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

Repotrectinib
(non-small cell lung cancer, ROS1-positive)

of 16 October 2025

At their session on 16 October 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. 6 to the information on the benefit assessment of Repotrectinib in accordance with the resolution of 16 October 2025:

Repotrectinib

Resolution of: 16 October 2025
Entry into force on: 16 October 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 13 January 2025):

AUGTYRO as monotherapy is indicated for the treatment of adult patients with ROS1-positive advanced non-small cell lung cancer (NSCLC).

Therapeutic indication of the resolution (resolution of 16 October 2025):

See therapeutic indication according to marketing authorisation.

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

a) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); no pretreatment with a ROS1 inhibitor

Appropriate comparator therapy:

– Crizotinib

Extent and probability of the additional benefit of repotrectinib compared to crizotinib:

An additional benefit is not proven.

b1) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression ≥ 50%

Appropriate comparator therapy:

– Pembrolizumab as monotherapy

or

– atezolizumab as monotherapy

or

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

or

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

or

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

or

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

or

– 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 repotrectinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

b2) <u>Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression < 50%</u>

Appropriate comparator therapy:

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

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)

or

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

or

– nivolumab in combination with ipilimumab and 2 cycles of 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 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 repotrectinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); no pretreatment with a ROS1 inhibitor

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		

b1) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression ≥ 50%

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.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-59) unless otherwise indicated.

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

b2) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression < 50%

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 with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); no pretreatment with a ROS1 inhibitor

Approx. 390 to 1090 patients

b1) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression ≥ 50%

Approx. 55 to 150 patients

b2) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression < 50%

Approx. 140 to 380 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 Augtyro (active ingredient: repotrectinib) at the following publicly accessible link (last access: 7 October 2025):

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

Treatment with repotrectinib 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.

A validated test is required for the selection of patients with ROS1-positive NSCLC. A ROS1-positive status must be confirmed prior to initiation of therapy with repotrectinib.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

4. Treatment costs

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

Annual treatment costs:

a) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); no pretreatment with a ROS1 inhibitor

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Repotrectinib	€ 115,083.04
Appropriate comparator therapy:	
Crizotinib	€ 65,997.48

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2025)

Costs for additionally required SHI services: not applicable

b1) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression ≥ 50%

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	

Designation of the therapy	Annual treatment costs/ patient
Repotrectinib	€ 115,083.04
Appropriate comparator therapy:	
Pembrolizumab as monotherapy	
Pembrolizumab	€ 81,438.79
Atezolizumab as monotherapy	
Atezolizumab	€ 67,771.78
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)	
Nivolumab	€ 75,862.26
Ipilimumab	€ 57,271.75
+ carboplatin	€ 991.84
+ 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
Nivolumab + ipilimumab + carboplatin + docetaxel	
Total (nivolumab + ipilimumab + carboplatin + docetaxel)	€ 135,105.99
Nivolumab + ipilimumab + carboplatin + gemcitabine	
Total (nivolumab + ipilimumab + carboplatin + gemcitabine)	€ 135,055.53
Nivolumab + ipilimumab + carboplatin + nab-paclitaxel	
Total (nivolumab + ipilimumab + carboplatin + nab-paclitaxel)	€ 139,018.85
Nivolumab + ipilimumab + carboplatin + paclitaxel	
Total (nivolumab + ipilimumab + carboplatin + paclitaxel)	€ 136,037.79
Additionally required SHI costs	€ 67.57
Nivolumab + ipilimumab + carboplatin + pemetrexed	
Total (nivolumab + ipilimumab + carboplatin + pemetrexed)	€ 136,266.25
Additionally required SHI costs	€ 34.90 – € 41.01

