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
Selpercatinib (reassessment after the deadline: non-small cell lung cancer, RET fusion+, first-line)

From 18 June 2026

At their session on 18 June 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 information on the active ingredient Selpercatinib in the version of the resolution of 15 December 2022 (Federal Gazette, BAnz AT 27.01.2023 B3) shall be replaced by the following information:**

Selpercatinib

Resolution of: 18 June 2026
Entry into force on: 18 June 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 21 June 2022):

Retsevmo as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.

Therapeutic indication of the resolution (resolution of 18 June 2026):

see therapeutic indication according to marketing authorisation.

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

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; 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 patients with ECOG-PS 0-1 are eligible)

or

- pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only patients with ECOG-PS 0-1 are eligible)

or

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

or

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

or

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

or

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

Extent and probability of the additional benefit of selpercatinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

Appropriate comparator therapy:

Individualised therapy with selection of

- pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy,
- atezolizumab as monotherapy (only patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells are eligible),
- atezolizumab in combination with bevacizumab, paclitaxel and carboplatin,
- atezolizumab in combination with nab-paclitaxel and carboplatin,
- nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy,
- cemiplimab in combination with platinum-based chemotherapy,
- durvalumab in combination with tremelimumab and platinum-based chemotherapy,
- 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 and
- carboplatin in combination with nab-paclitaxel

Extent and probability of the additional benefit of selpercatinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; 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 with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; 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		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-159), unless otherwise indicated.

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

a) Adults with advanced RET fusion-positive NSCLC with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

Approx. 45 to 80 patients

b) Adults with advanced RET fusion-positive NSCLC with PD-L1 expression < 50% of tumour cells; first-line therapy

Approx. 110 to 190 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 Retsevmo (active ingredient: selpercatinib) at the following publicly accessible link (last access: 9 June 2026):

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

Treatment with selpercatinib 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 other specialist groups participating in the Oncology Agreement.

RET testing

The presence of an RET gene fusion should be confirmed by a validated test prior to treatment with Retsevmo.

4. Treatment costs

Annual treatment costs:

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

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

Name of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Selpercatinib	€ 46,718.70
Appropriate comparator therapy:	
pembrolizumab as monotherapy	
Pembrolizumab	€ 80,030.78
Atezolizumab as monotherapy	
Atezolizumab	€ 68,352.94
Cemiplimab as monotherapy	
Cemiplimab	€ 70,925.18
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)	
Nivolumab	€ 75,862.26
Ipilimumab	€ 57,271.75
+ carboplatin	€ 939.54
+ cisplatin	€ 231.86 – € 286.88
+ docetaxel	€ 980.14
+ gemcitabine	€ 929.68
+ nab-paclitaxel	€ 4,893.00
+ paclitaxel	€ 1,911.94
+ pemetrexed	€ 2,140.40
+ vinorelbine	€ 576.64 – € 719.92
Total (nivolumab + ipilimumab + platinum-based chemotherapy)	€ 133,976.19 – € 138,966.55[2]
Additionally required SHI costs	€ 34.91 – € 183.62[3]

[2] The lower limit of the range results for nivolumab in combination with ipilimumab, cisplatin and vinorelbine. The upper limit of the range results for nivolumab in combination with ipilimumab, carboplatin and nab-paclitaxel.

[3] The lower limit of the range results for nivolumab in combination with ipilimumab, carboplatin and pemetrexed. The upper limit of the range results for nivolumab in combination with ipilimumab, cisplatin and paclitaxel.

Name of the therapy	Annual treatment costs/ patient
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only patients with ECOG-PS 0-1 are eligible)	
Pembrolizumab	€ 80,030.78
Pemetrexed	€ 18,621.48
Carboplatin	€ 8,174.00
Cisplatin	€ 2,017.18
Pembrolizumab + pemetrexed + carboplatin	
Total (pembrolizumab + pemetrexed + carboplatin)	€ 106,826.26
Additionally required SHI costs	€ 134.39 – € 188.19
Pembrolizumab + pemetrexed + cisplatin	
Total (pembrolizumab + pemetrexed + cisplatin)	€ 100,669.44
Additionally required SHI costs	€ 406.09 – € 529.67
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)	
Induction therapy (4 – 6 cycles)	
Atezolizumab	€ 15,713.32 – € 23,569.98
Bevacizumab (7.5 mg/kg or 15 mg/kg)	€ 3,858.00 – € 5,787.00 or € 7,601.52 – € 11,402.28
Paclitaxel	€ 3,823.88 – € 5,735.82
Carboplatin	€ 1,879.08 – € 2,818.62
Additionally required SHI costs	€ 85.12 – € 143.71
Maintenance treatment	
Atezolizumab	€ 44,782.96 (after 6 cycles of induction therapy) – € 52,639.62 (after 4 cycles of induction therapy)
Bevacizumab (7.5 mg/kg or 15 mg/kg)	€ 10,995.30 (after 6 cycles of induction therapy) – € 12,924.30 (after 4 cycles of induction therapy) or € 21,664.33 (after 6 cycles of induction therapy) – € 25,465.09 (after 4 cycles of induction therapy)
Total (cost range taking into account the number of induction cycles and bevacizumab dosage regimens)	<u>Combination with 7.5 mg/kg bevacizumab:</u> € 90,838.20 – € 93,689.68 (4 – 6 induction cycles) or <u>Combination with 15 mg/kg bevacizumab:</u>

