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)
Cemiplimab (new therapeutic indication: non-small cell lung cancer, first-line, PD-L1 expression ≥ 1%, combination with platinum-based chemotherapy)

of 19 October 2023

At its session on 19 October 2023, 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 Cemiplimab in accordance with the resolution of 19 October 2023 for the therapeutic indication: "for the treatment of adult patients with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy":**

Cemiplimab

Resolution of: 19 October 2023
Entry into force on: 19 October 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 24 March 2023):

LIBTAYO in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in ≥ 1% of tumour cells), with no EGFR, ALK or ROS1 aberrations, who have:

- locally advanced NSCLC who are not candidates for definitive chemoradiation, or
- metastatic NSCLC.

Therapeutic indication of the resolution (resolution of 19 October 2023):

See new therapeutic indication according to marketing authorisation.

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

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 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 carboplatin and either paclitaxel or nab-paclitaxel (only for patients with ECOG PS 0-1 and a squamous NSCLC)

or

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

or

– atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG PS 0-1 and a non-squamous NSCLC)

or

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

Extent and probability of the additional benefit of cemiplimab in combination with platinum-based chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

Appropriate comparator therapy:

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

or

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

or

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

or

– atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG PS 0-1 and a non-squamous NSCLC)

or

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

or

– nivolumab in combination with ipilimumab and 2 cycles of 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 or pemetrexed) 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 cemiplimab in combination with platinum-based chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

No adequate data are available to allow an assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	not assessable
Morbidity	n.a.	not assessable
Health-related quality of life	n.a.	not assessable
Side effects	n.a.	not assessable
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 with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

No adequate data are available to allow an assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	not assessable
Morbidity	n.a.	not assessable
Health-related quality of life	n.a.	not assessable
Side effects	n.a.	not assessable
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		

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-36) unless otherwise indicated.

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

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

Approx. 4,680 to 6,680 patients

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

approx. 4,860 to 6,220 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 Libtayo (active ingredient: cemiplimab) at the following publicly accessible link (last access: 20 July 2023):

https://www.ema.europa.eu/en/documents/product-information/libtayo-epar-product-information_en.pdf

Treatment with cemiplimab 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 European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card).

The training material contains, in particular, information and warnings about immune-mediated side effects as well as infusion-related reactions.

Patients are to be selected for treatment with cemiplimab on the basis of PD-L1 tumour expression, confirmed by a validated test.

4. Treatment costs

Annual treatment costs:

The costs for the first year of treatment are shown for the cost representation in the resolution.

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cemiplimab	€ 80,879.55
+ platinum-based chemotherapy (carboplatin or cisplatin + pemetrexed, carboplatin or cisplatin + paclitaxel):	
Carboplatin + pemetrexed	
Carboplatin	€ 8,718.27
Pemetrexed	€ 17,088.19
Total (pemetrexed + carboplatin)	€ 25,806.46
Cemiplimab + carboplatin + pemetrexed	€ 106,686.01
Additionally required SHI costs	€ 116.92 - € 154.63
Cisplatin + pemetrexed	
Cisplatin	€ 1,984.12
Pemetrexed	€ 17,088.19
Total (pemetrexed + cisplatin)	€ 19,072.31
Cemiplimab + cisplatin + pemetrexed	€ 99,951.86
Additionally required SHI costs	€ 445.50 - € 576.25
Carboplatin + paclitaxel	
Carboplatin	€ 8,718.27
Paclitaxel	€ 16,629.01
Total (carboplatin + paclitaxel)	€ 25,347.28
Cemiplimab + carboplatin + paclitaxel	€ 106,226.83
Additionally required SHI costs	€ 254.58
Cisplatin + paclitaxel	
Cisplatin	€ 2,266.87
Paclitaxel	€ 16,629.01