Designation of the therapy	Annual treatment costs/ patient
Nivolumab + ipilimumab + carboplatin + vinorelbine	
Total (nivolumab + ipilimumab + carboplatin + vinorelbine)	€ 134,702.49 – € 134,845.77
Nivolumab + ipilimumab + cisplatin + docetaxel	
Total (nivolumab + ipilimumab + cisplatin + docetaxel)	€ 134,346.01
Additionally required SHI costs	€ 116.05
Nivolumab + ipilimumab + cisplatin + gemcitabine	
Total (nivolumab + ipilimumab + cisplatin + gemcitabine)	€ 134,295.55 – € 134,350.57
Additionally required SHI costs	€ 116.05
Nivolumab + ipilimumab + cisplatin + paclitaxel	
Total (nivolumab + ipilimumab + cisplatin + paclitaxel)	€ 135,308.73
Additionally required SHI costs	€ 183.62
Nivolumab + ipilimumab + cisplatin + pemetrexed	
Total (nivolumab + ipilimumab + cisplatin + pemetrexed)	€ 135,506.27
Additionally required SHI costs	€ 150.95 – € 157.06
Nivolumab + ipilimumab + cisplatin + vinorelbine	
Total (nivolumab + ipilimumab + cisplatin + vinorelbine)	€ 133,973.43 – € 134,116.71
Additionally required SHI costs	€ 116.05
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients without ECOG-PS 0-1)	
Pembrolizumab	€ 81,438.79
Pemetrexed	€ 18,621.48
Carboplatin	€ 8,629.00
Cisplatin	€ 2,017.18
Pembrolizumab + pemetrexed + carboplatin	
Total (pembrolizumab + pemetrexed + carboplatin)	€ 108,689.27
Additionally required SHI costs	€ 134.39 – € 188.19
Pembrolizumab + pemetrexed + cisplatin	

Designation of the therapy	Annual treatment costs/ patient
Total (pembrolizumab + pemetrexed + cisplatin)	€ 102,077.45
Additionally required SHI costs	€ 406.09 – € 529.67
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)	
Induction therapy (4 – 6 cycles)	
Atezolizumab	€ 15,579.72 – € 23,369.58
Bevacizumab (7.5 mg/kg or 15 mg/kg)	€ 3,858.00 – € 5,787.00 or € 7,601.52 – € 11,402.28
Paclitaxel	€ 3,823.88 – € 5,735.82
Carboplatin	€ 1,983.68 – € 2,975.52
Additionally required SHI costs	€ 85.12 – € 143.71
Maintenance treatment	
Atezolizumab	€ 44,402.20 (after 6 cycles of induction therapy) – € 52,192.06 (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> € 90,361.64 – € 93,265.42 (4 – 6 induction cycles) or <u>Combination with 15 mg/kg bevacizumab:</u> € 106,645.95 – € 109,549.73 (4 – 6 induction cycles)
Additionally required SHI costs	€ 85.12 – € 143.71
Atezolizumab in combination with nab-paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)	
Induction therapy	
Atezolizumab	€ 15,579.72 – € 23,369.58
Carboplatin	€ 1,983.68 – € 2,975.52
Nab-paclitaxel	€ 9,786.00 – € 14,679.00
Total Atezolizumab + carboplatin + nab-paclitaxel (induction therapy)	€ 27,349.40 – € 41,024.10
Maintenance treatment	

Designation of the therapy	Annual treatment costs/ patient
Atezolizumab	€ 44,402.20 (after 6 cycles of induction therapy) – € 52,192.06 (after 4 cycles of induction therapy)
Total (cost range taking into account the number of induction cycles)	€ 79,541.46 – € 85,426.30
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; 4 cycles)	€ 43,995.60
+ 4 cycles of platinum-based chemotherapy	
Carboplatin	€ 1,983.68
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	€ 59,594.40
+ single dose of tremelimumab	€ 5,039.46
Total	€ 64,633.86
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed	
Durvalumab	€ 59,594.40
+ single dose of tremelimumab	€ 5,039.46
+ pemetrexed	€ 10,702.00
Total	€ 75,335.86
Additionally required SHI costs	€ 87.06 – € 128.48
Durvalumab + tremelimumab + carboplatin + docetaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + docetaxel (4 cycles)	€ 47,939.56
Total:	€ 112,573.42

