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
Pembrolizumab (New therapeutic indication: Unresectable non-epithelioid malignant pleural mesothelioma, first-line, combination with pemetrexed and platinum chemotherapy)

of 16 October 2025

At their session on 16 October 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. 5 to the information on the benefit assessment of Pembrolizumab in accordance with the resolution of 15 May 2025:

Pembrolizumab

Resolution of: 16 October 2025
Entry into force on: 16 October 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 4 April 2025):

KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adults with unresectable non-epithelioid malignant pleural mesothelioma.

Therapeutic indication of the resolution (resolution of 16 October 2025):

See new therapeutic indication according to marketing authorisation.

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

Adult patients with unresectable non-epithelioid malignant pleural mesothelioma; first-line therapy

Appropriate comparator therapy:

- Nivolumab in combination with ipilimumab

Extent and probability of the additional benefit of pembrolizumab in combination with pemetrexed and platinum chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adult patients with unresectable non-epithelioid malignant pleural mesothelioma; first-line therapy

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-53) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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		

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

Adult patients with unresectable non-epithelioid malignant pleural mesothelioma; first-line therapy

Approx. 55 – 105 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 Keytruda (active ingredient: pembrolizumab) at the following publicly accessible link (last access: 19 September 2025):

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

Treatment with pembrolizumab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of adults with lung cancer or malignant pleural mesothelioma, as well as specialists in internal medicine and pulmonology or specialists in pulmonary medicine and other doctors from other specialist groups participating in the Oncology Agreement.

In accordance with the 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 contains, in particular, instructions on the management of immune-mediated side effects potentially occurring with pembrolizumab as well as on infusion-related reactions.

4. Treatment costs

The annual treatment costs shown refer to the first year of treatment.

Annual treatment costs:

Adult patients with unresectable non-epithelioid malignant pleural mesothelioma; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pembrolizumab in combination with pemetrexed and cisplatin	
Pembrolizumab	€ 81,438.79
Pemetrexed	€ 18,621.48
Cisplatin	€ 2,017.18
Total (pembrolizumab + pemetrexed + cisplatin)	€ 102,077.45
Additionally required SHI services	€ 406.09 – € 529.67
Pembrolizumab in combination with pemetrexed and carboplatin	
Pembrolizumab	€ 81,438.79
Pemetrexed	€ 18,621.48
Carboplatin	€ 6,873.00
Total (pembrolizumab + pemetrexed + carboplatin)	€ 106,933.27
Additionally required SHI services	€ 134.39 – € 188.19
Appropriate comparator therapy:	
Nivolumab	€ 76,379.04
Ipilimumab	€ 57,271.75
Total (nivolumab + ipilimumab)	€ 133,650.79

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

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Pembrolizumab in combination with pemetrexed and platinum chemotherapy					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 (21-day) or 8.7 (42-day)	€ 1,740 (21-day) or € 870 (42-day)

Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4 (21-day)	€ 1,740 (21-day)
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4 (21-day)	€ 1,740 (21-day)
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4 (21-day)	€ 1,740 (21-day)
Appropriate comparator therapy					
Nivolumab in combination with ipilimumab					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 (21-day)	€ 1,740 (21-day)
Ipilimumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 (42-day)	€ 870 (42-day)

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:

Adult patients with unresectable non-epithelioid malignant pleural mesothelioma; first-line therapy

- No medicinal product with new active ingredients that can be used in a combination therapy that 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 16 October 2025.

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

Berlin, 16 October 2025

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

Prof. Hecken