Designation of the therapy	Annual treatment costs/ patient
Total (cisplatin + paclitaxel)	€ 18,895.88
Cemiplimab + cisplatin + paclitaxel	€ 99,775.43
Additionally required SHI costs	€ 583.16 - € 676.20
Appropriate comparator therapy:	
Monotherapies	
Atezolizumab	€ 64,877.81 - € 68,557.39
Cemiplimab	€ 80,879.55
Pembrolizumab	€ 93,515.26
Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)	
Nivolumab	€ 73,035.63
+ ipilimumab	€ 54,832.10
Total	€ 127,867.73
Carboplatin + paclitaxel	
Carboplatin	€ 1,002.10
Paclitaxel	€ 1,911.38
Total	€ 2,913.48
Nivolumab + ipilimumab + carboplatin + paclitaxel	€ 130,781.21
Additionally required SHI costs	€ 64.01
Carboplatin + pemetrexed	
Carboplatin	€ 1,002.10
Pemetrexed	€ 1,964.16
Total	€ 2,966.26
Nivolumab + ipilimumab + carboplatin + pemetrexed	€ 130,833.99
Additionally required SHI costs	€ 34.93 - € 41.13
Cisplatin + pemetrexed	
Cisplatin	€ 228.06
Pemetrexed	€ 1,964.16
Total	€ 2,192.22
Nivolumab + ipilimumab + cisplatin + pemetrexed	€ 130,059.95
Additionally required SHI costs	€ 147.82 - € 164.81
Atezolizumab + bevacizumab + paclitaxel + carboplatin (only for patients with ECOG PS 0-1 and non-squamous NSCLC)	

Designation of the therapy	Annual treatment costs/ patient
Induction therapy (4 -6 cycles)	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 10,506.88 - € 15,760.32 (840 mg; 4 -6 cycles) or € 14,914.44 - € 22,371.66 (1,200 mg; 4 -6 cycles) or € 21,013.76 - € 31,520.64 (1,680 mg; 4 -6 cycles)
+ bevacizumab (7.5 mg/kg or 15.5 mg/kg)	€ 8,486.88 - € 12,730.32 (7.5 mg/kg; 4 -6 cycles) or € 16,858.80 - € 25,288.20 (15 mg/kg; 4 -6 cycles)
+ paclitaxel	€ 3,822.76 - € 5,734.14
+ carboplatin	€ 2,004.20 - € 3,006.30
Maintenance treatment	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 52,797.07 - € 58,050.51 (840 mg; 20.1 -22.1 cycles) or € 42,506.15 - € 49,963.37 (1,200 mg; 11.4 -13.4 cycles) or € 36,774.08 - € 47,280.96 (1,680 mg; 7 -9 cycles)
+ bevacizumab (840 mg or 1,200 mg or 1,680 mg)	€ 24,187.61 – € 28,431.05 (7.5 mg/kg; 11.4 - 13.4 cycles) or € 48,047.58 - € 56,476.98 (15 mg/kg; 11.4 - 13.4 cycles)
Total *(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)*	<u>Combination with 7.5 mg/kg bevacizumab:</u> € 111,302.28 - € 114,215.76 (4 - 6 induction cycles with 840 mg atezolizumab) or € 107,622.70 - € 110,536.18 (4 - 6 induction cycles with 1,200 mg atezolizumab) or € 111,039.61 - € 113,953.09 (4 - 6 induction cycles with 1,680 mg atezolizumab) or <u>Combination with 15 mg/kg bevacizumab:</u>

Designation of the therapy	Annual treatment costs/ patient
	€ 147,720.13 - € 150,633.61 (4 - 6 induction cycles with 840 mg atezolizumab) € 144,040.55 - € 146,954.03 (4 - 6 induction cycles with 1,200 mg atezolizumab) or € 147,457.46 - € 150,370.94 (4 - 6 induction cycles with 1,680 mg atezolizumab)
Additionally required SHI costs	€ 80.20 - € 135.46
Atezolizumab + carboplatin + nab-paclitaxel *(only for patients with ECOG PS 0-1 and non-squamous NSCLC)*	
Induction therapy (4 -6 cycles)	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 10,506.88 - € 15,760.32 (840 mg; 4 - 6 cycles) or € 14,914.44 - € 22,371.66 (1,200 mg; 4 - 6 cycles) or € 21,013.76 - € 31,520.64 (1,680 mg; 4 - 6 cycles)
+ carboplatin	€ 2,004.20 - € 3,006.30
+ nab-paclitaxel	€ 9,780.48 - € 14,670.72
Maintenance treatment	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 52,797.07 - € 58,050.51 (840 mg; 20.1 -22.1 cycles) or € 42,506.15 - € 49,963.37 (1,200 mg; 11.4 -13.4 cycles) or € 36,774.08 - € 47,280.96 (1,680 mg; 7 - 9 cycles)
Total *(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)*	€ 80,342.07 - € 86,234.41 (4 - 6 induction cycles with 840 mg atezolizumab) or € 76,662.49 - € 82,554.83 (4 - 6 induction cycles with 1,200 mg atezolizumab) or € 80,079.40 - € 85,971.74 (4 - 6 induction cycles with 1,680 mg atezolizumab)
Pembrolizumab + carboplatin + (nab)-paclitaxel	

