

peanut allergen powder-dnfp (Palforzia)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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 age is consistent with the FDA approved indication (aged 1 through 17 years of age)
 - b. Request is for continuation in a patient who has started therapy between the ages of 1 and 17 years

Covered Doses:

Dosing Configuration for Initial Dose Escalation Ages 1 through 3 years (Single Day Dose Escalation) - Covered under the Medical Benefit

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) - Covered under the Medical Benefit

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

- First dose of each dose level is covered under the Medical Benefit
- Remainder doses of each dose level is covered under the Pharmacy Benefit

| 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 - Covered under the Pharmacy Benefit

| 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 are given in the home and obtained through the Pharmacy benefit.

ICD-10:

T78.01, Z91.010

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*