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: non-small cell lung cancer, non-squamous, PD-L1 expression ≥ 50%, first-line, combination with pemetrexed and platinum-containing 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, 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 8 July 2024):**

Tevimbra, in combination with pemetrexed and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with non-squamous NSCLC whose tumours have PD-L1 expression on ≥50% of tumour cells with no EGFR or ALK positive mutations and who have:

• locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or

• metastatic NSCLC.

**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 who have locally advanced non-squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic non-squamous NSCLC, with PD-L1 expression ≥ 50%, with no EGFR or ALK aberrations; first-line therapy

**Appropriate comparator therapy:**

- Pembrolizumab as monotherapy

*or*

- atezolizumab as monotherapy

*or*

- cemiplimab as monotherapy

*or*

- nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only for patients with ECOG PS 0-1)

*or*

- pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients without ECOG-PS 0-1)

*or*

- atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)

*or*

– atezolizumab in combination with nab-paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)

*or*

– cemiplimab in combination with platinum-based chemotherapy (only for patients with ECOG-PS 0-1)

*or*

– durvalumab in combination with tremelimumab and platinum-based chemotherapy (only for patients with ECOG-PS 0-1)

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

An additional benefit is not proven.

**Study results according to endpoints:**[1]

Adults who have locally advanced non-squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic non-squamous NSCLC, with PD-L1 expression ≥ 50%, with no EGFR or ALK aberrations; 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:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-127) unless otherwise indicated.

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

Adults who have locally advanced non-squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic non-squamous NSCLC, with PD-L1 expression ≥ 50%, with no EGFR or ALK aberrations; first-line therapy

Approx. 3,460 – 4,600 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: 3 June 2025):

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

## 4. Treatment costs

**Annual treatment costs:**

The annual treatment costs shown refer to the first year of treatment.

Adults who have locally advanced non-squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic non-squamous NSCLC, with PD-L1 expression ≥ 50%, with no EGFR or ALK aberrations; first-line therapy

