Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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

Override(s)	Approval Duration
Prior Authorization Quantity Limit	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

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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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

I. Individual has had severe or life-threatening anaphylaxis within the previous 60 days of initiation of therapy; **OR**
II. Individual has a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; **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.: 2020. 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: February 4, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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 February 4, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.