Name of the therapy	Annual treatment costs/ patient
	€ 107,122.51 – € 109,973.99 (4 – 6 induction cycles)
Additionally required SHI costs	€ 85.12 – € 143.71
Atezolizumab in combination with nab-paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)	
Induction therapy	
Atezolizumab	€ 15,713.32 – € 23,569.98
Carboplatin	€ 1,879.08 – € 2,818.62
Nab-paclitaxel	€ 9,786.00 – € 14,679.00
Total Atezolizumab + carboplatin + nab-paclitaxel (induction therapy)	€ 27,378.40 – € 41,067.60
Maintenance treatment	
Atezolizumab	€ 44,782.96 (after 6 cycles of induction therapy) – € 52,639.62 (after 4 cycles of induction therapy)
Total (cost range taking into account the number of induction cycles)	€ 80,018.02 – € 85,850.56
Cemiplimab in combination with platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)	
Cemiplimab	€ 70,925.18
+ carboplatin	€ 8,174.00
+ cisplatin	€ 2,017.18 – € 2,495.86
+ docetaxel	€ 8,527.22
+ gemcitabine	€ 8,088.22
+ nab-paclitaxel	€ 42,569.10
+ paclitaxel	€ 16,633.88
+ pemetrexed	€ 18,621.48
+ vinorelbine	€ 5,016.77 – € 6,263.31
Total (cemiplimab + platinum-based chemotherapy)	€ 78,252.15 – € 121,668.28[4]
Additionally required SHI costs	€ 134.39 – € 612.55[5]

[4] The lower limit of the range results for cemiplimab in combination with cisplatin and vinorelbine. The upper limit of the range results for cemiplimab in combination with carboplatin and nab-paclitaxel.

[5] The lower limit of the range results for cemiplimab in combination with carboplatin and pemetrexed. The upper limit of the range results for cemiplimab in combination with cisplatin and paclitaxel.

durvalumab in combination with tremelimumab and platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)	
Durvalumab	€ 23,596.08
Tremelimumab	€ 20,157.84
Total (durvalumab + tremelimumab; 4 cycles)	€ 43,753.92
+ 4 cycles of platinum-based chemotherapy	
Carboplatin	€ 1,879.08
Cisplatin	€ 463.72 – € 573.76
+ docetaxel	€ 1,960.28
+ gemcitabine	€ 1,859.36
+ nab-paclitaxel	€ 9,786.00
+ paclitaxel	€ 3,823.88
+ pemetrexed	€ 4,280.80
+ vinorelbine	€ 1,153.28 – € 1,439.84
Antibody maintenance treatment (without histology-based maintenance treatment with pemetrexed)	
Durvalumab	€ 58,990.20
+ single dose of tremelimumab	€ 5,039.46
Total	€ 64,029.66
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed	
Durvalumab	€ 58,990.20
+ single dose of tremelimumab	€ 5,039.46
+ pemetrexed	€ 10,702.00
Total	€ 74,731.66
Total: Durvalumab + tremelimumab + platinum-based chemotherapy (4 cycles) + Antibody maintenance treatment (± pemetrexed)	€ 109,467.94 – € 124,645.46[6]
Additionally required SHI costs	€ 85.12 – € 308.19[7]

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

[6] The lower limit of the range results for durvalumab in combination with tremelimumab, cisplatin and vinorelbine including maintenance treatment without pemetrexed. The upper limit of the range results for durvalumab in combination with tremelimumab, carboplatin and pemetrexed including histology-based maintenance treatment with pemetrexed.

[7] The lower limit of the range results for durvalumab in combination with tremelimumab, carboplatin and paclitaxel including maintenance treatment without pemetrexed. The upper limit of the range results for durvalumab in combination with tremelimumab, cisplatin and pemetrexed including histology-based maintenance treatment with pemetrexed.

