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, squamous, first-line, combination with carboplatin and either paclitaxel or nab-paclitaxel)

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

Tevimbra, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of adult patients with squamous NSCLC 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

a) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression ≥ 50%, first-line therapy

Appropriate comparator therapy for tislelizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel:

– 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 carboplatin and either paclitaxel or nab-paclitaxel (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 carboplatin and either paclitaxel or nab-paclitaxel compared with the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression < 50%, first-line therapy

Appropriate comparator therapy for tislelizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel:

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

or

– atezolizumab as monotherapy (only for patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells)

or

– nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (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)

or

– carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG-PS 2)

or

– carboplatin in combination with nab-paclitaxel (only for patients with ECOG-PS 2)

Extent and probability of the additional benefit of tislelizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression ≥ 50%, 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		

b) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression < 50%, first-line therapy

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-126) unless otherwise indicated.

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 who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression ≥ 50%, first-line therapy

Approx. 2,250 – 3,190 patients

b) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression < 50%, first-line therapy

Approx. 5,530 – 7,850 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

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.

a) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression ≥ 50%, first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel	
Tislelizumab	€ 75,142.25
Carboplatin	€ 6,319.68
Paclitaxel	€ 16,633.88
nab-paclitaxel	€ 42,569.10
Tislelizumab + carboplatin + paclitaxel	
Total (tislelizumab + carboplatin + paclitaxel)	€ 98,095.81
Additionally required SHI costs	*€ 269.60*
Tislelizumab + carboplatin + nab-paclitaxel	
Total (tislelizumab + carboplatin + nab-paclitaxel)	€ 124,031.03
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 (only for patients with ECOG-PS 0-1)	
Nivolumab	€ 76,219.31
Ipilimumab	€ 57,271.75
Carboplatin	€ 992.08
Paclitaxel	€ 1,911.94

Designation of the therapy	Annual treatment costs/ patient
Nivolumab + ipilimumab + carboplatin + paclitaxel	
Total (nivolumab + ipilimumab + carboplatin + paclitaxel)	€ 136,038.03
Additionally required SHI costs	*€ 67.25*
Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (only for patients with ECOG-PS 0-1)	
Pembrolizumab	€ 81,438.79
Carboplatin	€ 8,631.10
Paclitaxel	€ 16,633.88
nab-paclitaxel	€ 42,569.10
Pembrolizumab + carboplatin + paclitaxel	
Total (pembrolizumab + carboplatin + paclitaxel)	€ 106,703.77
Additionally required SHI costs	*€ 269.60*
Pembrolizumab + carboplatin + nab-paclitaxel	
Total (pembrolizumab + carboplatin + nab-paclitaxel)	€ 132,638.99
cemiplimab in combination with platinum-based chemotherapy (only for patients with ECOG-PS 0-1)	
Cemiplimab + carboplatin + paclitaxel	
Cemiplimab	€ 70,925.18
Carboplatin	€ 8,631.10
Paclitaxel	€ 16,633.88
Total (cemiplimab + carboplatin + paclitaxel)	€ 96,190.16
Additionally required SHI costs	*€ 269.60*
Cemiplimab + cisplatin + paclitaxel	
Cemiplimab	€ 70,925.18
Cisplatin	€ 2,286.18
Paclitaxel	€ 16,633.88
Total (cemiplimab + cisplatin + paclitaxel)	€ 89,845.24
Additionally required SHI costs	*€ 541.30 – € 611.08*
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

Designation of the therapy	Annual treatment costs/ patient
Total (durvalumab + tremelimumab, induction phase)	€ 43,995.60
+ 4 cycles of platinum-based chemotherapy (carboplatin or cisplatin + gemcitabine, nab-paclitaxel + carboplatin; induction phase*)*	
+ carboplatin + gemcitabine (induction phase)	
Carboplatin	€ 1,984.16
Gemcitabine	€ 1,859.36
Total (durvalumab + tremelimumab + carboplatin + gemcitabine)	€ 47,839.12
+ cisplatin + gemcitabine (induction phase)	
Cisplatin	€ 463.72
Gemcitabine	€ 1,859.36
Total (durvalumab + tremelimumab + cisplatin + gemcitabine)	€ 46,318.68
Additionally required SHI costs	*€ 130.98 – € 136.10*
+ 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	
Durvalumab	€ 59,594.40
Single dose of tremelimumab	€ 5,039.46
Total (durvalumab + tremelimumab; maintenance phase)	€ 64,633.86

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 carboplatin and either paclitaxel or nab-paclitaxel					
Tislelizumab	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
Paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220
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 or 17.4	€ 870 or € 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
Paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (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
Carboplatin	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
nab-paclitaxel	Surcharge for production of a parenteral solution	€ 100	3	52.2	€ 5,220

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
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
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 containing monoclonal antibodies	€ 100	1	4.0	€ 400
Tremelimumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400

