Drug Quantity Management – Per Rx
Allergen Immunotherapy – Palforzia

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108038

Effective 2/7/23: 80468

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Palforzia® (peanut [*Arachis hypogaea*] allergen powder-dnfp for oral administration)

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Palforzia. The quantities listed in this policy are sufficient to accomplish a one-day initial dose escalation, each two week up-dosing level, or 30 days of maintenance treatment. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Package Name	Package Content	Maximum Quantity per Rx
Palforzia® (peanut [*Arachis hypogaea*] allergen powder-dnfp for oral administration)	Palforzia Initial Dose Pack	2 x 0.5 mg capsules 11 x 1 mg capsules	13 capsules
	Palforzia 3 mg Level 1 Up-Dosing Pack	45 x 1 mg capsules	45 capsules
	Palforzia 6 mg Level 2 Up-Dosing Pack	90 x 1 mg capsules	90 capsules
	Palforzia 12 mg Level 3 Up-Dosing Pack	30 x 1 mg capsules 15 x 10 mg capsules	45 capsules
	Palforzia 20 mg Level 4 Up-Dosing Pack	15 x 20 mg capsules	15 capsules
	Palforzia 40 mg Level 5 Up-Dosing Pack	30 x 20 mg capsules	30 capsules
	Palforzia 80 mg Level 6 Up-Dosing Pack	60 x 20 mg capsules	60 capsules
	Palforzia 120 mg Level 7 Up-Dosing Pack	15 x 20 mg capsules 15 x 100 mg capsules	30 capsules
	Palforzia 160 mg Level 8 Up-Dosing Pack	45 x 20 mg capsules 15 x 100 mg capsules	60 capsules
	Palforzia 200 mg Level 9 Up-Dosing Pack	30 x 100 mg capsules	30 capsules
	Palforzia 240 mg Level 10 Up-Dosing Pack	30 x 20 mg capsules 30 x 100 mg capsules	60 capsules
	Palforzia 300 mg Level 11 Up-Dosing Pack	15 x 300 mg sachets	15 sachets
	Palforzia 300 mg Maintenance Pack	30 x 300 mg sachets	30 sachets

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Palforzia Level 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Up-Dosing Packs

1. If the individual requires greater than a 2 week Up-Dosing duration, approve the quantity listed below per dispensing.

Palforzia Up-Dosing Level	Total Quantity per Dispensing
Palforzia 3 mg Level 1 Up-Dosing Pack	90 capsules
Palforzia 6 mg Level 2 Up-Dosing Pack	180 capsules
Palforzia 12 mg Level 3 Up-Dosing Pack	90 capsules
Palforzia 20 mg Level 4 Up-Dosing Pack	30 capsules
Palforzia 40 mg Level 5 Up-Dosing Pack	60 capsules
Palforzia 80 mg Level 6 Up-Dosing Pack	120 capsules
Palforzia 120 mg Level 7 Up-Dosing Pack	60 capsules
Palforzia 160 mg Level 8 Up-Dosing Pack	120 capsules
Palforzia 200 mg Level 9 Up-Dosing Pack	60 capsules
Palforzia 240 mg Level 10 Up-Dosing Pack	120 capsules
Palforzia 300 mg Level 11 Up-Dosing Pack	30 capsules

Palforzia Initial Dose Pack, Palforzia 300 mg Maintenance Pack

No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Palforzia, an oral immunotherapy, is indicated for the mitigation of **allergic reactions**, including anaphylaxis, that may occur with accidental exposure to peanut.[1] It is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients 4 through 17 years of age; up-dosing and maintenance may be continued in patients ≥ 4 years of age. Palforzia is labeled to be used in conjunction with a peanut-avoidant diet. It is not indicated for the emergency treatment of allergic reactions, including anaphylaxis. Prior to initiation, the prescriber should verify that the patient has injectable epinephrine and has been instructed on its appropriate use.

