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: small cell lung cancer, first-line, combination with etoposide and platinum 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 18 June 2025 for the therapeutic indication "(new therapeutic indication: gastric or gastroesophageal junction adenocarcinoma, PD-L1 expression ≥ 5, HER2-negative, first-line, combination with platinum and fluoropyrimidine-based chemotherapy)":**

Tislelizumab

Resolution of: 19 March 2026
Entry into force on: 19 March 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 2 May 2025):

Tevimbra, in combination with etoposide and platinum chemotherapy, is indicated for the first-line treatment of adult patients with extensive-stage ES-SCLC.

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 extensive-stage small cell lung cancer (ES-SCLC); first-line

Appropriate comparator therapy:

– Atezolizumab in combination with carboplatin and etoposide

or

– durvalumab in combination with carboplatin and etoposide

or

– durvalumab in combination with cisplatin and etoposide

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with extensive-stage small cell lung cancer (ES-SCLC); first-line

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

Adults with extensive-stage small cell lung cancer (ES-SCLC); first-line

Approx. 3,820 to 8,124 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

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 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.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-118), unless otherwise indicated.

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 extensive-stage small cell lung cancer (ES-SCLC); first-line

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab in combination with cisplatin and etoposide	
Tislelizumab	€ 59,975.02
Cisplatin	€ 1,708.07 – € 2,286.18
Etoposide	€ 2,994.42 – € 6,258.26
Total	€ 64,677.51 - € 68,519.46
Additionally required SHI services	*€ 223.98 - € 326.88*
Tislelizumab in combination with carboplatin and etoposide	
Tislelizumab	€ 59,975.02
Carboplatin	€ 5,134.22
Etoposide	€ 2,994.42 – € 6,258.26
Total	€ 68,103.66 - € 71,367.50
Appropriate comparator therapy:	
Atezolizumab in combination with carboplatin and etoposide	
Atezolizumab	€ 67,771.78
Carboplatin	€ 1,579.76
Etoposide	€ 1,438.68
Total	€ 70,790.22
Durvalumab in combination with carboplatin and etoposide	
Durvalumab	€ 82,586.28
Carboplatin	€ 1,579.76
Etoposide	€ 1,438.68
Total	€ 85,604.72
Durvalumab in combination with cisplatin and etoposide	

Designation of the therapy	Annual treatment costs/ patient
Durvalumab	*€ 82,586.28*
Cisplatin	€ 525.56
Etoposide	€ 1,438.68
Total	€ 84,550.52
Additionally required SHI services	*€ 127.71 - € 139.37*

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

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 or 8.7	€ 1,740 or € 870
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0 – 17.4	€ 1,300 - € 1,740
Etoposide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	13.0 – 17.4	€ 3,900 - € 5,220
Appropriate comparator therapy:					
Carboplatin	Surcharge for production of a parenteral preparation	€ 100	1	4.0	€ 400

	containing cytostatic agents				
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0	€ 400
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	14.0	€ 1,400
Etoposide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	4.0	€ 1,200

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 extensive-stage small cell lung cancer (ES-SCLC); first-line

– 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.

Berlin, 19 March 2026

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

Prof. Hecken