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	€ 400
Cisplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8.0	€ 800
nab-paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	12.0	€ 1,200
Antibody maintenance treatment					
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

b) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression < 50%, first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel	
Tislelizumab	€ 75,142.25
Carboplatin	€ 6,319.68
Paclitaxel	€ 16,633.88
nab-paclitaxel	€ 42,569.10
Tislelizumab + carboplatin + paclitaxel	
Total (tislelizumab + carboplatin + paclitaxel)	€ 98,095.81
Additionally required SHI costs	*€ 269.60*
Tislelizumab + carboplatin + nab-paclitaxel	
Total (tislelizumab + carboplatin + nab-paclitaxel)	€ 124,031.03
Appropriate comparator therapy:	
Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (only for patients with ECOG-PS 0-1)	
Pembrolizumab	€ 81,438.79
Carboplatin	€ 8,631.10
Paclitaxel	€ 16,633.88
nab-paclitaxel	€ 42,569.10
Pembrolizumab + carboplatin + paclitaxel	
Total (pembrolizumab + carboplatin + paclitaxel)	€ 106,703.77
Additionally required SHI costs	*€ 269.60*
Pembrolizumab + carboplatin + nab-paclitaxel	
Total (pembrolizumab + carboplatin + nab-paclitaxel)	€ 132,638.99
Atezolizumab as monotherapy (only for patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells)	
Atezolizumab	€ 67,771.78
Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)	
Nivolumab	€ 75,862.26
Ipilimumab	€ 57,271.75

Designation of the therapy	Annual treatment costs/ patient
Carboplatin	€ 992.08
Paclitaxel	€ 1,911.94
Nivolumab + ipilimumab + carboplatin + paclitaxel	
Total (nivolumab + ipilimumab + carboplatin + paclitaxel)	€ 136,038.03
Additionally required SHI costs	*€ 67.25*
cemiplimab in combination with platinum-based chemotherapy (only for patients with ECOG-PS 0-1)	
Cemiplimab + carboplatin + paclitaxel	
Cemiplimab	€ 70,925.18
Carboplatin	€ 8,631.10
Paclitaxel	€ 16,633.88
Total (cemiplimab + carboplatin + paclitaxel)	€ 96,190.16
Additionally required SHI costs	*€ 269.60*
Cemiplimab + cisplatin + paclitaxel	
Cemiplimab	€ 70,925.18
Cisplatin	€ 2,286.18
Paclitaxel	€ 16,633.88
Total (cemiplimab + cisplatin + paclitaxel)	€ 89,845.24
Additionally required SHI costs	*€ 541.30 – € 611.08*
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)	€ 43,995.60
+ 4 cycles of platinum-based chemotherapy (carboplatin or cisplatin + gemcitabine, nab-paclitaxel + carboplatin; induction phase)	
+ carboplatin + gemcitabine (induction phase)	
Carboplatin	€ 1,984.16
Gemcitabine	€ 1,859.36
Total (durvalumab + tremelimumab + carboplatin + gemcitabine)	€ 47,839.12
+ cisplatin + gemcitabine (induction phase)	
Cisplatin	€ 463.72
Gemcitabine	€ 1,859.36

Designation of the therapy	Annual treatment costs/ patient
Total (durvalumab + tremelimumab + cisplatin + gemcitabine)	€ 46,318.68
Additionally required SHI costs	*€ 130.98 – € 136.10*
+ 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	
Durvalumab	€ 59,594.40
Single dose of tremelimumab	€ 5,039.46
Total (durvalumab + tremelimumab; maintenance phase)	€ 64,633.86
Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG-PS 2)	
Carboplatin + docetaxel	
Carboplatin	€ 8,631.10
Docetaxel	€ 8,527.22
Total (carboplatin + docetaxel)	€ 17,158.32
Carboplatin + gemcitabine	
Carboplatin	€ 8,631.10
Gemcitabine	€ 8,088.22
Total (carboplatin + gemcitabine)	€ 16,719.32
Carboplatin + paclitaxel	
Carboplatin	€ 8,631.10
Paclitaxel	€ 16,633.88
Total (carboplatin + paclitaxel)	€ 25,264.98
Additionally required SHI costs	*€ 269.60*
Carboplatin + vinorelbine	
Carboplatin	€ 8,631.10
Vinorelbine	€ 5,016.77 – € 6,263.31
Total (carboplatin + vinorelbine)	€ 14,894.41
Carboplatin in combination with nab-paclitaxel (only for patients with ECOG-PS 2)	
Carboplatin	€ 8,631.10
nab-paclitaxel	€ 42,569.10

Designation of the therapy	Annual treatment costs/ patient
Total (carboplatin + nab-paclitaxel)	€ 51,200.20

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 carboplatin and either paclitaxel or nab-paclitaxel					
Tislelizumab	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
Paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220
Appropriate comparator therapy					
Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (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
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				
Paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220
Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)					
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
Paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
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	€ 100	1	17.4	€ 1,740

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	monoclonal antibodies				
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
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 containing monoclonal antibodies	€ 100	1	4.0	€ 400
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

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	4.0	€ 800
nab-paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	12.0	€ 1,200
Antibody maintenance treatment					
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
Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG-PS 2)					
Carboplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Gemcitabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
Vinorelbine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Docetaxel	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
Carboplatin in combination with nab-paclitaxel (only for patients with ECOG-PS 2)					
Carboplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220

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 who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression ≥ 50%, 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.

b) Adults who have locally advanced squamous non-small cell lung cancer (NSCLC) and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic squamous NSCLC, with PD-L1 expression ≥ 50%, 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