Designation of the therapy	Annual treatment costs/ patient
(only for patients with ECOG-PS 0-1 and squamous NSCLC)	
Pembrolizumab + carboplatin + paclitaxel	
Pembrolizumab	€ 93,515.26
Carboplatin	€ 8,718.27
Paclitaxel	€ 16,629.01
Total	€ 118,862.53
Additionally required SHI costs	€ 254.58
Pembrolizumab + carboplatin + nab-paclitaxel	
Pembrolizumab	€ 93,515.26
Carboplatin	€ 8,718.27
nab-paclitaxel	€ 42,545.09
Total	€ 144,778.61
Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)	
Pembrolizumab + pemetrexed + cisplatin	
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 17,088.19
Cisplatin	€ 1,984.12
Total	€ 112,587.57
Additionally required SHI costs	€ 445.50 - € 576.26
Pembrolizumab + pemetrexed + carboplatin	
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 17,088.19
Carboplatin	€ 8,718.27
Total	€ 119,321.72
Additionally required SHI costs	€ 116.92 - € 154.64

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2023)

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					
Cemiplimab + platinum-based chemotherapy					
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 preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
+ cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
+ pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
+ paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					
Monotherapies					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610
				or	
				17.4	€ 1,740
				or	
				13.0	€ 1,300
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	€ 870
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
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
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200
Atezolizumab + bevacizumab + paclitaxel + carboplatin (only for patients with ECOG PS 0-1 and non-squamous NSCLC)					
Induction therapy					
Atezolizumab	Surcharge for the preparation of a	€ 100	1	4.0 - 6.0	€ 400 - € 600

	parenteral solution containing monoclonal antibodies				
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 preparation containing cytostatic agents	€ 100	1	4.0 - 6.0	€ 400 - € 600
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0 - 6.0	€ 400 - € 600
Maintenance treatment					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	20.1 - 22.1	€ 2,010 - € 2,210
				or	
				11.4 - 13.4	€ 1,140 - € 1,340
				or	
				7.0 - 9.0	€ 700 - € 900
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 and non-squamous NSCLC)*					
Induction therapy					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0 - 6.0	€ 400 - € 600
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0 - 6.0	€ 400 - € 600
nab-paclitaxel	Surcharge for production of a parenteral	€ 100	3	4.0 - 6.0	€ 1,200 - € 1,800

	preparation containing cytostatic agents				
Maintenance treatment					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	20.1 - 22.1	€ 2,010 - € 2,210
				or	
				11.4 - 13.4	€ 1,140 - € 1,340
				or	
				7.0 - 9.0	€ 700 - € 900
Pembrolizumab + carboplatin + (nab)-paclitaxel (only for patients with ECOG-PS 0-1 and squamous NSCLC)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
				or	
				8.7	€ 870
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	17.4	€ 5,220
Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
				or	
				8.7	€ 870
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral	€ 100	1	17.4	€ 1,740

	preparation containing cytostatic agents				
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cemiplimab	€ 80,879.55
+ platinum-based chemotherapy (carboplatin or cisplatin + pemetrexed, carboplatin or cisplatin + paclitaxel):	
Carboplatin + pemetrexed	
Carboplatin	€ 8,718.27
Pemetrexed	€ 17,088.19
Total (pemetrexed + carboplatin)	€ 25,806.46
Cemiplimab + carboplatin + pemetrexed	€ 106,686.01
Additionally required SHI costs	€ 116.92 - € 154.63
Cisplatin + pemetrexed	
Cisplatin	€ 1,984.12
Pemetrexed	€ 17,088.19
Total (pemetrexed + cisplatin)	€ 19,072.31
Cemiplimab + cisplatin + pemetrexed	€ 99,951.86
Additionally required SHI costs	€ 445.50 - € 576.25
Carboplatin + paclitaxel	
Carboplatin	€ 8,718.27
Paclitaxel	€ 16,629.01
Total (carboplatin + paclitaxel)	€ 25,347.28
Cemiplimab + carboplatin + paclitaxel	€ 106,226.83
Additionally required SHI costs	€ 254.58
Cisplatin + paclitaxel	
Cisplatin	€ 2,266.87
Paclitaxel	€ 16,629.01
Total (cisplatin + paclitaxel)	€ 18,895.88

