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) and Annex XIIa – Combinations of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Durvalumab (new therapeutic indication: non-small cell lung cancer, EGFR/ALK-negative, first-line, combination with tremelimumab and platinum-based chemotherapy)

of 5 October 2023

At its session on 5 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 Durvalumab in accordance with the resolution of 5 October 2023 for the therapeutic indication: "for the first-line treatment of unresectable or metastatic biliary tract cancer (BTC)":

Durvalumab

Resolution of: 5 October 2023
Entry into force on: 5 October 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 30 January 2023):

Imfinzi in combination with tremelimumab and platinum-based chemotherapy is indicated for the first-line treatment of adults with metastatic NSCLC with no sensitising EGFR mutations or ALK positive mutations.

Therapeutic indication of the resolution (resolution of 5 October 2023):

See therapeutic indication according to marketing authorisation.

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

a) Adults with metastatic NSCLC with PD-L1 expression ≥ 50% with no genomic EGFR or ALK tumour mutations; 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 durvalumab in combination with tremelimumab and platinum-based chemotherapy versus pembrolizumab:

An additional benefit is not proven.

b) Adults with metastatic NSCLC with PD-L1 expression < 50% with no genomic EGFR or ALK tumour mutations; 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 durvalumab in combination with tremelimumab and platinum-based chemotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with metastatic NSCLC with PD-L1 expression ≥ 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	↔	No relevant differences for the benefit assessment.
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		

Adjusted indirect comparison

Durvalumab + tremelimumab + platinum-based chemotherapy vs pembrolizumab via the bridge comparator platinum-based chemotherapy:

POSEIDON study:	Durvalumab + tremelimumab + platinum-based chemotherapy vs platinum-based chemotherapy; open-label RCT
KEYNOTE-024 study:	Pembrolizumab vs platinum-based chemotherapy; open-label RCT
KEYNOTE-042 study:	Pembrolizumab vs platinum-based chemotherapy; open-label RCT

[1] Data from the dossier assessment of the IQWiG (A23-29 | A23-31) and from the addenda (A23-84 and G23-20), unless otherwise indicated.

Mortality

Endpoint	Durvalumab + tremelimumab + platinum-based chemotherapy or Pembrolizumab		Platinum-based chemotherapy (bridge comparator)		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value
Overall survival					
Tremelimumab + durvalumab + platinum-based chemotherapy vs platinum-based chemotherapy					
POSEIDON (data cut-off 12.03.2021)	101	n.d. *69 (68.3)*	97	n.d. *80 (82.5)*	0.65 [0.47; 0.89]; n.d.
Pembrolizumab vs platinum-based chemotherapy					
KEYNOTE-024 (data cut-off 09.05.2016)	154	n.r. *44 (28.6)*	151	n.r. [9.4; n.c.] *64 (42.4)*	0.60 [0.41; 0.89]; 0.010
KEYNOTE-042 (data cut-off 26.02.2018)	299	20.0 [15.4; 24.9] n.d.	300	12.2 [10.4; 14.2] n.d.	0.69 [0.56; 0.85]; < 0.001
Total					0.67 [0.56; 0.80] < 0.001[a]
Adjusted indirect comparison via bridge comparators[b]: Tremelimumab + durvalumab + platinum-based chemotherapy vs pembrolizumab					0.97 [0.67; 1.41]; 0.873[c]

Morbidity

Endpoint	
Symptomatology (EORTC QLQ-C30, EORTC QLQ-LC13)	No suitable data for indirect comparison[d]
Health status (EQ-5D VAS)	No suitable data for indirect comparison[d]
Health status (PGIC)	No suitable data for indirect comparison[d]

Health-related quality of life

Endpoint	
Functional scales (EORTC QLQ-C30)	No suitable data for indirect comparison[d]

