVIDoa2300145. doi:10.1056/EVIDoa2300145.