Designation of the therapy	Annual treatment costs/ patient
Cemiplimab + cisplatin + paclitaxel	€ 99,775.43
Additionally required SHI costs	€ 583.16 - € 676.20
Appropriate comparator therapy:	
Monotherapies	
Atezolizumab	€ 64,877.81 - € 68,557.39
Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)	
Nivolumab	€ 73,035.63
+ ipilimumab	€ 54,832.10
Total	€ 127,867.73
Carboplatin + paclitaxel	
Carboplatin	€ 1,002.10
Paclitaxel	€ 1,911.38
Total	€ 2,913.48
Nivolumab + ipilimumab + carboplatin + paclitaxel	€ 130,781.21
Additionally required SHI costs	€ 64.01
Carboplatin + pemetrexed	
Carboplatin	€ 1,002.10
Pemetrexed	€ 1,964.16
Total	€ 2,966.26
Nivolumab + ipilimumab + carboplatin + pemetrexed	€ 130,833.99
Additionally required SHI costs	€ 34.93 - € 41.13
Cisplatin + pemetrexed	
Cisplatin	€ 228.06
Pemetrexed	€ 1,964.16
Total	€ 2,192.22
Nivolumab + ipilimumab + cisplatin + pemetrexed	€ 130,059.95
Additionally required SHI costs	€ 147.82 - € 164.81
Atezolizumab + bevacizumab + paclitaxel + carboplatin (only for patients with ECOG PS 0-1 and non-squamous NSCLC)	
Induction therapy (4 -6 cycles)	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 10,506.88 - € 15,760.32 (840 mg; 4 - 6 cycles) or € 14,914.44 - € 22,371.66 (1,200 mg; 4 - 6 cycles) or

Designation of the therapy	Annual treatment costs/ patient
	€ 21,013.76 - € 31,520.64 (1,680 mg; 4 - 6 cycles)
+ bevacizumab (7.5 mg/kg or 15.5 mg/kg)	€ 8,486.88 - € 12,730.32 (7.5 mg/kg; 4 - 6 cycles) or € 16,858.80 - € 25,288.20 (15 mg/kg; 4 - 6 cycles)
+ paclitaxel	€ 3,822.76 - € 5,734.14
+ carboplatin	€ 2,004.20 - € 3,006.30
Maintenance treatment	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 52,797.07 - € 58,050.51 (840 mg; 20.1 - 22.1 cycles) or € 42,506.15 - € 49,963.37 (1,200 mg; 11.4 - 13.4 cycles) or € 36,774.08 - € 47,280.96 (1,680 mg; 7 - 9 cycles)
+ bevacizumab (840 mg or 1,200 mg or 1,680 mg)	€ 24,187.61 - € 28,431.05 (7.5 mg/kg; 11.4 - 13.4 cycles) or € 48,047.58 - € 56,476.98 (15 mg/kg; 11.4 - 13.4 cycles)
Total *(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)*	<u>Combination with 7.5 mg/kg bevacizumab:</u> € 111,302.28 - € 114,215.76 (4 - 6 induction cycles with 840 mg atezolizumab) or € 107,622.70 - € 110,536.18 (4 - 6 induction cycles with 1,200 mg atezolizumab) or € 111,039.61 - € 113,953.09 (4 - 6 induction cycles with 1,680 mg atezolizumab) or <u>Combination with 15 mg/kg bevacizumab:</u> € 147,720.13 - € 150,633.61 (4 - 6 induction cycles with 840 mg atezolizumab) € 144,040.55 - € 146,954.03 (4 - 6 induction cycles with 1,200 mg atezolizumab) or

Designation of the therapy	Annual treatment costs/ patient
	€ 147,457.46 - € 150,370.94 (4 - 6 induction cycles with 1,680 mg atezolizumab)
Additionally required SHI costs	€ 80.20 - € 135.46
Atezolizumab + carboplatin + nab-paclitaxel *(only for patients with ECOG PS 0-1 and non-squamous NSCLC)*	
Induction therapy (4 -6 cycles)	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 10,506.88 - € 15,760.32 (840 mg; 4 -6 cycles) or € 14,914.44 - € 22,371.66 (1,200 mg; 4 - 6 cycles) or € 21,013.76 - € 31,520.64 (1,680 mg; 4 - 6 cycles)
+ carboplatin	€ 2,004.20 - € 3,006.30
+ nab-paclitaxel	€ 9,780.48 - € 14,670.72
Maintenance treatment	
Atezolizumab (840 mg or 1,200 mg or 1,680 mg)	€ 52,797.07 - € 58,050.51 (840 mg; 20.1 -22.1 cycles) or € 42,506.15 - € 49,963.37 (1,200 mg; 11.4 - 13.4 cycles) or € 36,774.08 - € 47,280.96 (1,680 mg; 7 - 9 cycles)
Total *(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)*	€ 80,342.07 - € 86,234.41 (4 - 6 induction cycles with 840 mg atezolizumab) or € 76,662.49 - € 82,554.83 (4 - 6 induction cycles with 1,200 mg atezolizumab) or € 80,079.40 - € 85,971.74 (4 - 6 induction cycles with 1,680 mg atezolizumab)
Pembrolizumab + carboplatin + (nab)-paclitaxel *(only for patients with ECOG-PS 0-1 and squamous NSCLC)*	
Pembrolizumab + carboplatin + paclitaxel	
Pembrolizumab	€ 93,515.26
Carboplatin	€ 8,718.27
Paclitaxel	€ 16,629.01
Total	€ 118,862.53