Side effects

Endpoint	**Durvalumab + tremelimumab + platinum-based chemotherapy or Pembrolizumab**		**Platinum-based chemotherapy (bridge comparator)**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[k]
Total adverse events (presented additionally)					
Tremelimumab + durvalumab + platinum-based chemotherapy vs platinum-based chemotherapy					
POSEIDON[e] (data cut-off 12.03.2021)	99	0.1 [0.1; 0.3] *98 (99.0)*	93	0.2 [0.1; 0.3] *88 (94.6)*	–
Pembrolizumab vs platinum-based chemotherapy					
KEYNOTE-024 (data cut-off 09.05.2016)	154	1.1 [0.7; 1.7] 148 (96.1)	150	0.6 [0.4; 0.9] 145 (96.7)	–
KEYNOTE-042 (data cut-off 26.02.2018)[f]	299	n.d.	300	n.d.	n.d.
Serious adverse events (SAE)					
Tremelimumab + durvalumab + platinum-based chemotherapy vs platinum-based chemotherapy					
POSEIDON[e] (data cut-off 12.03.2021)	99	15.4 [7.2; n.c.] *47 (47.5)*	93	18.3 [6.8; n.c.] *37 (39.8)*	0.92 [0.59; 1.43] 0.697
Pembrolizumab vs platinum-based chemotherapy					
KEYNOTE-024 (data cut-off 09.05.2016)	154	54.1 [27.1; n.c.] *68 [44.2]*	150	65.4 [23.1; n.c.] *66 (44.0)*	1.00 [0.71; 1.41] 0.994
KEYNOTE-042 (data cut-off 26.02.2018)[f]	299	n.d.	300	n.d.	n.d.

Endpoint	**Durvalumab + tremelimumab + platinum-based chemotherapy or Pembrolizumab**		**Platinum-based chemotherapy (bridge comparator)**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[k]
Adjusted indirect comparison via bridge comparators[b]: Tremelimumab + durvalumab + platinum-based chemotherapy vs pembrolizumab					0.92 [0.53; 1.61] 0.770[i]
Severe adverse events (CTCAE grade ≥ 3)					
Tremelimumab + durvalumab + platinum-based chemotherapy vs platinum-based chemotherapy					
POSEIDON[h] (data cut-off 12.03.2021)	No suitable data for indirect comparison				
Pembrolizumab vs platinum-based chemotherapy					
KEYNOTE-024 (data cut-off 09.05.2016)	154	27.1 [18.1; 44.4] 82 (53.2)	150	5.9 [4.4; 9.0] 109 (72.7)	0.49 [0.36; 0.66]; < 0.001 AD: 21.2 months
KEYNOTE-042 (data cut-off 26.02.2018)[f]	299	n.d.	300	n.d.	n.d.
Adjusted indirect comparison via bridge comparators[b]: Tremelimumab + durvalumab + platinum-based chemotherapy vs pembrolizumab					–[j]
Therapy discontinuation due to adverse events					
Tremelimumab + durvalumab + platinum-based chemotherapy vs platinum-based chemotherapy					
POSEIDON[e] (data cut-off 12.03.2021)	99	n.r. [16.4; n.c.] 31 (31.3)	93	n.r. 16 (17.2)	1.31 [0.72; 2.50]; 0.385
Pembrolizumab vs platinum-based chemotherapy					
KEYNOTE-024 (data cut-off 09.05.2016)	154	n.r. 14 (9.1)	150	n.r. 21 (14.0)	0.60 [0.31; 1.19]; 0.144
KEYNOTE-042 (data cut-off 26.02.2018)[e]	299	n.d.	300	n.d.	n.d.