Other SHI services:

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Pembrolizumab as monotherapy					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 or 17.4	€ 870 or € 1,740
Cemiplimab as monotherapy					
Cemiplimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)					
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0	€ 400
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	6	€ 600
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0	€ 400
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only patients with ECOG-PS 0-1 are eligible)					
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)					
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0 – 6.0	€ 400 – € 600
Carboplatin	Surcharge for the preparation 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 in combination with nab-paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)					
Induction therapy					
Carboplatin	Surcharge for the preparation of a parenteral solution	€ 100	1	4.0 – 6.0	€ 400 – € 600

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	12.0 – 18.0	€ 1,200 – € 1,800
Cemiplimab in combination with platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)					
Cemiplimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220
Paclitaxel	Surcharge for the preparation of a	€ 100	1	17.4	€ 1,740

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing cytostatic agents				
Pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
durvalumab in combination with tremelimumab and platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)					
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8.0	€ 800
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	12.0	€ 1,200
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8.0	€ 800
Antibody maintenance treatment and 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
+ pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	10.0	€ 1,000

b) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

Name of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Selpercatinib	€ 46,718.70
Appropriate comparator therapy:	
Individualised therapy with selection of	
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy	
Pembrolizumab	€ 80,030.78
Pemetrexed	€ 18,621.48
Carboplatin	€ 8,174.00
Cisplatin	€ 2,017.18
Pembrolizumab + pemetrexed + carboplatin	
Total (pembrolizumab + pemetrexed + carboplatin)	€ 106,826.26
Additionally required SHI costs	€ 134.39 – € 188.19
Pembrolizumab + pemetrexed + cisplatin	
Total (pembrolizumab + pemetrexed + cisplatin)	€ 100,669.44
Additionally required SHI costs	€ 406.09 – € 529.67
Atezolizumab as monotherapy (only patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells are eligible)	
Atezolizumab	€ 68,352.94
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin	
Induction therapy (4 – 6 cycles)	
Atezolizumab	€ 15,713.32 – € 23,569.98
Bevacizumab (7.5 mg/kg or 15 mg/kg)	€ 3,858.00 – € 5,787.00 or € 7,601.52 – € 11,402.28
Paclitaxel	€ 3,823.88 – € 5,735.82
Carboplatin	€ 1,879.08 – € 2,818.62
Additionally required SHI costs	€ 85.12 – € 143.71
Maintenance treatment	
Atezolizumab	€ 44,782.96 (after 6 cycles of induction therapy) – € 52,639.62 (after 4 cycles of induction therapy)
Bevacizumab (7.5 mg/kg or 15 mg/kg)	€ 10,995.30 (after 6 cycles of induction therapy) –

Name of the therapy	Annual treatment costs/ patient
	€ 12,924.30 (after 4 cycles of induction therapy) or € 21,664.33 (after 6 cycles of induction therapy) – € 25,465.09 (after 4 cycles of induction therapy)
Total (cost range taking into account the number of induction cycles and bevacizumab dosage regimens)	<u>Combination with 7.5 mg/kg bevacizumab:</u> € 90,838.20 – € 93,689.68 (4 – 6 induction cycles) or <u>Combination with 15 mg/kg bevacizumab:</u> € 107,122.51 – € 109,973.99 (4 – 6 induction cycles)
Additionally required SHI costs	€ 85.12 – € 143.71
Atezolizumab in combination with nab-paclitaxel and carboplatin	
Induction therapy	
Atezolizumab	€ 15,713.32 – € 23,569.98
Carboplatin	€ 1,879.08 – € 2,818.62
Nab-paclitaxel	€ 9,786.00 – € 14,679.00
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Maintenance treatment	
Atezolizumab	€ 44,782.96 (after 6 cycles of induction therapy) – € 52,639.62 (after 4 cycles of induction therapy)
Total (cost range taking into account the number of induction cycles)	€ 80,018.02 – € 85,850.56
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy	
Nivolumab	€ 75,862.26
Ipilimumab	€ 57,271.75
+ carboplatin	€ 939.54
+ cisplatin	€ 231.86 – € 286.88
+ docetaxel	€ 980.14
+ gemcitabine	€ 929.68
+ nab-paclitaxel	€ 4,893.00
+ paclitaxel	€ 1,911.94
+ pemetrexed	€ 2,140.40
+ vinorelbine	€ 576.64 – € 719.92