Designation of the therapy	Annual treatment costs/ patient
Durvalumab + tremelimumab + carboplatin + docetaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	
Durvalumab + tremelimumab + carboplatin + gemcitabine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + gemcitabine (4 cycles)	€ 47,838.64
Total: Durvalumab + tremelimumab + carboplatin + gemcitabine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 112,472.50
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (4 cycles)	€ 55,765.28
Total: Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 120,399.14
Durvalumab + tremelimumab + carboplatin + paclitaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + paclitaxel (4 cycles)	€ 49,803.16
Additionally required SHI costs	€ 85.12
Total: Durvalumab + tremelimumab + carboplatin + paclitaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 114,437.02
Total additionally required SHI costs	€ 85.12

Designation of the therapy	Annual treatment costs/ patient
Durvalumab + tremelimumab + carboplatin + pemetrexed (± antibody maintenance treatment and maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + pemetrexed (4 cycles)	€ 50,260.08
Additionally required SHI costs	€ 31.23 – € 43.61
Total: Durvalumab + tremelimumab + carboplatin + pemetrexed (4 cycles) + Antibody maintenance treatment (with pemetrexed)	€ 125,595.94
Total additionally required SHI costs	€ 118.29 – € 172.09
Durvalumab + tremelimumab + carboplatin + vinorelbine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + vinorelbine (4 cycles)	€ 47,132.56 – € 47,419.12
Total: Durvalumab + tremelimumab + carboplatin + vinorelbine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 111,766.42 – € 112,052.98
Durvalumab + tremelimumab + cisplatin + docetaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + docetaxel (4 cycles)	€ 46,419.60
Additionally required SHI costs	€ 130.98 – € 136.10
Total: Durvalumab + tremelimumab + cisplatin + docetaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 111,053.46
Total additionally required SHI costs	€ 130.98 – € 136.10
Durvalumab + tremelimumab + cisplatin + gemcitabine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total:	€ 46,318.68 – € 46,428.72

Designation of the therapy	Annual treatment costs/ patient
Durvalumab + tremelimumab + cisplatin + gemcitabine (4 cycles)	
Additionally required SHI costs	€ 130.98 – € 136.10
Total: Durvalumab + tremelimumab + cisplatin + gemcitabine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 110,952.54 – € 111,062.58
Total additionally required SHI costs	€ 130.98 – € 136.10
Durvalumab + tremelimumab + cisplatin + paclitaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + paclitaxel (4 cycles)	€ 48,345.04
Additionally required SHI costs	€ 216.10 – € 221.22
Total: Durvalumab + tremelimumab + cisplatin + paclitaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 112,978.90
Total additionally required SHI costs	€ 216.10 – € 221.22
Durvalumab + tremelimumab + cisplatin + pemetrexed (± antibody maintenance treatment and maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + pemetrexed (4 cycles)	€ 48,740.12
Additionally required SHI costs	€ 162.21 – € 179.71
Total: Durvalumab + tremelimumab + cisplatin + pemetrexed (4 cycles) + Antibody maintenance treatment (with pemetrexed)	€ 124,075.98
Total additionally required SHI costs	€ 249.27 – € 308.19
Durvalumab + tremelimumab + cisplatin + vinorelbine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total:	€ 45,674.44 – € 45,961.00

Designation of the therapy	Annual treatment costs/ patient
Durvalumab + tremelimumab + cisplatin + vinorelbine (4 cycles)	
Additionally required SHI costs	€ 130.98 – € 136.10
Total: Durvalumab + tremelimumab + cisplatin + vinorelbine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 110,308.30 – € 110,594.86
Total additionally required SHI costs	€ 130.98 – € 136.10

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2025)

Other SHI services:

Designation 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
Nivolumab in combination with ipilimumab and 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 the preparation of a parenteral solution	€ 100	1	2.0	€ 200

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	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
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients without ECOG-PS 0-1)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution	€ 100	1	8.7 or 17.4	€ 870 or € 1,740

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing monoclonal antibodies				
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 (only for patients with ECOG-PS 0-1)					
Induction therapy					
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0 – 6.0	€ 400 – € 600
Paclitaxel	Surcharge for 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	€ 100	1	11.4 – 13.4	€ 1,140 – € 1,340

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing monoclonal antibodies				
Atezolizumab in combination with nab-paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)					
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
Durvalumab in combination with tremelimumab and platinum-based chemotherapy (only for patients with ECOG-PS 0-1)					
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