Endpoint	Durvalumab + tremelimumab + platinum-based chemotherapy or Pembrolizumab		Platinum-based chemotherapy (bridge comparator)		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[k]
Adjusted indirect comparison via bridge comparators[b]: Tremelimumab + durvalumab + platinum-based chemotherapy vs pembrolizumab					-[g]
Specific adverse events					
PRO-CTCAE	No suitable data for indirect comparison[j]				
Immune-mediated AEs	No suitable data for indirect comparison[j]				

a Meta-analysis calculated using a model with fixed effects
b Indirect comparison according to Bucher
c IQWiG calculation (effect, CI, p value)
d The data of the Poseidon study are not assessable due to asynchronous collection times of the PRO data and the resulting different representation of the patients' burden; PCIG was only collected in the POSEIDON study
e No data are available for the relevant sub-population for the predefined final data cut-off from 12.03.2021. The data from the dossier are used since the information on the total population between the final predefined data cut-off and the data cut-off submitted by the pharmaceutical company in the dossier (25.10.2021) is not relevantly different or identical.
f These analyses only cover just under 50% of the relevant sub-population and are only available separately by histology.
g The requirement for certainty of results for carrying out an adjusted indirect comparison is not met
h No data on the relevant sub-population are available for the final data cut-off from 12.03.2021. In relation to the total population, the number of patients with an event at the data cut-off from 25.10.2021 deviates relevantly from the number of patients in the predefined final data cut-off, which is why the data from the dossier are not used.
i IQWiG calculation
j Infeasible as no suitable data are available or none at all.
k Indication of absolute difference (AD) only in case of statistically significant difference; own calculation

Abbreviations used:
CTCAE = Common Terminology Criteria for Adverse Events; ECOG-PS = European Cooperative Oncology Group Performance Status EORTC = European Organisation for Research and Treatment of Cancer; HR = hazard ratio; n.d.= no data available; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least 1) event; n.c. = not calculable; n.r. = not reached; PD L1 = Programmed Cell Death-Ligand-1; PGIC = Patient Global Impression of Change; PRO-CTCAE = Patient-reported Outcome - CTCAE; QLQ-C30 = Quality of Life Questionnaire - Cancer 30; QLQ-LC13 = Quality of Life Questionnaire - Lung Cancer 13; RCT = randomised controlled trial; SAE = serious adverse event; AE = adverse event; VAS = visual analogue scale; vs = versus

b) Adults with metastatic NSCLC with PD-L1 expression < 50% with no genomic EGFR or ALK tumour mutations, 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.	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 metastatic NSCLC with PD-L1 expression ≥ 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

approx. 3,860 – 6,850 patients

b) Adults with metastatic NSCLC with PD-L1 expression < 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

Approx. 10,610 to 17,810 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 Imfinzi (active ingredient: durvalumab) at the following publicly accessible link (last access: 26 May 2023):

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

Treatment with durvalumab 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.

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 metastatic NSCLC with PD-L1 expression ≥ 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Durvalumab	€ 23,505.96
+ Tremelimumab	€ 25,261.80
Total	€ 48,767.76
+ 4 cycles of platinum-based chemotherapy (carboplatin or cisplatin + pemetrexed, carboplatin or cisplatin + gemcitabine, nab-paclitaxel + carboplatin)	
+ Carboplatin + pemetrexed	
Carboplatin	€ 2,004.20
Pemetrexed	€ 4,352.32
Total	€ 6,356.52
Durvalumab + tremelimumab + carboplatin + pemetrexed	€ 55,124.28
Additionally required SHI costs	€ 27.34 - € 36.02
+Cisplatin + pemetrexed	
Cisplatin	€ 456.12
Pemetrexed	€ 4,352.32
Total	€ 4,808.44
Durvalumab + tremelimumab + cisplatin + pemetrexed	€ 53,576.20
Additionally required SHI costs	€ 162.02 - € 192.28
+ Carboplatin + gemcitabine	
Carboplatin	€ 2,004.20
Gemcitabine	€ 1,852.00
Total	€ 3,856.20
Durvalumab + tremelimumab + carboplatin + gemcitabine	€ 52,623.96
+ cisplatin + gemcitabine	

