

peanut allergen powder-dnfp (Palforzia)**Medical Benefit Drug Policy****Place of Service**

Office Administration (*for initial doses*)

Self-Administration (*maintenance kit*) – *Can be requested from Pharmacy Benefit*

Drug Details

USP Category: IMMUNOLOGICAL AGENTS

Mechanism of Action: The exact mechanism of action of peanut (*Arachis hypogaea*) allergen powder has not been established

HCPCS:

J3590:Unclassified biologics

How Supplied:

- 0.5 mg, 1 mg, 10 mg, 20 mg and 100 mg Capsules or 300 mg Sachets in the following kits (Commercial packaging):
 - Initial dose escalation kit ages 1 through 3 years [4 doses]
 - Initial dose escalation kit ages 4 through 17 years [5 doses]
 - Up-dosing kits by dose level [15 doses per kit]
 - Level 0 (1 mg kit)
 - Level 1 (3 mg kit)
 - Level 2 (6 mg kit)
 - Level 3 (12 mg kit)
 - Level 4 (20 mg kit)
 - Level 5 (40 mg kit)
 - Level 6 (80 mg kit)
 - Level 7 (120 mg kit)
 - Level 8 (160 mg kit)
 - Level 9 (200 mg kit)
 - Level 10 (240 mg kit)
 - Level 11 (300 mg kit)
 - Maintenance 300mg kit

Condition(s) listed in policy (*see coverage criteria for details*)

- Peanut Allergy

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Peanut Allergy

Meets medical necessity if all the following are met:

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

Covered Doses:

Dosing Configuration for Initial Dose Escalation Ages 1 through 3 years (Single Day Dose Escalation)

Initial Dose Escalation supplied as a single card consisting of 4 blisters containing a total of 7 capsules.

Dose Level	Total Dose	Dose Configuration
A	0.5 mg	One 0.5 mg capsule
B	1 mg	One 1 mg capsule
C	1.5 mg	One 0.5 mg capsule; One 1 mg capsule
D	3 mg	Three 1 mg capsules

Dosing Configuration for Initial Dose Escalation Ages 4 through 17 years (Single Day Dose Escalation)

Initial Dose Escalation supplied as a single card consisting of 5 blisters containing a total of 13 capsules.

Dose Level	Total Dose	Dose Configuration
A	0.5 mg	One 0.5 mg capsule
B	1 mg	One 1 mg capsule
C	1.5 mg	One 0.5 mg capsule; One 1 mg capsule
D	3 mg	Three 1 mg capsules
E	6 mg	Six 1 mg capsules

Daily Dosing Configuration for Up-Dosing

Dose Level	Total Daily Dose	Daily Dose Configuration	Dose Duration (weeks)	Patient Age (years)
0	1 mg	One 1 mg capsule	2	1-3
1	3 mg	Three 1 mg capsules	2	1-17
2	6 mg	Six 1 mg capsules	2	1-17
3	12 mg	Two 1 mg capsules; One 10 mg capsule	2	1-17
4	20 mg	One 20 mg capsule	2	1-17
5	40 mg	Two 20 mg capsule	2	1-17
6	80 mg	Four 20 mg capsule	2	1-17
7	120 mg	One 20 mg capsule; One 100 mg capsule	2	1-17
8	160 mg	Three 20 mg capsules; One 100 mg capsule	2	1-17
9	200 mg	Two 100 mg capsules	2	1-17
10	240 mg	Two 20 mg capsules; Two 100 mg capsules	2	1-17
11	300 mg	One 300 mg sachet	2	1-17

Daily Dosing Configuration for Maintenance

Dose Level	Total Daily Dose	Daily Dose Configuration
11	300 mg	One 300 mg sachet

Coverage Period:

Initial dose escalation: 1 day

Up-dosing: 24 weeks. The first dose of each new Up-Dosing level is administered under the supervision of a health care professional. Other doses besides the first dose of each Dose Level can be given in the home and obtained through the Pharmacy benefit.

References

1. Palforzia (peanut [Arachis hypogaea] allergen powder-dnfp) Prescribing Information. Greer Laboratories, Inc., Lenoir, NC: 9/2024.

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*