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Tislelizumab in combination with pemetrexed and platinum-containing chemotherapy | |
| Tislelizumab | € 75,142.25 |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Pemetrexed | € 18,621.48 |
| Carboplatin | € 6,319.68 |
| Cisplatin | € 2,017.18 |
| Tislelizumab + pemetrexed + carboplatin | |
| Total<br>(tislelizumab + pemetrexed + carboplatin) | € 100,083.41 |
| *Additionally required SHI costs* | *€ 133.88 – € 187.17* |
| Tislelizumab + pemetrexed + cisplatin | |
| Total<br>(tislelizumab + pemetrexed + cisplatin) | € 95,780.91 |
| *Additionally required SHI costs* | *€ 405.58 – € 528.65* |
| Appropriate comparator therapy: | |
| Monotherapies with immune checkpoint inhibitors | |
| Atezolizumab | € 67,771.78 |
| Cemiplimab | € 70,925.18 |
| Pembrolizumab | € 81,438.79 |
| Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy<br>(only for patients with ECOG-PS 0-1) | |
| Nivolumab | € 75,862.26 |
| Ipilimumab | € 57,271.75 |
| Carboplatin | € 992.08 |
| Cisplatin | € 231.86 |
| Pemetrexed | € 2,140.40 |
| Nivolumab + ipilimumab + carboplatin + pemetrexed | |
| Total<br>(nivolumab + ipilimumab + carboplatin + pemetrexed) | € 136,266.49 |
| *Additionally required SHI costs* | *€ 38.21 – € 40.87* |
| Nivolumab + ipilimumab + cisplatin + pemetrexed | |
| Total<br>(nivolumab + ipilimumab + cisplatin + pemetrexed) | € 135,506.27 |
| *Additionally required SHI costs* | *€ 154.26 – € 156.92* |
| Atezolizumab + bevacizumab + paclitaxel + carboplatin<br>(only for patients with ECOG-PS 0-1) | |
| Induction therapy (4 – 6 cycles) | |
| Atezolizumab | € 15,579.72 – € 23,369.58 |
| Bevacizumab (7.5 mg/kg or 15.5 mg/kg) | € 5,067.68 – € 7,601.52<br>or |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| | € 7,601.52 – € 11,402.28 |
| Paclitaxel | € 3,823.88 – € 5,735.82 |
| Carboplatin | € 1,984.16 – € 2,976.24 |
| *Additionally required SHI costs* | *€ 84.70 – € 142.97* |
| Maintenance treatment | |
| Atezolizumab | € 44,402.20 (after 6 cycles of induction therapy)<br>–<br>€ 52,192.06 (after 4 cycles of induction therapy) |
| Bevacizumab (7.5 mg/kg or 15.5 mg/kg) | € 14,442.89 (after 6 cycles of induction therapy)<br>–<br>€ 16,976.73 (after 4 cycles of induction therapy)<br>or<br>€ 21,664.33 (after 6 cycles of induction therapy)<br>–<br>€ 25,465.09 (after 4 cycles of induction therapy) |
| Total<br>(cost range taking into account the number of induction cycles and bevacizumab dosage regimens) | <u>Combination with 7.5 mg/kg bevacizumab:</u><br>€ 95,624.23 – € 98,528.25<br>(4 - 6 induction cycles)<br><br>or<br><br><u>Combination with 15 mg/kg bevacizumab:</u><br>€ 106,646.43 – € 109,550.45<br>(4 - 6 induction cycles) |
| *Additionally required SHI costs* | *€ 84.70 – € 142.97* |
| Atezolizumab + carboplatin + nab-paclitaxel<br>(only for patients with ECOG-PS 0-1) | |
| Induction therapy | |
| Atezolizumab | € 15,579.72 – € 23,369.58 |
| Carboplatin | € 1,984.16 – € 2,976.24 |
| nab-paclitaxel | € 9,786.00 – € 14,679.00 |
| Total<br>Atezolizumab + carboplatin + nab-paclitaxel<br>(induction therapy) | € 27,349.88 – € 41,024.82 |
| Maintenance treatment | |
| Atezolizumab | € 44,402.20 (after 6 cycles of induction therapy)<br>–<br>€ 52,192.06 (after 4 cycles of induction therapy) |
| Total<br>(cost range taking into account the number of induction cycles) | € 79,541.94 – € 85,427.02 |
| Pembrolizumab + pemetrexed + platinum-containing chemotherapy<br>(only for patients with ECOG-PS 0-1) | |
| Pembrolizumab | € 81,438.79 |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Pemetrexed | € 18,621.48 |
| Carboplatin | € 8,631.10 |
| Cisplatin | € 2,017.18 |
| Pembrolizumab + pemetrexed + carboplatin | |
| Total (pembrolizumab + pemetrexed + carboplatin) | € 108,691.37 |
| *Additionally required SHI costs* | *€ 133.88 – € 187.17* |
| Pembrolizumab + pemetrexed + cisplatin | |
| Total (pembrolizumab + pemetrexed + cisplatin) | € 102,077.45 |
| *Additionally required SHI costs* | *€ 405.58 – € 528.65* |
| Cemiplimab in combination with platinum-based chemotherapy (only for patients with ECOG-PS 0-1) | |
| Cemiplimab | € 70,925.18 |
| *+ carboplatin + pemetrexed* | |
| Carboplatin | € 8,631.10 |
| Pemetrexed | € 18,621.48 |
| Total (cemiplimab + carboplatin + pemetrexed) | € 98,177.76 |
| *Additionally required SHI costs* | *€ 133.88 – € 187.17* |
| *+ cisplatin + pemetrexed* | |
| Cisplatin | € 2,017.18 |
| Pemetrexed | € 18,621.48 |
| Total (cemiplimab + cisplatin + pemetrexed) | € 91,563.84 |
| *Additionally required SHI costs* | *€ 405.58 – € 528.65* |
| *+ carboplatin + paclitaxel* | |
| Carboplatin | € 8,631.10 |
| Paclitaxel | € 16,633.88 |
| Total (cemiplimab + carboplatin + paclitaxel) | € 96,190.16 |
| *Additionally required SHI costs* | *€ 269.60* |
| *+ cisplatin + paclitaxel* | |
| Cisplatin | € 2,286.18 |
| Paclitaxel | € 16,633.88 |
| Total (cemiplimab + cisplatin + paclitaxel) | 89,845.25 |
| *Additionally required SHI costs* | *€ 541.30 – € 611.08* |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Durvalumab in combination with tremelimumab and platinum-based chemotherapy (only for patients with ECOG-PS 0-1) | |
| Durvalumab | € 23,837.76 |
| Tremelimumab | € 20,157.84 |
| Total (durvalumab + tremelimumab; induction phase) | € 43,995.60 |
| *+ carboplatin + pemetrexed (induction phase)* | |
| Carboplatin | € 1,984.16 |
| Pemetrexed | € 4,280.80 |
| Total (durvalumab + tremelimumab + carboplatin + pemetrexed) | € 50,260.56 |
| *Additionally required SHI costs* | *€ 31.11 - € 43.38* |
| *+ cisplatin + pemetrexed (induction phase)* | |
| Cisplatin | € 463.72 |
| Pemetrexed | € 4,280.80 |
| Total (durvalumab + tremelimumab + cisplatin + pemetrexed) | € 48,740.12 |
| *Additionally required SHI costs* | *€ 162.09 – € 179.48* |
| *+ carboplatin + nab-paclitaxel (induction phase)* | |
| Carboplatin | € 1,984.16 |
| nab-paclitaxel | € 9,786.00 |
| Total (durvalumab + tremelimumab + carboplatin + nab-paclitaxel) | € 55,765.76 |
| *Antibody maintenance treatment including histology-based maintenance treatment with pemetrexed* | |
| Durvalumab | € 59,594.40 |
| Single dose of tremelimumab | € 5,039.46 |
| Pemetrexed | € 10,702.00 |
| Total (durvalumab + tremelimumab + pemetrexed; maintenance phase) | € 75,335.86 |
| *Additionally required SHI costs* | *€ 86.67 - € 127.69* |