Dosing
There are three sequential phases of Palforzia administration: Initial Dose Escalation, Up-Dosing, and Maintenance.[1]

Initial Dose Escalation. The Initial Dose Escalation is administered on a single day under the supervision of a healthcare professional in a healthcare setting with the ability to manage possibly severe allergic reactions, including anaphylaxis. Doses are administered in a sequential order (Levels A-E; 0.5 mg to 6 mg) as outlined in Table 1. Each dose is given 20 to 30 minutes apart while the patient is observed. After the last dose, patients should be monitored for 60 minutes. Palforzia should be discontinued if the patient has symptoms requiring medical intervention following any dose.

Table 1. Dosing Configuration for Palforzia Initial Dose Escalation.[1*]

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

[*] Each dose is administered 20 to 30 minutes apart while the patient is observed.

Up-Dosing. Patients who tolerate at least the 3 mg dose during the Initial Dose Escalation must return to the healthcare setting for initiation of Up-Dosing.[1] If possible, Up-Dosing should begin the day after Initial Dose Escalation. If the patient is unable to begin Up-Dosing within 4 days, Initial Dose Escalation in a healthcare setting must be repeated. Up-Dosing is initiated at a 3 mg dose (Level 1) and consists of 11 dosing levels (Table 2). The first dose of each new level must be administered under the supervision of a healthcare professional in a healthcare setting where the patient is monitored for at least 60 minutes. If the new dose level is tolerated, the patient may continue daily dosing at that dose level at home. Up-Dosing is done over the course of approximately 22 weeks to achieve the maintenance dose of 300 mg.

Table 2. Daily Dosing Configuration for Up-Dosing.[1*]

Dose Level	Total Daily Dose	Dose Configuration	Dose Duration (Weeks)
1	3 mg	Three 1 mg capsules	2
2	6 mg	Six 1 mg capsules	2
3	12 mg	Two 1 mg capsules; one 10 mg capsule	2
4	20 mg	One 20 mg capsule	2
5	40 mg	Two 20 mg capsules	2
6	80 mg	Four 20 mg capsules	2
7	120 mg	One 20 mg capsule: one 100 mg capsule	2
8	160 mg	Three 20 mg capsules; one 100 mg capsule	2
9	200 mg	Two 100 mg capsules	2
10	240 mg	Two 20 mg capsules; two 100 mg capsules	2
11	300 mg	One 300 mg sachet	2

[*] The first dose of each level is administered in a healthcare setting.

Maintenance. Following completion of all levels of Up-Dosing, the maintenance dose of Palforzia is 300 mg once daily (QD) supplied in a sachet.[1] Daily maintenance dosing is required to maintain Palforzia's effect. The patient should be contacted at regular intervals during maintenance dosing to assess for adverse reactions.

Dose Modification. The dose should not be modified during Initial Dose Escalation.[1] In some situations, dose modification may be appropriate during Up-Dosing or Maintenance. Palforzia should be discontinued in patients who are unable to tolerate at least the 3 mg dose during Initial Dose Escalation (e.g., patients with suspected eosinophilic esophagitis; patients unable to be compliant with daily dosing requirements; and patients who have recurrent asthma exacerbations or persistent loss of asthma control).

Availability
Palforzia is available as capsules containing 0.5 mg, 1 mg, 10 mg, 20 mg, and 100 mg of peanut protein and a sachet containing 300 mg of peanut protein. The capsules are supplied in an Initial Dose Escalation Kit (13 capsules of various strengths to facilitate dosing), as well as kits to accommodate each level of Up-Dosing and Maintenance. Contents of each kit are provided in the Quantity Limit table below. Office Dose Kits are also available to facilitate administration of each Up-Dosing level in the healthcare setting and are not targeted in this policy.

References

1. Palforzia® [prescribing information]. Brisbane, CA: Aimmune Therapeutics; March 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No change to criteria.	04/19/2022