

# 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

Tislelizumab (new therapeutic indication: non-small cell lung  
cancer, high risk of recurrence, neoadjuvant and adjuvant  
treatment, monotherapy or combination with platinum-  
based chemotherapy)

From 19 March 2026

At their session on 19 March 2026, 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 Tislelizumab in accordance with the resolution of 19 March  
2026 (recurrent or metastatic nasopharyngeal carcinoma (NPC), first-line, combination  
with gemcitabine and cisplatin):**

## **Tislelizumab**

Resolution of: 19 March 2026

Entry into force on: 19 March 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

### **Therapeutic indication (according to the marketing authorisation of 21 August 2025):**

Tislelizumab (Tevimbra), in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of adult patients with resectable NSCLC at high risk of recurrence.

### **Therapeutic indication of the resolution (resolution of 19 March 2026):**

See new therapeutic indication according to marketing authorisation.

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

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

#### **Appropriate comparator therapy:**

- Neoadjuvant treatment with nivolumab in combination with platinum-based therapy followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression  $\geq 1\%$ )

*or*

- Neoadjuvant treatment with pembrolizumab in combination with platinum-based therapy followed by adjuvant treatment with pembrolizumab

#### **Extent and probability of the additional benefit of tislelizumab in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by tislelizumab as monotherapy compared with the appropriate comparator therapy:**

An additional benefit is not proven.

## Study results according to endpoints:<sup>1</sup>

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

No data available.

### Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
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		

---

<sup>1</sup> Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-122), unless otherwise indicated.

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

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

Approx. 5,090 to 5,780 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 Tevimbra (active ingredient: tislelizumab) at the following publicly accessible link (last access: 10 March 2026):

[https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/tevimbra-epar-product-information_en.pdf)

Treatment with tislelizumab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with non-small cell lung cancer, 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 (including patient identification card).

The training material contains, in particular, information and warnings about immune-mediated side effects as well as infusion-related reactions.

#### 4. Treatment costs

##### Treatment costs:

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

Designation of the therapy	Treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by tislelizumab as monotherapy (adjuvant treatment)	
Neoadjuvant treatment:	
Tislelizumab + platinum-based chemotherapy	
Tislelizumab	€ 10,340.52 – € 13,787.36
Carboplatin	€ 1,089.60 – € 1,706.72
Cisplatin	€ 347.79 – € 573.76
Docetaxel	€ 1,470.21 – € 1,960.28
Gemcitabine	€ 1,394.52 – € 1,859.36
Paclitaxel	€ 2,867.91 – € 3,823.88
Pemetrexed	€ 3,210.60 – € 4,280.80
Vinorelbine	€ 864.96 – € 1,439.84
Total (tislelizumab + platinum-based chemotherapy; neoadjuvant)	€ 11,553.27 – € 19,774.88 <sup>2</sup>
Adjuvant treatment:	
Tislelizumab (monotherapy)	
Tislelizumab	€ 55,149.44
Appropriate comparator therapy:	
Neoadjuvant treatment with nivolumab in combination with platinum-based therapy followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression ≥ 1%)	
Neoadjuvant treatment:	
Nivolumab + platinum-based chemotherapy	
Nivolumab	€ 17,439.60
Carboplatin	€ 1,452.80 – € 1,706.72
Cisplatin	€ 463.72 – € 573.76
Docetaxel	€ 1,960.28
Gemcitabine	€ 1,859.36

<sup>2</sup> The lower limit of the range results for tislelizumab in combination with cisplatin and vinorelbine. The upper limit of the range results for tislelizumab in combination with carboplatin and pemetrexed.

Designation of the therapy	Treatment costs/ patient
Paclitaxel	€ 3,823.88
Pemetrexed	€ 4,280.80
Vinorelbine	€ 1,153.28 – € 1,439.84
Total (nivolumab + platinum-based chemotherapy; neoadjuvant)	€ 19,056.60 – € 23,427.12 <sup>3</sup>
Monitoring wait-and-see approach	
Not calculable	
Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab as monotherapy (adjuvant treatment)	
Neoadjuvant treatment:	
Pembrolizumab + platinum-based chemotherapy	
Pembrolizumab	€ 18,721.56
Carboplatin	€ 1,452.80 – € 1,706.72
Cisplatin	€ 463.72 – € 573.76
Docetaxel	€ 1,960.28
Gemcitabine	€ 1,859.36
Paclitaxel	€ 3,823.88
Pemetrexed	€ 4,280.80
Vinorelbine	€ 1,153.28 – € 1,439.84
Total (pembrolizumab + platinum-based chemotherapy; neoadjuvant)	€ 20,338.56 – € 24,709.08 <sup>3</sup>
Adjuvant treatment:	
Pembrolizumab (monotherapy)	
Pembrolizumab	€ 60,845.07 – € 65,525.46

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 January 2026)

<sup>3</sup> The lower limit of the range results for nivolumab in combination with cisplatin and vinorelbine. The upper limit of the range results for nivolumab in combination with carboplatin and pemetrexed.

Costs for additionally required SHI services: not applicable

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:					
Tislelizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by tislelizumab as monotherapy (adjuvant treatment)					
Neoadjuvant treatment:					
Tislelizumab + platinum-based chemotherapy					
Tislelizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	3 – 4	€ 300 – € 400
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	3 – 4	€ 300 – € 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3 – 4	€ 300 – € 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	3 – 4	€ 300 – € 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	6 – 8	€ 600 – € 800
Paclitaxel	Surcharge for the preparation of a	€ 100	1	3 – 4	€ 300 – € 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing cytostatic agents				
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3 – 4	€ 300 – € 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	6 – 8	€ 600 – € 800
Adjuvant treatment:					
Tislelizumab (monotherapy)					
Tislelizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8	€ 800
Appropriate comparator therapy:					
Neoadjuvant treatment with nivolumab in combination with platinum-based therapy followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression $\geq 1\%$ )					
Neoadjuvant treatment:					
Nivolumab + platinum-based chemotherapy					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4	€ 400
Carboplatin	Surcharge for the preparation of a parenteral	€ 100	1	4	€ 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	solution containing cytostatic agents				
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8	€ 800
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8	€ 800
Monitoring wait-and-see approach					
Not calculable					
Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab as monotherapy (adjuvant treatment)					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Neoadjuvant treatment:					
Pembrolizumab + platinum-based chemotherapy					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2 – 4	€ 200 – € 400
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8	€ 800
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Pemetrexed	Surcharge for production of a parenteral preparation	€ 100	1	4	€ 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8	€ 800
Adjuvant treatment:					
Pembrolizumab (monotherapy)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	7 - 13	€ 700 – € 1,300

**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:

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

- No medicinal product with new active ingredients for use in combination therapy in compliance with 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 statutory 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 G-BA website on 19 March 2026.**

The justification to this resolution will be published on the G-BA website at [www.g-ba.de](http://www.g-ba.de).

Berlin, 19 March 2026

Federal Joint Committee  
in accordance with Section 91 SGB V  
The Chair

Prof. Hecken