Designation 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	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
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

Designation 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	10.0	€ 1,000

b2) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression < 50%

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Repotrectinib	€ 115,083.04
Appropriate comparator therapy:	
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients without ECOG-PS 0-1)	
Pembrolizumab	€ 81,438.79
Pemetrexed	€ 18,621.48
Carboplatin	€ 8,629.00
Cisplatin	€ 2,017.18
Pembrolizumab + pemetrexed + carboplatin	
Total (pembrolizumab + pemetrexed + carboplatin)	€ 108,689.27
Additionally required SHI costs	€ 134.39 – € 188.19
Pembrolizumab + pemetrexed + cisplatin	
Total (pembrolizumab + pemetrexed + cisplatin)	€ 102,077.45
Additionally required SHI costs	€ 406.09 – € 529.67
Atezolizumab as monotherapy (only for patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells)	
Atezolizumab	€ 67,771.78
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)	
Induction therapy (4 – 6 cycles)	
Atezolizumab	€ 15,579.72 – € 23,369.58
Bevacizumab (7.5 mg/kg or 15 mg/kg)	€ 3,858.00 – € 5,787.00 or € 7,601.52 – € 11,402.28

Designation of the therapy	Annual treatment costs/ patient
Paclitaxel	€ 3,823.88 – € 5,735.82
Carboplatin	€ 1,983.68 – € 2,975.52
Additionally required SHI costs	€ 85.12 – € 143.71
Maintenance treatment	
Atezolizumab	€ 44,402.20 (after 6 cycles of induction therapy) – € 52,192.06 (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> € 90,361.64 – € 93,265.42 (4 – 6 induction cycles) or <u>Combination with 15 mg/kg bevacizumab:</u> € 106,645.95 – € 109,549.73 (4 – 6 induction cycles)
Additionally required SHI costs	€ 85.12 – € 143.71
Atezolizumab in combination with nab-paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)	
Induction therapy	
Atezolizumab	€ 15,579.72 – € 23,369.58
Carboplatin	€ 1,983.68 – € 2,975.52
Nab-paclitaxel	€ 9,786.00 – € 14,679.00
Total Atezolizumab + carboplatin + nab-paclitaxel (induction therapy)	€ 27,349.40 – € 41,024.10
Maintenance treatment	
Atezolizumab	€ 44,402.20 (after 6 cycles of induction therapy) – € 52,192.06 (after 4 cycles of induction therapy)
Total (cost range taking into account the number of induction cycles)	€ 79,541.46 – € 85,426.30
Nivolumab in combination with ipilimumab and 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	€ 991.84
+ 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
Nivolumab + ipilimumab + carboplatin + docetaxel	
Total (nivolumab + ipilimumab + carboplatin + docetaxel)	€ 135,105.99
Nivolumab + ipilimumab + carboplatin + gemcitabine	
Total (nivolumab + ipilimumab + carboplatin + gemcitabine)	€ 135,055.53
Nivolumab + ipilimumab + carboplatin + nab-paclitaxel	
Total (nivolumab + ipilimumab + carboplatin + nab-paclitaxel)	€ 139,018.85
Nivolumab + ipilimumab + carboplatin + paclitaxel	
Total (nivolumab + ipilimumab + carboplatin + paclitaxel)	€ 136,037.79
Additionally required SHI costs	€ 67.57
Nivolumab + ipilimumab + carboplatin + pemetrexed	
Total (nivolumab + ipilimumab + carboplatin + pemetrexed)	€ 136,266.25
Additionally required SHI costs	€ 34.90 – € 41.01
Nivolumab + ipilimumab + carboplatin + vinorelbine	
Total (nivolumab + ipilimumab + carboplatin + vinorelbine)	€ 134,702.49 – € 134,845.77
Nivolumab + ipilimumab + cisplatin + docetaxel	
Total (nivolumab + ipilimumab + cisplatin + docetaxel)	€ 134,346.01
Additionally required SHI costs	€ 116.05
Nivolumab + ipilimumab + cisplatin + gemcitabine	
Total	€ 134,295.55 – € 134,350.57

