Peanut Allergy Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
06-01-2024	05-01-2020

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Palforzia® peanut [Arachis hypogaea] allergen powder-dnfp) Capsules Sachets	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.		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Peanut Allergy

Palforzia administration occurs in three sequential phases: initial dose escalation, up-dosing, and maintenance. Initial dose escalation is administered on a single day under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. The initial dose escalation should be administered sequentially beginning at level A. Discontinue Palforzia if symptoms requiring medical intervention (e.g., use of epinephrine) occur with any dose during initial dose escalation. Patients who tolerate at least the 3 mg single dose of Palforzia during initial dose escalation must return to the health care setting for initiation of up-dosing. If possible, begin up-dosing the day after initial dose escalation. Repeat initial dose escalation in a health care setting if the patient is unable to begin up-dosing within 4 days.(1)

Palforzia Initial Dose Escalation:(1)

Dose Level	Total Dose (mg)	Dose Configuraton
A	0.5	1 x 0.5 mg capsule
B	1	1 x 1 mg capsule
C	1.5	1 x 0.5 mg capsule + 1 x 1 mg capsule
D	3	3 x 1 mg capsules
E	6	6 x 1 mg capsules

Up-dosing consists of 11 dose levels and is initiated at the 3 mg dose. The first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe

allergic reactions, including anaphylaxis. If the patient tolerates the first dose of the increase dose level, the patient may continue that dose level at home. All dose levels in the up-dosing schedule should be administered in sequential order at 2-week intervals if tolerated. No more than 1 dose should be consumed per day. Consider dose modification or discontinuation for patients who do not tolerate up-dosing as scheduled in label.(1)

Palforzia Daily Dosing Configuration for Up-Dosing:(1)

Dose Level	Total Daily Dose (mg)	Daily Dose Configuration	Dose Duration (weeks)
1	3	3 x 1 mg capsules	2
2	6	6 x 1 mg capsules	2
3	12	2 x 1 mg capsules; 1 x 10 mg capsule	2
4	20	1 x 20 mg capsule	2
5	40	2 x 20 mg capsules	2
6	80	4 x 20 mg capsules	2
7	120	1 x 20 mg capsule; 1 x 100 mg capsule	2
8	160	3 x 20 mg capsules; 1 x 100 mg capsule	2
9	200	2 x 100 mg capsules	2
10	240	2 x 20 mg capsules; 2 x 100 mg capsules	2
11	300	1 x x 300 mg sachet	2

All dose levels of the up-dosing must be completed before starting maintenance. The maintenance dose of Palforzia is 300 mg daily. Daily maintenance is required to maintain the effect of Palforzia. During maintenance, patients should be contacted and assessed at regular intervals for adverse reaction to Palforzia.(1)

Temporary dose modification may be required for patients who experience allergic reactions during up-dosing or maintenance, for patients who miss doses, or for practical reasons of patient management. Allergic reactions, including gastrointestinal reactions, that are severe, recurrent, bothersome, or last longer than 90 minutes during up-dosing or maintenance should be actively managed with dose modifications. Use clinical judgment to determine the best course of action, which can include maintaining the dose level for longer than 2 weeks, reducing, withholding, or discontinuing Palforzia doses. Following 1 to 2 consecutive days of missed doses, patients may resume Palforzia at the same dose level. Data are insufficient to inform resumption of Palforzia following 3 or more consecutive days of missed doses. Patients who miss 3 or more consecutive days of Palforzia should consult their healthcare providers; resumption of Palforzia should be done under medical supervision. Discontinue Palforzia for: patients who are unable to tolerate doses up to and including the 3 mg dose during initial dose escalation, patients with suspected eosinophilic esophagitis, patients unable to comply with the daily dosing requirements, patients with recurrent asthma exacerbations or persistent loss of asthma control. It should be verified prior to initiation and during therapy with Palforzia that the patient has injectable epinephrine and has been instructed on its use.(1)

