

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

PALFORZIA
(peanut [Arachis hypogaea] allergen powder-dnfp)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

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 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age and older.

Palforzia is to be used in conjunction with a peanut-avoidant diet.

Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

COVERAGE CRITERIA

Peanut Allergy

Authorization may be granted when the requested drug is being prescribed for the mitigation of allergic reactions, including anaphylaxis, in a patient with a confirmed diagnosis of peanut allergy when ALL of the following criteria are met:

- The diagnosis of peanut allergy has been confirmed by a serum IgE or skin-prick test
- The requested drug is being used in conjunction with a peanut-avoidant diet
- The requested drug is being prescribed by, or in consultation with, an allergist or immunologist [NOTE: The Initial Dose Escalation and first dose of each Up-Dosing level must only be administered in a healthcare setting equipped to monitor patients, and to identify and manage anaphylaxis.]
- The patient does not have ANY of the following: uncontrolled asthma, history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
- The patient meets ONE of the following:
 - The patient is 1 to 17 years of age
 - The request is for Up-dosing or Maintenance phase of treatment in a patient 1 year of age or older

DURATION OF APPROVAL (DOA)

- 3522-A: DOA: 12 months

REFERENCES

1. Palforzia [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc.; July 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed January 02, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 01/02/2024).
4. Palisade Group of Clinical Investigators. AR101 Oral Immunotherapy for Peanut Allergy. *N Engl J Med* 2018; 379:1991-2001.

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