UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2182-6
Program	Prior Authorization – Medical Necessity
Medication	Palforzia [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp]
P&T Approval Date	1/2020, 3/2020, 3/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:
Palforzia [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp]is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. 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. Palforzia is to be used in conjunction with a peanut-avoidant diet.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Palforzia** will be approved based on the following criteria:

   a. Diagnosis and clinical history of peanut allergy as documented by **both** of the following:

      (1) A serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L
      (2) A mean wheal diameter that is at least 3mm larger than the negative control on skin-prick testing for peanut

- AND -

   b. **One** of the following

      (1) **Both** of the following

         (a) Patient is 4 to 17 years of age
         (b) Patient is in the initial dose escalation phase therapy

-OR-

      (2) **Both** of the following:

         (a) Patient is 4 years of age and older
         (b) Patient is in the up-dosing or maintenance phase of therapy

-AND-

   c. Used in conjunction with a peanut-avoidant diet

-AND-

d. Patient does not have any of the following

(1) History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
(2) History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months
(3) Severe or poorly controlled asthma

-AND-

e. Prescribed by or in consultation with an allergist/immunologist

-AND-

f. Prescriber is certified/enrolled in the Palforzia REMS Program

Authorization will be issued for 12 months.

B. Reauthorization

1. **Palforzia** will be approved based on the following criteria:

a. Documentation of positive clinical response to Palforzia therapy

-AND-

b. Used in conjunction with a peanut-avoidant diet

-AND-

c. Prescribed by or in consultation with an allergist/immunologist

-AND-

d. Prescriber is certified/enrolled in the Palforzia REMS Program

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply

4. References:

1. The PALISADE Group of Clinical Investigators. AR101 Oral Immunotherapy for Peanut Allergy. *N Engl J Med.* 379(21):1991-2001.
2. Palforzia [prescribing information]. Brisbane, CA: Aimmune Therapeutics, Inc.; March 2023.

Program	Prior Authorization – Medical Necessity – Palforzia
Change Control	
1/2020	New program.
3/2020	Updated background section. Added age requirements for initial phase and up-dosing/maintenance phase. Added that it is being used along with a peanut-avoidant diet. Added the prescriber is certified/enrolled in the Palforzia REMS Program. Updated references.
3/2021	Annual review. Updated references.
3/2022	Annual review. No changes.
3/2023	Annual review. No changes.
3/2024	Annual review. Updated references.