Efficacy	Peanut oral immunotherapy was studied in a phase 3 trial (NCT02635776) with patients 4 to 55 years of age with peanut allergy for allergic dose-limiting symptoms

	at a challenge dose of 100 mg or less of peanut protein (approximately one third of a peanut kernel) in a double-blind, placebo-controlled food challenge.(2) Subjects were required to have serum IgE to peanut greater than or equal to 0.35 kUA/L within 12 months before study entry and/or a mean wheal diameter on skin prick test to peanut greater than or equal to 3 mm greater than the negative control. At study entry, subjects reacted at 100 mg or less of peanut protein in a double-blind, placebo-controlled food challenge (DBPCFC).(1) Participants with an allergic response were randomly assigned, in a 3:1 ratio, to receive AR101 (a peanut-derived investigational biologic oral immunotherapy drug) or placebo in an escalating-dose program. Participants who completed the regimen (i.e., received 300 mg per day of the maintenance regimen for approximately 24 weeks) underwent a double-blind, placebo-controlled food challenge at trial exit. The primary efficacy end point was the proportion of participants 4 to 17 years of age who could ingest a challenge dose of 600 mg or more, without dose limiting symptoms.(2) Of the 551 participants who received AR101 or placebo, 496 were 4 to 17 years of age; of these, 250 of 372 participants (67.2%) who received active treatment, as compared with 5 of 124 participants (4.0%) who received placebo, were able to ingest a dose of 600 mg or more of peanut protein, without dose-limiting symptoms, at the exit food challenge (difference, 63.2 percentage points; 95% confidence interval, 53.0 to 73.3; P <0.001). During the exit food challenge, the maximum severity of symptoms was moderate in 25% of the participants in the active-drug group and 59% of those in the placebo group and severe in 5% and 11%, respectively. Adverse events during the intervention period affected more than 95% of the participants 4 to 17 years of age. A total of 34.7% of the participants in the active-drug group had mild events, as compared with 50.0% of those in the placebo group; 59.7% and 44.4% of the participants, respectively, had events that were graded as moderate, and 4.3% and 0.8%, respectively, had events that were graded as severe. Efficacy was not shown in the participants 18 years of age or older.(2)
Safety	Palforzia is contraindicated in the following:(1) • Uncontrolled asthma • A history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease Palforzia has the following boxed warning:(1) • Palforzia can cause anaphylaxis, which may be life-threatening and can occur at any time during Palforzia therapy. • Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use. • Do not administer Palforzia to patients with uncontrolled asthma. • Dose modifications may be necessary following an anaphylactic reaction. • Observe patients during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes. • Palforzia is available only through a restricted program called the Palforzia REMS

REFERENCES

Number	Reference
1	Palforzia prescribing information. Aimmune Therapeutics. March 2023.
2	Vickery, B. P., Vereda, A., Casale, T. B., Beyer, K., du Toit, G., Hourihane, J. O., Jones, S. M., Shreffler, W. G., Marcantonio, A., Zawadzki, R., Sher, L., Carr, W. W., Fineman, S., Greos, L., Rachid, R., Ibanez, D., Tilles, S., Assa'ad, A. H., Nilsson, C., … Burks, A. wesley. (2018). AR101 Oral Immunotherapy for Peanut Allergy. New England Journal of Medicine, 379(21), 1991–2001. https://doi.org/10.1056/nejmoa1812856

