ALASKA MEDICAID
Prior Authorization Criteria

Palforzia®
(Arachis hypogaea)
Allergen Powder-dnfp

FDA INDICATIONS AND USAGE[1]

Palforzia is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

APPROVAL CRITERIA[1,2,3]

1. Patient is between 4 to 17 years of age **AND;**
2. Patient has a clinical history of allergic reaction to peanuts **AND**;
3. Is being prescribed by or in consultation with an immunologist or allergist **AND**;
4. The patient must have a serum immunoglobulin E (IgE) to peanut ≥0.35 kUA/L (kilos of allergen-specific units per liter within the past 12 months) and/or a positive skin prick test (SPT) to peanut ≥3 mm compared to control **AND**;
5. The patient is using in conjunction to a peanut allergen avoidance diet to reduce the risk of anaphylaxis due to accidental exposer **AND**;
6. The patient has a confirmed prescription for and auto-injectable epinephrine agent.

DENIAL CRITERIA

1. Failure to meet approval criteria **OR**;
2. Patient uncontrolled asthma **OR**;
3. Patient has a history of esophagitis or other eosinophilic gastrointestinal disease **OR**;
4. The patient has a history of a mast cell disorder, including mastocytosis, urticaria pigmentosa, chronic idiopathic or chronic physical urticaria beyond simple dermatographism (e.g., cold urticaria, cholinergic urticaria), and hereditary or idiopathic Angioedema **OR**;
5. The patient has a history of severe or life-threatening episode of anaphylaxis or anaphylactic shock within 60 days of screening.

CAUTIONS[1,2,3]

- Palforzia can cause anaphylaxis and patients should be properly trained on how to use injectable epinephrine.
- Patients should be monitored for signs and symptoms of eosinophilic esophagitis and should discontinued if suspected.

- Observe patients during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes.

- If patients develop chronic or recurrent local gastrointestinal allergic symptoms, consider dose modification or discontinuation of treatment.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 34 day supply

REFERENCES / FOOTNOTES:

1. Palforzia® (arachis hypogaea) [package insert]. Brisbane, CA. Aimmune Therapeutics; January 2020. Available at: https://www.palforzia.com/static/pi_palforzia.pdf Accessed September 28, 2020
2. Vickery BP, Vereda A, Casale TB, et al for the PALISADE group of clinical investigators. AR101 oral immunotherapy for peanut allergy. New England Journal of Medicine. 2018;379(21):1991-2001.
3. 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 Clinc Immunol. 2017;139(1):29-44.