Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts) (new therapeutic indication: peanut allergy, ≥ 1 to < 4 years)

of 3 July 2025

At their session on 3 July 2025, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts) in accordance with the resolution of 7 April 2022 last modified on 28 June 2022:

Peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts)

Resolution of: 3 July 2025
Entry into force on: 3 July 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 December 2024):

Palforzia is indicated for the treatment of patients aged 1 to 17 years with a confirmed diagnosis of peanut allergy. Palforzia may be continued in patients 18 years of age and older. Palforzia should be used in conjunction with a peanut-avoidant diet.

Therapeutic indication of the resolution (resolution of 3 July 2025):

Palforzia is indicated for the treatment of patients aged 1 to 3 years with a confirmed diagnosis of peanut allergy. Palforzia should be used in conjunction with a peanut-avoidant diet.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

Children aged 1 to 3 years with a confirmed diagnosis of peanut allergy

Appropriate comparator therapy:

- monitoring wait-and-see approach

Extent and probability of the additional benefit of peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts) in combination with a peanut-avoidant diet compared to monitoring wait-and-see approach:

Hint for a non-quantifiable additional benefit

Study results according to endpoints:[1]

Children aged 1 to 3 years with a confirmed diagnosis of peanut allergy

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-04) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No deaths occurred.
Morbidity	↑	Advantage in the absence of symptoms during provocation testing.
Health-related quality of life	∅	No data available.
Side effects	↔	No relevant differences for the benefit assessment; in detail disadvantage in the specific AE "Gastrointestinal disorders".

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: No data available.
n.a.: not assessable

ARC005 study: Peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts) vs placebo

Mortality

Endpoint	Peanut protein		Placebo		Peanut protein vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[a]
Overall mortality[b]					
	98	0 (0)	48	0 (0)	-

Morbidity

Endpoint	Peanut protein		Placebo		Peanut protein vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[a]
Allergic reactions due to accidental exposure to peanuts					
	98	5 (5.1)	48	3 (6.3)	0.82 [0.20; 3.27]; 0.835[c]
Absence of symptoms in all tested doses (up to 2,000 mg) in the exit DBPCFC[d]					
	98	50 (51.0)	48	2 (4.2)	12.32 [3.13; 8.45]; < 0.001

Endpoint	Peanut protein		Placebo		Peanut protein vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[a]
Maximum symptom severity in all tested doses (maximum 2,000 mg) in the exit DBPCFC[e]					
Mild (grade 1)	98	29 (29.6)	48	23 (47.9)	–
Moderate (grade 2)	98	17 (17.3)	48	21 (43.8)	–
Severe (grade ≥ 3)	98	2 (2.0)	48	2 (4.2)	0.49 [0.07; 3.36]; 0.466

Health-related quality of life

No data collected.

Side effects

Endpoint	Peanut protein		Placebo		Peanut protein vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[a]
Total adverse events (*presented additionally*)					
	98	96 (98.0)	48	47 (97.9)	-
Serious adverse events (SAE)					
	98	6 (6.1)	48	2 (4.2)	1.47 [0.31; 7.01]; 0.629
Severe adverse events[f]					
	98	5 (5.1)	48	2 (4.2)	1.22 [0.25; 6.08]; 0.804
Therapy discontinuation due to adverse events					
	98	6 (6.1)	48	0 (0)	6.43 [0.37; 111.90]; 0.201
Systemic allergic reactions (AEs)[g, h]					
	98	8 (8.2)	48	4 (8.3)	0.98 [0.31; 3.09]; 0.972
Severe systemic allergic reactions (severe AEs)[g, i]					
	98	0 (0)	48	0 (0)	-
Gastrointestinal disorders (SOC, AEs)					
	98	82 (83.7)	48	31 (64.6)	1.30 [1.03; 1.63]; 0.025

Endpoint	Peanut protein		Placebo		Peanut protein vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[a]

a. Unless otherwise stated, RR, 95% CI and p value result from a log-binomial regression; for absence of symptoms and maximum symptom severity, additional adjustments were made by region.
b. The results on overall mortality are based on the data on fatal AEs.
c. IQWiG calculation of RR, 95% CI (asymptotic) and p value (unconditional exact test, CSZ method according to Martín Andrés & Silva Mato, 1994)
d. Severity grade 0 (no symptoms) as per severity grading of allergic reactions according to CoFAR
e. Severity grading of allergic reactions according to CoFAR
f. Severe AEs ≥ grade 3: Severity grading of allergic reactions according to CoFAR, systemic allergic reactions according to EAACI and all other AEs according to CTCAE.
g. Called anaphylactic reaction in Module 4 A; defined according to adapted diagnostic criteria according to Sampson et al, 2006
h. Severity grade 1 to 3 (mild, moderate, severe) according to modified EAACI criteria
i. Severity grade 3 (severe) according to modified EAACI criteria; also includes anaphylactic shock

Abbreviations used:
CoFAR: Consortium for Food Allergy Research; CTCAE = Common Terminology Criteria for Adverse Events; DBPCFC: Double-Blind Placebo-Controlled Food Challenge; EAACI: European Academy of Allergy and Clinical Immunology; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; PT: preferred term; RCT: randomised controlled trial; RR: relative risk; SOC: system organ class; SAE: serious adverse event; AE: adverse event; vs: versus

2. Number of patients or demarcation of patient groups eligible for treatment

Children aged 1 to 3 years with a confirmed diagnosis of peanut allergy

Approx. 9,960 to 22,700 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Palforzia (active ingredient: peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts)) freely available at the following link (last access: 17 April 2025):

https://www.ema.europa.eu/en/documents/product-information/palforzia-epar-product-information_en.pdf

Treatment with peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts) should only be initiated and monitored by specialists experienced in the treatment of allergies.

The initial build-up dosing and the first dose of each new dose escalation level shall be administered under medical supervision in a specialised healthcare facility ready to treat potentially severe allergic reactions. The patient must have adrenaline (epinephrine) available for self-injection at all times.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients. The training material includes instructions on how to deal with the any side effects caused by peanut protein, especially anaphylaxis and eosinophilic oesophagitis.

4. Treatment costs

Annual treatment costs:

Children aged 1 to 3 years with a confirmed diagnosis of peanut allergy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Peanut protein as defatted powder of *Arachis hypogaea L.*, semen (peanuts)	
First year:	€ 2,167.65
Subsequent years:	€ 2,393.67
Additionally required SHI services:	Different from patient to patient
Appropriate comparator therapy:	
Monitoring wait-and-see approach	Not calculable
Additionally required SHI services:	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 June 2025)

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Children aged 1 to 3 years with a confirmed diagnosis of peanut allergy

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 3 July 2025.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 3 July 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken