

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp]
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Palforzia, approved by the FDA in 2020, is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. It 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 not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

Peanut allergy is one of the most common food allergies to occur in children and adults. It is commonly associated with anaphylaxis leading to a severe and potentially life-threatening reaction. The standard of care is to adopt a diet that avoids peanuts. However, patients can unknowingly ingest peanuts at any time.

Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] will be considered for coverage when the following criteria are met:

Peanut Allergy

For **initial** authorization:

1. Member is between 1 and 17 years of age; AND
2. Medication is prescribed by or in consultation by an allergist or immunologist; AND
3. Member has a diagnosis of a peanut allergy confirmed by clinical history of allergic reactions; AND
4. Chart notes document serum IgE > 0.35kUa/L OR Skin Prick Test wheal > 3mm compared to control; AND
5. Provider attests medication will be used concomitantly with a peanut avoidant diet; AND
6. Provider attests that member does **NOT** have any of the following:
 - a. Anaphylaxis in the last 60 days;
 - b. Uncontrolled asthma;
 - c. Eosinophilic esophagitis or other eosinophilic gastrointestinal disease; AND
7. Medication will **NOT** be used with Xolair; AND
8. Provider attests the member has been assessed for ability to comply with daily dosing requirement and can adhere to the daily dosing schedule.
9. **Dosage allowed/Quantity limit:** Treatment is administered in 3 sequential phases: initial dose escalation, up-dosing, and maintenance. See package insert for titration tables.
Maintenance dose: One 300 mg sachet orally once daily. (Maintenance QL: 30 sachets/ 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. If the member is over 17 years of age, therapy must have been initiated between 4-17 years of age; AND
2. Chart notes have been provided to show the member is clinically benefiting from therapy and has NOT had anaphylaxis requiring advanced medical care.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/15/2020	New Policy for Palforzia created.
05/08/2024	Transferred to new template; added in consultation with for prescriber specialty and added immunologist; removed cardiovascular disease or uncontrolled hypertension contraindication; removed that member continues to not have contraindications; added that medication will not be used with Xolair; clarified dosing and QL; extended reauthorization length from 6 months to 12 months; added that member must have a clinical history of allergic reactions; added references; removed member is compliant with daily dosing from reauthorization criteria.
08/20/2024	Lowered minimum age limit from 4 to 1 year of age (label update); changed dosing info to summarize and refer to PI for titrating.

References:

1. Palforzia [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc.; 2024.
2. PALISADE Group of Clinical Investigators, et al. AR101 oral immunotherapy for peanut allergy. *N Engl J Med*. 2018;379(21):1991-2001. doi: 10.1056/NEJMoa1812856.
3. Chu DK, Wood RA, French S, et al. Oral immunotherapy for peanut allergy (PACE): a systematic review and meta-analysis of efficacy and safety [published correction appears in *Lancet*. 2019 May 11;393(10184):1936]. *Lancet*. 2019;393(10187):2222-2232. doi:10.1016/S0140-6736(19)30420-9
4. Patrawala M, Shih J, Lee G, Vickery B. Peanut Oral Immunotherapy: a Current Perspective. *Curr Allergy Asthma Rep*. 2020;20(5):14. Published 2020 Apr 20. doi:10.1007/s11882-020-00908-6
5. Togias A, Cooper SF, Acebal ML, et al. Addendum guidelines for the prevention of peanut allergy in the United States. *JAAPA*. 2017;30(3):1-5. doi:10.1097/01.JAA.0000512231.15808.66

Effective date: 01/01/2025

Revised date: 08/20/2024