Peanut (*Arachis hypogaea*) Allergen Powderdnfp (Palforzia™)

Place of Service

Office Administration (for initial doses) Self-Administration (maintenance kit) –

Can be requested from Pharmacy Benefit

HCPCS: J3590

NDCs:

- 71881-113-13: Initial dose escalation kit [contains 13 capsules]
- 71881-101-45 per 3mg kit
- 71881-102-90 per 6mg kit
- 71881-103-45 per 12mg kit
- 71881-104-15 per 20mg kit
- 71881-105-30 per 40mg kit
- 71881-106-60 per 80mg kit
- 71881-107-30 per 120mg kit
- 71881-108-60 per 160mg kit
- 71881-109-30 per 200mg kit
- 71881-110-60 per 240mg kit
- 71881-111-15 per 300mg kit

Condition listed in policy (see criteria for details)

Peanut allergy

AHFS therapeutic class: Allergenic extracts, therapeutic

Mechanism of action: Oral immunotherapy

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for peanut allergen powder (Palforzia[™]) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Peanut allergy

- 1. Being prescribed by or in consultation with an allergist or immunologist, AND
- 2. One of the following:
 - a. Request is for initial therapy and patient is aged 4 through 17 years of age, or
 - b. Request is for continuation in a patient who has started therapy between ages of 4 and 17 years

Covered Doses

Treatment Phase Dose level

Initial dose escalation (all 5 dose levels administered on the same day) Medical Benefit	0.5 mg x1 followed by 1 mg x1 followed by 1.5 mg x1 followed by 3 mg x1 followed by 6 mg x1
Up-dosing (each dose level taken daily for 2 weeks with first dose of each dose level administered under supervision of healthcare professional) Medical Benefit – First dose of each dose level	3 mg per day x 14 days followed by 6 mg per day x 14 days followed by 12 mg per day x 14 days followed by 20 mg per day x 14 days followed by 40 mg per day x 14 days followed by 80 mg per day x 14 days followed by 120 mg per day x 14 days followed by 160 mg per day x 14 days followed by 200 mg per day x 14 days followed by 240 mg per day x 14 days followed by
<i>Pharmacy Benefit</i> – Remainder doses of each dose level	300 mg per day x 14 days 300 mg per day x 14 days
Maintenance	300 mg per day
Pharmacy Benefit	

Coverage Period

Initial dose: 1 day needed Up-dosing: 1 day needed for the first dose of each dose level ICD-10: T78.01

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for peanut allergen powder (Palforzia[™]) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code §</u> 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 0.5 mg 1 mg, 10 mg, 20 mg and 100 mg Capsules or 300 mg Sachets in the following kits:
 - Initial dose escalation kit [5 doses]
 - Up-dosing kits by dose level [15 doses per kit]
 - Level 1 (3mg kit)
 - Level 2 (6mg kit)
 - Level 3 (12mg kit)
 - Level 4 (20mg kit)
 - Level 5 (40mg kit)
 - Level 6 (80mg kit)
 - Level 7 (120mg kit)
 - Level 8 (160mg kit)

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peanut allergen powder (Palforzia™)

- Level 9 (200mg kit)
- Level 10 (240mg kit)
- Level 11 (300mg kit)
- Maintenance 300mg kit [30 sachet doses per kit]

(6) References

- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex[®]. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- Palforzia[™] [Peanut (Arachis hypogaea) Allergen Powder-dnfp] [Prescribing information]. Brisbane, CA: Aimmune Therapeutics, Inc.; 1/2020.

(7) Policy Update

Date of last review: 4Q2022 Date of next review: 4Q2023 Changes from previous policy version:

• No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee

PHP Medi-Cal