Name of the therapy	Annual treatment costs/ patient
Total (nivolumab + ipilimumab + platinum-based chemotherapy)	€ 133,976.19 – € 138,966.55[2]
Additionally required SHI costs	€ 34.91 – € 183.62[3]
Cemiplimab in combination with platinum-based chemotherapy	
Cemiplimab	€ 70,925.18
+ carboplatin	€ 8,174.00
+ cisplatin	€ 2,017.18 – € 2,495.86
+ docetaxel	€ 8,527.22
+ gemcitabine	€ 8,088.22
+ nab-paclitaxel	€ 42,569.10
+ paclitaxel	€ 16,633.88
+ pemetrexed	€ 18,621.48
+ vinorelbine	€ 5,016.77 – € 6,263.31
Total (cemiplimab + platinum-based chemotherapy)	€ 78,252.15 – € 121,668.28[4]
Additionally required SHI costs	€ 134.39 – € 612.55[5]
Durvalumab in combination with tremelimumab and platinum-based chemotherapy	
Durvalumab	€ 23,596.08
Tremelimumab	€ 20,157.84
Total (durvalumab + tremelimumab; 4 cycles)	€ 43,753.92
+ 4 cycles of platinum-based chemotherapy	
Carboplatin	€ 1,879.08
Cisplatin	€ 463.72 – € 573.76
+ docetaxel	€ 1,960.28
+ gemcitabine	€ 1,859.36
+ nab-paclitaxel	€ 9,786.00
+ paclitaxel	€ 3,823.88
+ pemetrexed	€ 4,280.80
+ vinorelbine	€ 1,153.28 – € 1,439.84
Antibody maintenance treatment (without histology-based maintenance treatment with pemetrexed)	
Durvalumab	€ 58,990.20
+ single dose of tremelimumab	€ 5,039.46
Total	€ 64,029.66
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed	

Name of the therapy	Annual treatment costs/ patient
Durvalumab	€ 58,990.20
+ single dose of tremelimumab	€ 5,039.46
+ pemetrexed	€ 10,702.00
Total	€ 74,731.66
Total: Durvalumab + tremelimumab + platinum-based chemotherapy (4 cycles) + Antibody maintenance treatment (± pemetrexed)	€ 109,467.94 – € 124,645.46[6]
Additionally required SHI costs	€ 85.12 – € 308.19[7]
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	
Carboplatin	€ 8,631.10
+ docetaxel	€ 8,527.22
+ gemcitabine	€ 8,088.22
+ paclitaxel	€ 16,633.88
+ pemetrexed	€ 18,621.48
+ vinorelbine	€ 5,016.77 – € 6,263.31
Carboplatin + docetaxel	
Total (carboplatin + docetaxel)	€ 17,158.32
Carboplatin + gemcitabine	
Total (carboplatin + gemcitabine)	€ 16,719.32
Carboplatin + paclitaxel	
Total (carboplatin + paclitaxel)	€ 25,264.98
Additionally required SHI costs	€ 271.07
Carboplatin + pemetrexed	
Total (carboplatin + pemetrexed)	€ 27,252.58
Additionally required SHI costs	€ 134.39 – € 188.19
Carboplatin + vinorelbine	
Total (carboplatin + vinorelbine)	€ 13,647.87 – € 14,894.41
Carboplatin in combination with nab-paclitaxel	
Carboplatin	€ 8,174.00
Nab-paclitaxel	€ 42,569.10
Total	€ 50,743.10

Name of the therapy	Annual treatment costs/ patient
(carboplatin + with nab-paclitaxel)	

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

Other SHI services:

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy					
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin					
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 the preparation of a parenteral solution	€ 100	1	4.0 – 6.0	€ 400 – € 600

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Carboplatin	Surcharge for the preparation 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 in combination with nab-paclitaxel and carboplatin					
Induction therapy					
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0 – 6.0	€ 400 – € 600
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	12.0 – 18.0	€ 1,200 – € 1,800
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy					
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 the preparation of a	€ 100	1	2.0	€ 200

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing cytostatic agents				
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0	€ 400
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	6	€ 600
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0	€ 200
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0	€ 400
Cemiplimab in combination with platinum-based chemotherapy					
Cemiplimab	Surcharge for the preparation of a parenteral solution	€ 100	1	17.4	€ 1,740

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing monoclonal antibodies				
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Durvalumab in combination with tremelimumab and platinum-based chemotherapy					
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 the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8.0	€ 800
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	12.0	€ 1,200
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8.0	€ 800
Antibody maintenance treatment and 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
+ pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	10.0	€ 1,000
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					
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Gemcitabine	Surcharge for the preparation of a	€ 100	2	34.8	€ 3,480

Name of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing cytostatic agents				
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Pemetrexed	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
Carboplatin in combination with nab-paclitaxel					
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220

1. **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 advanced RET fusion-positive NSCLC with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

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

b) Adults with advanced RET fusion-positive NSCLC with PD-L1 expression < 50% of tumour cells; first-line therapy

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

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution entered into force on the day of its publication on the G-BA website on 18 June 2026.

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

Berlin, 18 June 2026

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

Prof. Hecken