Designation of the therapy	Annual treatment costs/ patient
(nivolumab + ipilimumab + cisplatin + gemcitabine)	
Additionally required SHI costs	€ 116.05
Nivolumab + ipilimumab + cisplatin + paclitaxel	
Total (nivolumab + ipilimumab + cisplatin + paclitaxel)	€ 135,308.73
Additionally required SHI costs	€ 183.62
Nivolumab + ipilimumab + cisplatin + pemetrexed	
Total (nivolumab + ipilimumab + cisplatin + pemetrexed)	€ 135,506.27
Additionally required SHI costs	€ 150.95 – € 157.06
Nivolumab + ipilimumab + cisplatin + vinorelbine	
Total (nivolumab + ipilimumab + cisplatin + vinorelbine)	€ 133,973.43 – € 134,116.71
Additionally required SHI costs	€ 116.05
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)	
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	€ 271.07
Carboplatin + pemetrexed	
Carboplatin	€ 8,631.10
Pemetrexed	€ 18,621.48

Designation of the therapy	Annual treatment costs/ patient
Total (carboplatin + pemetrexed)	€ 27,252.58
Additionally required SHI costs	€ 134.39 – € 188.19
Carboplatin + vinorelbine	
Carboplatin	€ 8,631.10
Vinorelbine	€ 5,016.77 – € 6,263.31
Total (carboplatin + vinorelbine)	€ 13,647.87 – € 14,894.41
Carboplatin in combination with nab-paclitaxel (only for patients with ECOG-PS 2)	
Carboplatin	€ 8,629.00
Nab-paclitaxel	€ 42,569.10
Total (carboplatin + nab-paclitaxel)	€ 51,198.10
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; 4 cycles)	€ 43,995.60
+ 4 cycles of platinum-based chemotherapy	
Carboplatin	€ 1,983.68
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	€ 59,594.40
+ single dose of tremelimumab	€ 5,039.46
Total	€ 64,633.86
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed	
Durvalumab	€ 59,594.40
+ single dose of tremelimumab	€ 5,039.46
+ pemetrexed	€ 10,702.00
Total	€ 75,335.86

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI costs	€ 87.06 – € 128.48
Durvalumab + tremelimumab + carboplatin + docetaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + docetaxel (4 cycles)	€ 47,939.56
Total: Durvalumab + tremelimumab + carboplatin + docetaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 112,573.42
Durvalumab + tremelimumab + carboplatin + gemcitabine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + gemcitabine (4 cycles)	€ 47,838.64
Total: Durvalumab + tremelimumab + carboplatin + gemcitabine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 112,472.50
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (4 cycles)	€ 55,765.28
Total: Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 120,399.14
Durvalumab + tremelimumab + carboplatin + paclitaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + paclitaxel (4 cycles)	€ 49,803.16
Additionally required SHI costs	€ 85.12
Total:	€ 114,437.02

Designation of the therapy	Annual treatment costs/ patient
Durvalumab + tremelimumab + carboplatin + paclitaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	
Total additionally required SHI costs	€ 85.12
Durvalumab + tremelimumab + carboplatin + pemetrexed (± antibody maintenance treatment and maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + pemetrexed (4 cycles)	€ 50,260.08
Additionally required SHI costs	€ 31.23 – € 43.61
Total: Durvalumab + tremelimumab + carboplatin + pemetrexed (4 cycles) + Antibody maintenance treatment (with pemetrexed)	€ 125,595.94
Total additionally required SHI costs	€ 118.29 – € 172.09
Durvalumab + tremelimumab + carboplatin + vinorelbine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + carboplatin + vinorelbine (4 cycles)	€ 47,132.56 – € 47,419.12
Total: Durvalumab + tremelimumab + carboplatin + vinorelbine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 111,766.42 – € 112,052.98
Durvalumab + tremelimumab + cisplatin + docetaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + docetaxel (4 cycles)	€ 46,419.60
Additionally required SHI costs	€ 130.98 – € 136.10
Total: Durvalumab + tremelimumab + cisplatin + docetaxel (4 cycles) +	€ 111,053.46

