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)
Tislelizumab (new therapeutic indication: oesophageal squamous cell carcinoma (OSCC), PD-L1 expression TAP score ≥ 5%, first-line, combination with platinum-based chemotherapy)

of 18 June 2025

At their session on 18 June 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 Tislelizumab in accordance with the resolution of 18 June 2025 for the therapeutic indication: "Non-small cell lung cancer, after previous therapy":

Tislelizumab

Resolution of: 18 June 2025
Entry into force on: 18 June 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 25 November 2024):

Tevimbra, in combination with platinum-based chemotherapy, is indicated for the first-line treatment of adult patients with unresectable, locally advanced or metastatic OSCC whose tumours express PD-L1 with a TAP score ≥ 5%.

Therapeutic indication of the resolution (resolution of 18 June 2025):

See new therapeutic indication according to marketing authorisation.

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

a) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have a tumour cell PD-L1 expression ≥ 1% or a combined positive score (CPS) ≥ 10; first-line therapy

Appropriate comparator therapy:

- Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (only for patients with tumour cell PD-L1 expression ≥ 1%)

or

- nivolumab in combination with ipilimumab (only for patients with tumour cell PD-L1 expression ≥ 1%)

or

- pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (only for patients with a combined positive score (CPS) ≥ 10)

Extent and probability of the additional benefit of tislelizumab in combination with platinum-containing chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have no tumour cell PD-L1 expression ≥ 1% and no combined positive score (CPS) ≥ 10; first-line therapy

Appropriate comparator therapy:

– Cisplatin in combination with 5-fluorouracil

Extent and probability of the additional benefit of tislelizumab in combination with platinum-containing chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have a tumour cell PD-L1 expression ≥ 1% or a combined positive score (CPS) ≥ 10; first-line therapy

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-129) unless otherwise indicated.

b) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have no tumour cell PD-L1 expression ≥ 1% and no combined positive score (CPS) ≥ 10; first-line therapy

There are no assessable data.

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

a) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have a tumour cell PD-L1 expression ≥ 1% or a combined positive score (CPS) ≥ 10; first-line therapy

Approx. 1,010 - 1,390 patients

b) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have no tumour cell PD-L1 expression ≥ 1% and no combined positive score (CPS) ≥ 10; first-line therapy

Approx. 520 – 660 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) agreed upon in

the context of the marketing authorisation at the following publicly accessible link (last access: 11 June 2025):

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

Therapy with tislelizumab should only be initiated and monitored by specialists in internal medicine, haematology and oncology as well as specialists in internal medicine and gastroenterology and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of patients with oesophageal carcinoma.

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, instructions on the management of immune-mediated side effects potentially occurring with tislelizumab.

4. Treatment costs

Annual treatment costs:

The costs for the first year of treatment are shown for the cost representation in the resolution.

a) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have a tumour cell PD-L1 expression ≥ 1% or a combined positive score (CPS) ≥ 10; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab in combination with platinum-based chemotherapy	
Tislelizumab	€ 75,142.25
Cisplatin	€ 1,785.94- € 2,286.19
5-fluorouracil	€ 1,814.82
Total	€ 78,743.01- € 79,243.26
Additionally required SHI services	€ 271.70 - € 341.48
Appropriate comparator therapy:	
Nivolumab in combination with fluoropyrimidine and platinum-based combination chemotherapy	
Nivolumab	€ 75,571.60 - € 75,862.26
Cisplatin	€ 1,708.07
5-fluorouracil	€ 1,355.90
Total	€ 78,635.57 - € 78,926.23

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI services	€ 203.00 - € 255.13
Nivolumab in combination with ipilimumab	
Nivolumab	€ 75,862.26
Ipilimumab	€ 57,271.75
Total	€ 133,134.01
Pembrolizumab in combination with platinum and fluoropyrimidine-based chemotherapy	
Pembrolizumab	€ 81,438.79
Cisplatin	€ 2,286.19
5-fluorouracil	€ 1,814.82
Total	€ 85,539.80
Additionally required SHI services	€ 271.70 - € 341.48

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 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:					
Tislelizumab in combination with platinum-based chemotherapy					
Tislelizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-fluorouracil	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Appropriate comparator therapy:					

Nivolumab in combination with fluoropyrimidine and platinum-based combination chemotherapy					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0 or 26.1	€ 1,300 or € 2,610
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
5-fluorouracil	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	65.0	€ 6,500
Nivolumab in combination with ipilimumab					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 or 26.1	€ 1,740 or € 2,610
Ipilimumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7	€ 870
Pembrolizumab in combination with platinum and fluoropyrimidine-based chemotherapy					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 or 17.4	€ 870 or € 1,740

Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-fluorouracil	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700

b) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have no tumour cell PD-L1 expression ≥ 1% and no combined positive score (CPS) ≥ 10; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab in combination with platinum-based chemotherapy	
Tislelizumab	€ 75,142.25
Cisplatin	€ 1,785.94- € 2,286.19
5-fluorouracil	€ 1,814.82
Total	€ 78,743.01- € 79,243.26
Appropriate comparator therapy:	
Cisplatin + 5-fluorouracil	
Cisplatin	€ 2,495.86
5-fluorouracil	€ 1,814.82
Total	€ 4,310.68

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 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:					
Tislelizumab in combination with platinum-based chemotherapy					
Tislelizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-fluorouracil	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Appropriate comparator therapy:					
Cisplatin + 5-fluorouracil					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-fluorouracil	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700

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:

a) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have a tumour cell PD-L1 expression ≥ 1% or a combined positive score (CPS) ≥ 10; 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.

b) Adults with unresectable, locally advanced or metastatic, non-curatively treatable oesophageal squamous cell carcinoma, whose tumours express PD-L1 with a TAP score ≥ 5% and also have no tumour cell PD-L1 expression ≥ 1% and no combined positive score (CPS) ≥ 10; 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 18 June 2025.

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

Berlin, 18 June 2025

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

Prof. Hecken