

# 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 (oesophageal squamous cell carcinoma, after  
previous therapy)

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. Annex XII shall be amended in alphabetical order to include the active ingredient  
Tislelizumab as follows:**

## **Tislelizumab**

Resolution of: 18 June 2025

Entry into force on: 18 June 2025

Federal Gazette, BAnz AT DD. MM YYYY Bx

### **Therapeutic indication (according to the marketing authorisation of 15 September 2023):**

#### Oesophageal squamous cell carcinoma (OSCC)

Tevimbra as monotherapy is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic OSCC after prior platinum-based chemotherapy.

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

See therapeutic indication according to marketing authorisation.

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

#### Adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy

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

- Nivolumab

#### **Extent and probability of the additional benefit of tislelizumab compared to nivolumab:**

An additional benefit is not proven.

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

Adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy

### Summary of results for relevant clinical endpoints

There are no assessable data.

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 unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy

Approx. 330 to 540 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: 5 May 2025):

[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)

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<sup>1</sup> Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-130) unless otherwise indicated.

Treatment 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 cancer.

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:

Adults with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab	€ 75,142.25
Appropriate comparator therapy:	
Nivolumab	€ 75,571.60 - € 75,862.26

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

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	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy:					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0 – 26.1	€ 1,300 - € 2,610

**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 unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma after prior platinum-based chemotherapy

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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](http://www.g-ba.de).

Berlin, 18 June 2025

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

Prof. Hecken