Designation of the therapy	Annual treatment costs/ patient
Cisplatin	€ 456.12
Gemcitabine	€ 1,852.00
Total	€ 2,308.12
Durvalumab + tremelimumab + cisplatin + gemcitabine	€ 51,075.88
Additionally required SHI costs	€ 134.68 - € 156.26
+ Carboplatin + nab-paclitaxel	
Carboplatin	€ 2,004.20
nab-paclitaxel	€ 9,780.48
Total	€ 11,784.68
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel	€ 60,552.44
Antibody maintenance treatment (without histology-based maintenance treatment with pemetrexed)	
Durvalumab	€ 58,764.90
+ single dose of tremelimumab	€ 6,315.45
Total	€ 65,080.35
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed	
Durvalumab	€ 58,764.90
+ single dose of tremelimumab	€ 6,315.45
Pemetrexed	€ 10,880.80
Total	€ 75,961.15
Additionally required SHI costs	€ 74.33 - € 103.37
Overall presentation: *Durvalumab + tremelimumab + 4 cycles of platinum-based chemotherapy + maintenance treatment*	
Durvalumab + tremelimumab + carboplatin + pemetrexed + maintenance treatment	
Durvalumab + tremelimumab + carboplatin + pemetrexed (4 cycles)	€ 55,124.28
Additionally required SHI costs	€ 27.34 - € 36.02
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy) + pemetrexed	€ 75,961.15
Additionally required SHI costs	€ 74.33 - € 103.37
Total	€ 131,085.43
Total additionally required SHI costs	€ 101.67 - € 139.39
Durvalumab + tremelimumab + cisplatin + pemetrexed + maintenance treatment	
Durvalumab + tremelimumab + cisplatin + pemetrexed	€ 53,576.20

Designation of the therapy	Annual treatment costs/ patient
(4 cycles)	
Additionally required SHI costs	€ 162.02 - € 192.28
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy) + pemetrexed	€ 75,961.15
Additionally required SHI costs	€ 74.33 - € 103.37
Total	€ 129,537.35
Total additionally required SHI costs	€ 236.35 - € 295.65
Durvalumab + tremelimumab + carboplatin + gemcitabine + maintenance treatment	
Durvalumab + tremelimumab + carboplatin + gemcitabine (4 cycles)	€ 52,623.96
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy)	€ 65,080.35
Total	€ 117,704.31
Durvalumab + tremelimumab + cisplatin + gemcitabine + maintenance treatment	
Durvalumab + tremelimumab + cisplatin + gemcitabine (4 cycles)	€ 51,075.88
Additionally required SHI costs	€ 134.68 - € 156.26
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy)	€ 65,080.35
Total	€ 116,156.23
Total additionally required SHI costs	€ 134.68 - € 156.26
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel + maintenance treatment	
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (4 cycles)	€ 60,552.44
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy)	€ 65,080.35
Total	€ 125,632.79
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

Designation of the therapy	Annual treatment costs/ patient
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	€ 2,176.16
Total	€ 3,178.26
Nivolumab + ipilimumab + carboplatin + pemetrexed	€ 131,045.99
Additionally required SHI costs	€ 34.93 - € 41.13
Cisplatin + pemetrexed	
Cisplatin	€ 228.06
Pemetrexed	€ 2,176.16
Total	€ 2,404.22
Nivolumab + ipilimumab + cisplatin + pemetrexed	130271.95
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 € 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	€ 52,797.07 - € 58,050.51

Designation of the therapy	Annual treatment costs/ patient
(840 mg or 1,200 mg or 1,680 mg)	(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 € 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)

Designation of the therapy	Annual treatment costs/ patient
	or € 21,013.76 - € 31,520.64 (1,680 mg; 4 -6 cycles)
+ Carboplatin	€ 2,004.20 - € 3,006.3
+ 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
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	

Designation of the therapy	Annual treatment costs/ patient
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 18,932.59
Cisplatin	€ 1,984.12
Total	€ 114,431.97
Additionally required SHI costs	€ 445.50 - € 576.26
Pembrolizumab + pemetrexed + carboplatin	
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 18,932.59
Carboplatin	€ 8,718.27
Total	€ 121,166.12
Additionally required SHI costs	€ 116.92 - € 154.64

