Effective Date: 11/15/2020
Reviewed: 9/2020 Scope: Medicaid

PALFORZIA (peanut [Arachis hypogaea] allergen powder-dnfp)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Palforzia 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.

Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR APPROVAL

Authorization of 12 months may be granted when all of the following criteria are met:
A. The requested drug is being prescribed for the mitigation of allergic reactions, including anaphylaxis, in a patient with a confirmed diagnosis of peanut allergy
B. The diagnosis of peanut allergy has been confirmed with an IgE or skin-prick test
C. The requested drug is being used in conjunction with a peanut-avoidant diet
D. The requested drug is being prescribed by, or in consultation with, an allergist or immunologist
[Note: The Initial Dose Escalation and first dose of each Up-Dosing level must only be administered in a healthcare setting equipped to monitor patients, and to identify and manage anaphylaxis.]
E. Prescriber is certified/enrolled in the Palforzia REMS Program.
F. The patient is 4 to 17 years of age at initiation of therapy
G. The patient does not have uncontrolled asthma OR a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease

III. QUANTITY LIMIT

Treatment with Palforzia is administered in 3 sequential phases:
- Initial Dose Escalation - administered in sequential order on a single day, beginning at dose level A (total of 5 levels A-E), and each dose should be separated by an observation period of 20-30 minutes; this is administered under supervision to manage potentially severe allergic reactions, including anaphylaxis
- Up-Dosing – consists of 11 dose levels, administered in sequential order at 2 week intervals; no dose level should be omitted; the first dose is administered under supervision to manage potentially severe allergic reactions, including anaphylaxis
- Maintenance – all levels of Up-dosing should be completed before starting Maintenance at 300 mg daily; daily maintenance is required to maintain the effect of Palforzia and the patient should be assessed for adverse reactions at regular intervals

Drug Name	GPI Name	Quantity Limit (Daily Dose)
PALFORZIA INITIAL DOSE ESCALATION	PEANUT POWDER-DNFP STARTER PACK 0.5 & 1 & 1.5 & 3 & 6 MG	13
PALFORZIA LEVEL 1	PEANUT POWDER-DNFP CAP SPRINKLE PACK 3 X 1 MG (3 MG DOSE)	3
PALFORZIA LEVEL 2	PEANUT POWDER-DNFP CAP SPRINKLE PACK 6 X 1 MG (6 MG DOSE)	6
PALFORZIA LEVEL 3	PEANUT POWDER-DNFP PACK 2 X 1 MG & 10 MG (12 MG DOSE)	3
PALFORZIA LEVEL 4	PEANUT POWDER-DNFP CAP SPRINKLE PACK 20 MG (20 MG DOSE)	1
PALFORZIA LEVEL 5	PEANUT POWDER-DNFP CAP SPRINKLE PACK 2 X 20 MG (40 MG DOSE)	2
PALFORZIA LEVEL 6	PEANUT POWDER-DNFP CAP SPRINKLE PACK 4 X 20 MG (80 MG DOSE)	4
PALFORZIA LEVEL 7	PEANUT POWDER-DNFP PACK 20 MG & 100 MG (120 MG DOSE)	2
PALFORZIA LEVEL 8	PEANUT POWDER-DNFP PACK 3 X 20 MG & 100 MG (160 MG DOSE)	4
PALFORZIA LEVEL 9	PEANUT POWDER-DNFP PACK 2 X 100 MG (200 MG DOSE)	2
PALFORZIA LEVEL 10	PEANUT POWDER-DNFP PACK 2 X 20 MG & 2 X 100 MG (240 MG DOSE)	4
PALFORZIA LEVEL 11 (TITRATION)	PEANUT ALLERGEN POWDER-DNFP TITRATION PACKET 300 MG	1
PALFORZIA LEVEL 11 (MAINTENANCE)	PEANUT ALLERGEN POWDER-DNFP MAINTENANCE PACKET 300 MG	1

IV. REFERENCES

1. Palforzia [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc.; January 2020.
2. Palisade Group of Clinical Investigators. AR101 Oral Immunotherapy for Peanut Allergy. *N Engl J Med* 2018; 379:1991-2001.