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: gastric or gastroesophageal junction adenocarcinoma, PD-L1 expression TAP score ≥ 5, HER2-, first-line, combination with platinum and fluoropyrimidine-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: "Oesophageal squamous cell carcinoma, PD-L1 expression TAP score ≥ 5%, first-line, combination with platinum-based chemotherapy":

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 and fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of adult patients with HER-2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (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

Adults with HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (TAP) score ≥ 5%; first-line therapy

Appropriate comparator therapy:

- Nivolumab in combination with fluoropyrimidine and platinum-based combination chemotherapy (only for tumours with PD-L1 expression (CPS) ≥ 5)

  or

- pembrolizumab in combination with fluoropyrimidine and platinum-based combination chemotherapy (only for tumours with PD-L1 expression (CPS) ≥ 1)

Extent and probability of the additional benefit of tislelizumab with platinum and fluoropyrimidine-based chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (TAP) score ≥ 5%; first-line therapy

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

Adults with HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (TAP) score ≥ 5%; first-line therapy

Approx. 1,941 – 3,067 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: 1 April 2025):

https://www.ema.europa.eu/en/documents/overview/tevimbra-epar-medicine-overview_en.pdf

https://www.ema.europa.eu/en/documents/overview/tevimbra-epar-medicine-overview_en.pdf

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-131) unless otherwise indicated.

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 gastric or gastroesophageal junction carcinomas.

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.

Adults with HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (TAP) score ≥ 5%; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab in combination with cisplatin and 5-fluorouracil (5-FU)	
Tislelizumab	€ 75,142.25
Cisplatin	€ 2,286.19
5-FU	€ 1,814.82
Total	€ 79,243.25
Tislelizumab in combination with oxaliplatin and capecitabine	
Tislelizumab	€ 75,142.25
Oxaliplatin	€ 8,295.28
Capecitabine	€ 2,090.21
Total	€ 85,527.73
Appropriate comparator therapy:	
Pembrolizumab in combination with cisplatin and 5-fluorouracil (5-FU)	
Pembrolizumab	€ 81,438.79
Cisplatin	2,286.19
5-FU	€ 1,814.82
Total	85,539.79
Pembrolizumab in combination with oxaliplatin and capecitabine	
Pembrolizumab	€ 81,438.79

Designation of the therapy	Annual treatment costs/ patient
Oxaliplatin	€ 8,295.28
Capecitabine	€ 2,090.21
Total	€ 91,824.27
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (FOLFOX-4) (only for tumours with PD-L1 expression (CPS ≥ 5))	
Nivolumab	€ 75,862.26
5-FU	1,844.75
Folinic acid	€ 11,616.07
Oxaliplatin	€ 9,804.99
Total	€ 99,128.06
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (mod. FOLFOX-6) (only for tumours with PD-L1 expression (CPS ≥ 5))	
Nivolumab	€ 75,862.26
5-FU	€ 1,172.67
Folinic acid	€ 10,824.98
Oxaliplatin	€ 9,804.99
Total	€ 97,664.90
Nivolumab in combination with capecitabine and oxaliplatin (only for tumours with PD-L1 expression (CPS ≥ 5))	
Nivolumab	€ 75,862.26
Capecitabine	€ 2,090.21
Oxaliplatin	€ 8,295.28
Total	€ 86,247.75

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2025)

Additionally required SHI services: not applicable

If 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	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a	€ 100	1	17.4	€ 1,740

	parenteral preparation containing cytostatic agents				
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					
Pembrolizumab in combination with cisplatin and 5-FU					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 - 17.4	€ 870 - € 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Pembrolizumab in combination with oxaliplatin and capecitabine					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 - 17.4	€ 870 or € 1,740
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (FOLFOX-4) (only for tumours with PD-L1 expression (CPS ≥ 5))					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 - 26.1	€ 1,740 or € 2,610
5-FU Bolus	Surcharge for production of a	€ 100	2	52.2	€ 5,220

	parenteral preparation containing cytostatic agents				
5-FU 22 h infusion	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	52.2	€ 5,220
Folinic acid	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	52.2	€ 5,220
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (FOLFOX-6) (only for tumours with PD-L1 expression (CPS ≥ 5))					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 - 26.1	€ 1,740 - € 2,610
5-FU Bolus	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
5-FU 22 h infusion	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Folinic acid	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Nivolumab in combination with capecitabine and oxaliplatin (only for tumours with PD-L1 expression (CPS ≥ 5))					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Oxaliplatin	Surcharge for production of a	€ 100	1	17.4	€ 1,740

	parenteral preparation containing cytostatic agents				

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 HER2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumours express PD-L1 with a tumour area positivity (TAP) score ≥ 5%; first-line therapy

- 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 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