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Palforzia level 11 (maint	Peanut Allergen Powder-dnfp Maintenance Packet 300 MG	300 MG	M ; N ; O ; Y	N		
Palforzia level 11 (titra	Peanut Allergen Powder-dnfp Titration Packet 300 MG	300 MG	M ; N ; O ; Y	N		
Palforzia level 5	Peanut Powder-dnfp Cap Sprinkle Pack 2 x 20 MG (40 MG Dose)	20 MG	M ; N ; O ; Y	N		
Palforzia level 4	Peanut Powder-dnfp Cap Sprinkle Pack 20 MG (20 MG Dose)	20 MG	M ; N ; O ; Y	N		
Palforzia level 1	Peanut Powder-dnfp Cap Sprinkle Pack 3 x 1 MG (3 MG Dose)	1 MG	M ; N ; O ; Y	N		
Palforzia level 6	Peanut Powder-dnfp Cap Sprinkle Pack 4 x 20 MG (80 MG Dose)	20 MG	M ; N ; O ; Y	N		
Palforzia level 2	Peanut Powder-dnfp Cap Sprinkle Pack 6 x 1 MG (6 MG Dose)	1 MG	M ; N ; O ; Y	N		
Palforzia level 3	Peanut Powder-dnfp Pack 2 x 1 MG & 10 MG (12 MG Dose)	2 x 1 MG & 10 MG	M ; N ; O ; Y	N		
Palforzia level 9	Peanut Powder-dnfp Pack 2 x 100 MG (200 MG Dose)	100 MG	M ; N ; O ; Y	N		
Palforzia level 10	Peanut Powder-dnfp Pack 2 x 20 MG & 2 x 100 MG (240 MG Dose)	2 x 20 MG & 2 x 100 MG	M ; N ; O ; Y	N		
Palforzia level 7	Peanut Powder-dnfp Pack 20 MG & 100 MG (120 MG Dose)	20 MG & 100 MG	M ; N ; O ; Y	N		
Palforzia level 8	Peanut Powder-dnfp Pack 3 x 20 MG & 100 MG (160 MG Dose)	3 x 20 MG & 100 MG	M ; N ; O ; Y	N		
Palforzia initial dose es	Peanut Powder-dnfp Starter Pack 0.5 & 1 & 1.5 & 3 & 6 MG	0.5 & 1 & 1.5 & 3 & 6 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Palforzia initial dose es	Peanut Powder-dnfp Starter Pack 0.5 & 1 & 1.5 & 3 & 6 MG	0.5 & 1 & 1.5 & 3 & 6 MG	1	Kit	180	DAYS			
Palforzia level 1	Peanut Powder-dnfp Cap Sprinkle Pack 3 x 1 MG (3 MG Dose)	1 MG	90	Capsules	30	DAYS			
Palforzia level 10	Peanut Powder-dnfp Pack 2 x 20 MG & 2 x	2 x 20 MG & 2	120	Capsules	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	100 MG (240 MG Dose)	x 100 MG							
Palforzia level 11 (maint	Peanut Allergen Powder-dnfp Maintenance Packet 300 MG	300 MG	30	Packets	30	DAYS			
Palforzia level 11 (titra	Peanut Allergen Powder-dnfp Titration Packet 300 MG	300 MG	30	Packets	30	DAYS			
Palforzia level 2	Peanut Powder-dnfp Cap Sprinkle Pack 6 x 1 MG (6 MG Dose)	1 MG	180	Capsules	30	DAYS			
Palforzia level 3	Peanut Powder-dnfp Pack 2 x 1 MG & 10 MG (12 MG Dose)	2 x 1 MG & 10 MG	90	Capsules	30	DAYS			
Palforzia level 4	Peanut Powder-dnfp Cap Sprinkle Pack 20 MG (20 MG Dose)	20 MG	30	Capsules	30	DAYS			
Palforzia level 5	Peanut Powder-dnfp Cap Sprinkle Pack 2 x 20 MG (40 MG Dose)	20 MG	60	Capsules	30	DAYS			
Palforzia level 6	Peanut Powder-dnfp Cap Sprinkle Pack 4 x 20 MG (80 MG Dose)	20 MG	120	Capsules	30	DAYS			
Palforzia level 7	Peanut Powder-dnfp Pack 20 MG & 100 MG (120 MG Dose)	20 MG & 100 MG	60	Capsules	30	DAYS			
Palforzia level 8	Peanut Powder-dnfp Pack 3 x 20 MG & 100 MG (160 MG Dose)	3 x 20 MG & 100 MG	120	Capsules	30	DAYS			
Palforzia level 9	Peanut Powder-dnfp Pack 2 x 100 MG (200 MG Dose)	100 MG	60	Capsules	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Palforzia initial dose es	Peanut Powder-dnfp Starter Pack 0.5 & 1 & 1.5 & 3 & 6 MG	0.5 & 1 & 1.5 & 3 & 6 MG	Medicaid
Palforzia level 1	Peanut Powder-dnfp Cap Sprinkle Pack 3 x 1 MG (3 MG Dose)	1 MG	Medicaid
Palforzia level 10	Peanut Powder-dnfp Pack 2 x 20 MG & 2 x 100 MG (240 MG Dose)	2 x 20 MG & 2 x 100 MG	Medicaid
Palforzia level 11 (maint	Peanut Allergen Powder-dnfp Maintenance Packet 300 MG	300 MG	Medicaid
Palforzia level 11 (titra	Peanut Allergen Powder-dnfp Titration Packet 300 MG	300 MG	Medicaid
Palforzia level 2	Peanut Powder-dnfp Cap Sprinkle Pack 6 x 1 MG (6 MG Dose)	1 MG	Medicaid
Palforzia level 3	Peanut Powder-dnfp Pack 2 x 1 MG & 10 MG (12 MG Dose)	2 x 1 MG & 10 MG	Medicaid
Palforzia level 4	Peanut Powder-dnfp Cap Sprinkle Pack 20 MG (20 MG Dose)	20 MG	Medicaid
Palforzia level 5	Peanut Powder-dnfp Cap Sprinkle Pack 2 x 20 MG (40 MG Dose)	20 MG	Medicaid