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI costs	€ 254.58
Pembrolizumab + carboplatin + nab-paclitaxel	
Pembrolizumab	€ 93,515.26
Carboplatin	€ 8,718.27
nab-paclitaxel	€ 42,545.09
Total	€ 144,778.61
Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)	
Pembrolizumab + pemetrexed + cisplatin	
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 17,088.19
Cisplatin	€ 1,984.12
Total	€ 112,587.57
Additionally required SHI costs	€ 445.50 - € 576.26
Pembrolizumab + pemetrexed + carboplatin	
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 17,088.19
Carboplatin	€ 8,718.27
Total	€ 119,321.72
Additionally required SHI costs	€ 116.92 - € 154.64
Carboplatin + nab-paclitaxel (only for patients with ECOG-PS 2)	
Carboplatin	€ 8,718.27
nab-paclitaxel	€ 42,545.09
Total	€ 51,263.36
Carboplatin + third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG-PS 2)	
Carboplatin + vinorelbine	
Carboplatin	€ 8,718.27
Vinorelbine	€ 4,717.11 - € 5,686.60
Total	€ 13,435.38 - € 14,404.87
Carboplatin + gemcitabine	
Carboplatin	€ 8,718.27
Gemcitabine	€ 8,056.20
Total	€ 16,774.47

Designation of the therapy	Annual treatment costs/ patient
Carboplatin + docetaxel	
Carboplatin	€ 8,718.27
Docetaxel	€ 8,523.22
Total	€ 17,241.49
Carboplatin + paclitaxel	
Carboplatin	€ 8,718.27
Paclitaxel	€ 16,629.01
Total	€ 25,347.28
Additionally required SHI costs	€ 254.58
Carboplatin + pemetrexed	
Carboplatin	€ 8,718.27
Pemetrexed	€ 17,088.19
Total	€ 25,806.46
Additionally required SHI costs	€ 116.92 - € 154.64

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2023)

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					
Cemiplimab + platinum-based chemotherapy					
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 preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
+ cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
+ pemetrexed	Surcharge for production of a parenteral	€ 100	1	17.4	€ 1,740

	preparation containing cytostatic agents				
+ paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					
Monotherapy					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610
				or	
				17.4	€ 1,740
				or	
				13.0	€ 1,300
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
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2.0	€ 200

Atezolizumab + bevacizumab + paclitaxel + carboplatin *(only for patients with ECOG PS 0-1 and non-squamous NSCLC)*					
Induction therapy					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0 - 6.0	€ 400 - € 600
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 preparation containing cytostatic agents	€ 100	1	4.0 - 6.0	€ 400 - € 600
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0 - 6.0	€ 400 - € 600
Maintenance treatment					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	20.1 - 22.1	€ 2,010 - € 2,210
				or	
				11.4 - 13.4	€ 1,140 - € 1,340
				or	
				7.0 - 9.0	€ 700 - € 900
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 and non-squamous NSCLC)*					
Induction therapy					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0 - 6.0	€ 400 - € 600

Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0 - 6.0	€ 400 - € 600
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	4.0 - 6.0	€ 1,200 - € 1,800
Maintenance treatment					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	20.1 - 22.1	€ 2,010 - € 2,210
				or	
				11.4 - 13.4	€ 1,140 - € 1,340
				or	
				7.0 - 9.0	€ 700 - € 900
Pembrolizumab + carboplatin + (nab)-paclitaxel (only for patients with ECOG-PS 0-1 and squamous NSCLC)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
				or	
				8.7	€ 870
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	17.4	€ 5,220
Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
				or	
				8.7	€ 870

Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Carboplatin + nab-paclitaxel (only for patients with ECOG-PS 2)					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	17.4	€ 5,220
Carboplatin + third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG-PS 2)					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	17.4	€ 3,480
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	17.4	€ 3,480
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Paclitaxel	Surcharge for production of a parenteral	€ 100	1	17.4	€ 1,740

	preparation containing cytostatic agents				
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740

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 with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 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.

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; 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 19 October 2023.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 19 October 2023

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

Prof. Hecken