UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Palforzia

Program	Palforzia
Medication	Palforzia [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp]
Markets in Scope	Arizona, California, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	1/2020
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

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

2. Coverage Criteria:

A. Initial Authorization

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

a. Diagnosis and clinical history of peanut allergy as documented by all 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 of 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.

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.; January 2020.

Program	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.