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Palforzia level 6	Peanut Powder-dnfp Cap Sprinkle Pack 4 x 20 MG (80 MG Dose)	20 MG	Medicaid
Palforzia level 7	Peanut Powder-dnfp Pack 20 MG & 100 MG (120 MG Dose)	20 MG & 100 MG	Medicaid
Palforzia level 8	Peanut Powder-dnfp Pack 3 x 20 MG & 100 MG (160 MG Dose)	3 x 20 MG & 100 MG	Medicaid
Palforzia level 9	Peanut Powder-dnfp Pack 2 x 100 MG (200 MG Dose)	100 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Palforzia initial dose es	Peanut Powder-dnfp Starter Pack 0.5 & 1 & 1.5 & 3 & 6 MG	0.5 & 1 & 1.5 & 3 & 6 MG	Medicaid
Palforzia level 1	Peanut Powder-dnfp Cap Sprinkle Pack 3 x 1 MG (3 MG Dose)	1 MG	Medicaid
Palforzia level 10	Peanut Powder-dnfp Pack 2 x 20 MG & 2 x 100 MG (240 MG Dose)	2 x 20 MG & 2 x 100 MG	Medicaid
Palforzia level 11 (maint	Peanut Allergen Powder-dnfp Maintenance Packet 300 MG	300 MG	Medicaid
Palforzia level 11 (titra	Peanut Allergen Powder-dnfp Titration Packet 300 MG	300 MG	Medicaid
Palforzia level 2	Peanut Powder-dnfp Cap Sprinkle Pack 6 x 1 MG (6 MG Dose)	1 MG	Medicaid
Palforzia level 3	Peanut Powder-dnfp Pack 2 x 1 MG & 10 MG (12 MG Dose)	2 x 1 MG & 10 MG	Medicaid
Palforzia level 4	Peanut Powder-dnfp Cap Sprinkle Pack 20 MG (20 MG Dose)	20 MG	Medicaid
Palforzia level 5	Peanut Powder-dnfp Cap Sprinkle Pack 2 x 20 MG (40 MG Dose)	20 MG	Medicaid
Palforzia level 6	Peanut Powder-dnfp Cap Sprinkle Pack 4 x 20 MG (80 MG Dose)	20 MG	Medicaid
Palforzia level 7	Peanut Powder-dnfp Pack 20 MG & 100 MG (120 MG Dose)	20 MG & 100 MG	Medicaid
Palforzia level 8	Peanut Powder-dnfp Pack 3 x 20 MG & 100 MG (160 MG Dose)	3 x 20 MG & 100 MG	Medicaid
Palforzia level 9	Peanut Powder-dnfp Pack 2 x 100 MG (200 MG Dose)	100 MG	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent within the past 30 days **OR** B. The prescriber states the patient has been treated with the requested agent within the past 30 days AND is at risk if therapy is changed **OR** C. BOTH of the following: 1. The patient has a diagnosed peanut allergy confirmed by ONE of the following: A. A serum peanut-specific IgE level greater than or equal to 0.35 kUA/L **OR** B. A positive skin-prick test determined by a mean wheal diameter that is at least 3mm larger than the negative control upon skin-prick testing for peanut **OR** C. The patient has a positive result to an oral peanut food challenge **AND** 2. If the requested agent is Palforzia, the patient was 4-17 years of age at the time of initiating therapy **AND**

Module	Clinical Criteria for Approval
	2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient has injectable epinephrine on hand **AND** 4. The requested agent is to be used in conjunction with a peanut-avoidance diet **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **Length of Approval:** up to 12 months