Designation of the therapy	Annual treatment costs/ patient
Antibody maintenance treatment (without pemetrexed)	
Total additionally required SHI costs	€ 130.98 – € 136.10
Durvalumab + tremelimumab + cisplatin + gemcitabine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + gemcitabine (4 cycles)	€ 46,318.68 – € 46,428.72
Additionally required SHI costs	€ 130.98 – € 136.10
Total: Durvalumab + tremelimumab + cisplatin + gemcitabine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 110,952.54 – € 111,062.58
Total additionally required SHI costs	€ 130.98 – € 136.10
Durvalumab + tremelimumab + cisplatin + paclitaxel (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + paclitaxel (4 cycles)	€ 48,345.04
Additionally required SHI costs	€ 216.10 – € 221.22
Total: Durvalumab + tremelimumab + cisplatin + paclitaxel (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 112,978.90
Total additionally required SHI costs	€ 216.10 – € 221.22
Durvalumab + tremelimumab + cisplatin + pemetrexed (± antibody maintenance treatment and maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + pemetrexed (4 cycles)	€ 48,740.12
Additionally required SHI costs	€ 162.21 – € 179.71
Total: Durvalumab + tremelimumab + cisplatin + pemetrexed (4 cycles) +	€ 124,075.98

Designation of the therapy	Annual treatment costs/ patient
Antibody maintenance treatment (with pemetrexed)	
Total additionally required SHI costs	€ 249.27 – € 308.19
Durvalumab + tremelimumab + cisplatin + vinorelbine (± antibody maintenance treatment without maintenance treatment with pemetrexed)	
Total: Durvalumab + tremelimumab + cisplatin + vinorelbine (4 cycles)	€ 45,674.44 – € 45,961.00
Additionally required SHI costs	€ 130.98 – € 136.10
Total: Durvalumab + tremelimumab + cisplatin + vinorelbine (4 cycles) + Antibody maintenance treatment (without pemetrexed)	€ 110,308.30 – € 110,594.86
Total additionally required SHI costs	€ 130.98 – € 136.10

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2025)

Other SHI services:

Designation 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 (only for patients without ECOG-PS 0-1)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 or 17.4	€ 870 or € 1,740
Pemetrexed	Surcharge for 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 (only for patients with ECOG-PS 0-1)					
Induction therapy					
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0 – 6.0	€ 400 – € 600
Paclitaxel	Surcharge for 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 for patients with ECOG-PS 0-1)					
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	€ 100	3	12.0 – 18.0	€ 1,200 – € 1,800

	containing cytostatic agents				
Nivolumab in combination with ipilimumab and 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 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
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
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 parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
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	€ 100	1	17.4	€ 1,740

	parenteral solution containing cytostatic agents				
Nab-paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220
Durvalumab in combination with tremelimumab and platinum-based chemotherapy (only for patients with ECOG-PS 0-1)					
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	€ 100	3	12.0	€ 1,200

	containing cytostatic agents				
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

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 ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); no pretreatment with a ROS1 inhibitor

- 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 authorised in monotherapy.

b1) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression ≥ 50%

- 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 authorised in monotherapy.

b2) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); pretreatment with a ROS1 inhibitor and with PD-L1 expression < 50%

- 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 authorised 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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product repotrectinib (Augtyro) is a medicinal product placed on the market from 1 January 2025.

No information was provided on the number of study participants involved in the clinical studies of the medicinal product in the therapeutic indication under assessment, which were conducted or commissioned by the pharmaceutical company at study sites within the scope of SGB V and/or on the total number of study participants.

Due to the absence of information, it is therefore not possible to determine that the percentage of study participants reached or exceeded the relevance threshold of at least 5 per cent.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

II. Entry into force

1st The resolution will enter into force on the day of its publication on the website of the G-BA on 16 October 2025.

2nd The period of validity of the resolution is limited in accordance with the following regulations:

The statements made for the patient group

a) Adults with ROS1-positive, advanced or metastatic non-small cell lung cancer (NSCLC); no pretreatment with a ROS1 inhibitor

in numbers 1, 2, 3, 4, 5 and 6 are limited until 1 July 2027.

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

Berlin, 16 October 2025

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

Prof. Hecken