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 pemetrexed and platinum-containing chemotherapy | | | | | |
| Tislelizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| Pemetrexed | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Carboplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Cisplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Appropriate comparator therapy | | | | | |
| Monotherapies | | | | | |
| Cemiplimab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 8.7<br>or<br>17.4 | € 870<br>or<br>€ 1,740 |
| Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1) | | | | | |

| Designation of the therapy | Type of service | Costs/ unit | Number/ cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| Nivolumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| Ipilimumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 8.7 | € 870 |
| Carboplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Cisplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Pemetrexed | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Atezolizumab + bevacizumab + paclitaxel + carboplatin (only for patients with ECOG-PS 0-1) | | | | | |
| Induction therapy | | | | | |
| Bevacizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 4.0 – 6.0 | € 400 - € 600 |
| Paclitaxel | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 4.0 – 6.0 | € 400 - € 600 |

| Designation of the therapy | Type of service | Costs/ unit | Number/ cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| Carboplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 4.0 – 6.0 | € 400 - € 600 |
| Maintenance treatment | | | | | |
| Bevacizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 11.4 – 13.4 | € 1,140 – € 1,340 |
| Atezolizumab + carboplatin + nab-paclitaxel (only for patients with ECOG-PS 0-1) | | | | | |
| Induction therapy | | | | | |
| Carboplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 4.0 – 6.0 | € 400 - € 600 |
| nab-paclitaxel | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 3 | 12.0 – 18.0 | € 1,200 - € 1,800 |
| Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1) | | | | | |
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 8.7 or 17.4 | € 870 or € 1,740 |
| Pemetrexed | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Carboplatin | Surcharge for production of a parenteral solution | € 100 | 1 | 17.4 | € 1,740 |

| Designation of the therapy | Type of service | Costs/ unit | Number/ cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| | containing cytostatic agents | | | | |
| Cisplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Cemiplimab in combination with platinum-based chemotherapy (only for patients with ECOG-PS 0-1) | | | | | |
| Cemiplimab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| Carboplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Cisplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Paclitaxel | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Pemetrexed | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Durvalumab in combination with tremelimumab and platinum-based chemotherapy (only for patients with ECOG-PS 0-1) | | | | | |
| *Induction* | | | | | |
| Durvalumab | Surcharge for the preparation of a parenteral solution | € 100 | 1 | 4.0 | € 400 |

| Designation of the therapy | Type of service | Costs/ unit | Number/ cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| | containing monoclonal antibodies | | | | |
| Tremelimumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 4.0 | € 400 |
| Carboplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 4.0 | € 400 |
| Cisplatin | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 4.0 | € 400 |
| Pemetrexed | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 4.0 | € 400 |
| nab-paclitaxel | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 3 | 12.0 | € 1,200 |
| *Antibody maintenance treatment including histology-based maintenance treatment with pemetrexed* | | | | | |
| Durvalumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 10.0 | € 1,000 |
| Tremelimumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 1.0 | € 100 |

| Designation of the therapy | Type of service | Costs/ unit | Number/ cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| Pemetrexed | Surcharge for production of a parenteral solution containing cytostatic agents | € 100 | 1 | 10.0 | € 1,000 |

**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 who have locally advanced non-squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic non-squamous NSCLC, with PD-L1 expression ≥ 50%, with no EGFR or ALK aberrations; 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