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2023

Costs for additionally required SHI services: not applicable

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					
Induction					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400
+ Tremelimumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400
+ Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0	€ 400
+ Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0	€ 400

+ Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	4.0	€ 800
+ Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0	€ 400
+ Nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3.0	€ 300
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 production of a parenteral preparation containing cytostatic agents	€ 100	1	10.0	€ 1,000
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	€ 100	1	8.7	€ 870

	containing monoclonal antibodies				
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 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

b) Adults with metastatic NSCLC with PD-L1 expression < 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Durvalumab	€ 23,505.96
+ tremelimumab	€ 25,261.80
Total	€ 48,767.76
+ 4 cycles of platinum-based chemotherapy (carboplatin or cisplatin + pemetrexed, carboplatin or cisplatin + gemcitabine, nab-paclitaxel + carboplatin)	
+ Carboplatin + pemetrexed	
Carboplatin	€ 2,004.20
Pemetrexed	€ 4,352.32
Total	€ 6,356.52
Durvalumab + tremelimumab + carboplatin + pemetrexed	€ 55,124.28
Additionally required SHI costs	€ 27.34 - € 36.02
+ Cisplatin + pemetrexed	
Cisplatin	€ 456.12
Pemetrexed	€ 4,352.32
Total	€ 4,808.44
Durvalumab + tremelimumab + cisplatin + pemetrexed	€ 53,576.20
Additionally required SHI costs	€ 162.02 - € 192.28
+ Carboplatin + gemcitabine	
Carboplatin	€ 2,004.20
Gemcitabine	€ 1,852.00
Total	€ 3,856.20
Durvalumab + tremelimumab + carboplatin + gemcitabine	€ 52,623.96
+ Cisplatin + gemcitabine	
Cisplatin	€ 456.12
Gemcitabine	€ 1,852.00
Total	€ 2,308.12
Durvalumab + tremelimumab + cisplatin + gemcitabine	€ 51,075.88
Additionally required SHI costs	€ 134.68 - € 156.26
+ Carboplatin + nab-paclitaxel	

Designation of the therapy	Annual treatment costs/ patient
Carboplatin	€ 2,004.20
nab-paclitaxel	€ 9,780.48
Total	€ 11,784.68
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel	€ 60,552.44
Antibody maintenance treatment (without histology-based maintenance treatment with pemetrexed)	
Durvalumab	€ 58,764.90
+ single dose of tremelimumab	€ 6,315.45
Total	€ 65,080.35
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed	
Durvalumab	€ 58,764.90
+ single dose of tremelimumab	€ 6,315.45
Pemetrexed	€ 10,880.80
Total	€ 75,961.15
Additionally required SHI costs	€ 74.33 - € 103.37
Overall presentation: *Durvalumab + tremelimumab + 4 cycles of platinum-based chemotherapy + maintenance treatment*	
Durvalumab + tremelimumab + carboplatin + pemetrexed + maintenance treatment	
Durvalumab + tremelimumab + carboplatin + pemetrexed (4 cycles)	€ 55,124.28
Additionally required SHI costs	€ 27.34 - € 36.02
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy) + pemetrexed	€ 75,961.15
Additionally required SHI costs	€ 74.33 - € 103.37
Total	€ 131,085.43
Total additionally required SHI costs	€ 101.67 - € 139.39
Durvalumab + tremelimumab + cisplatin + pemetrexed + maintenance treatment	
Durvalumab + tremelimumab + cisplatin + pemetrexed (4 cycles)	€ 53,576.20
Additionally required SHI costs	€ 162.02 - € 192.28
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy) + pemetrexed	€ 75,961.15

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI costs	€ 74.33 - € 103.37
Total	€ 129,537.35
Total additionally required SHI costs	€ 236.35 - € 295.65
Durvalumab + tremelimumab + carboplatin + gemcitabine + maintenance treatment	
Durvalumab + tremelimumab + carboplatin + gemcitabine (4 cycles)	€ 52,623.96
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy)	€ 65,080.35
Total	€ 117,704.31
Durvalumab + tremelimumab + cisplatin + gemcitabine + maintenance treatment	
Durvalumab + tremelimumab + cisplatin + gemcitabine (4 cycles)	€ 51,075.88
Additionally required SHI costs	€ 134.68 - € 156.26
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy)	€ 65,080.35
Total	€ 116,156.23
Total additionally required SHI costs	€ 134.68 - € 156.26
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel + maintenance treatment	
Durvalumab + tremelimumab + carboplatin + nab-paclitaxel (4 cycles)	€ 60,552.44
Maintenance treatment (Single dose of tremelimumab + durvalumab monotherapy)	€ 65,080.35
Total	€ 125,632.79
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	€ 73035.63
+ Ipilimumab	€ 54,832.10
Total	€ 127,867.73
Carboplatin + paclitaxel	
Carboplatin	€ 1,002.10
Paclitaxel	€ 1,911.38
Total	€ 2,913.48

Designation of the therapy	Annual treatment costs/ patient
Nivolumab + ipilimumab + carboplatin + paclitaxel	€ 130,781.21
Additionally required SHI costs	€ 64.01
Carboplatin + pemetrexed	
Carboplatin	€ 1,002.10
Pemetrexed	€ 2,176.16
Total	€ 3,178.26
Nivolumab + ipilimumab + carboplatin + pemetrexed	€ 131,045.99
Additionally required SHI costs	€ 34.93 - € 41.13
Cisplatin + pemetrexed	
Cisplatin	€ 228.06
Pemetrexed	€ 2,176.16
Total	€ 2,404.22
Nivolumab + ipilimumab + cisplatin + pemetrexed	€ 130,271.95
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 € 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

Designation of the therapy	Annual treatment costs/ patient
	€ 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 € 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

Designation of the therapy	Annual treatment costs/ patient
	€ 21,013.76 - € 31,520.64 (1,680 mg; 4 -6 cycles)
+ Carboplatin	€ 2,004.20 - € 3,006.3
+ 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
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	

Designation of the therapy	Annual treatment costs/ patient
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 18,932.59
Cisplatin	€ 1,984.12
Total	€ 114,431.97
Additionally required SHI costs	€ 445.50 - € 576.26
Pembrolizumab + pemetrexed + carboplatin	
Pembrolizumab	€ 93,515.26
Pemetrexed	€ 18,932.59
Carboplatin	€ 8,718.27
Total	€ 121,166.12
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
Carboplatin + docetaxel	
Carboplatin	€ 8,718.27
Docetaxel	€ 8,523.22
Total	€ 17,241.49
Carboplatin + paclitaxel	
Carboplatin	€ 8,718.27
Paclitaxel	€ 16,629.01

Designation of the therapy	Annual treatment costs/ patient
Total	€ 25,347.28
Additionally required SHI costs	€ 254.58
Carboplatin + pemetrexed	
Carboplatin	€ 8,718.27
Pemetrexed	€ 18,932.59
Total	€ 27,650.86
Additionally required SHI costs	€ 116.92 - € 154.64

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2023

Costs for additionally required SHI services: not applicable

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					
Induction					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400
Tremelimumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400
+ Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0	€ 400
+ Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0	€ 400
+ Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	4.0	€ 800

+ Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4.0	€ 400
+Nnab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3.0	€ 300
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 production of a parenteral preparation containing cytostatic agents	€ 100	1	10.0	€ 1,000
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	€ 100	1	8.7	€ 870

	containing monoclonal antibodies				
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	€ 100	1	20.1 - 22.1	€ 2,010 - € 2,210
				or	

	parenteral solution containing monoclonal antibodies			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 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

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 metastatic NSCLC with PD-L1 expression ≥ 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

The following medicinal products with new active ingredients that can be used in a combination therapy with durvalumab in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredient and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Tremelimumab (tremelimumab AstraZeneca), tremelimumab (Imjudo)

b) Adults with metastatic NSCLC with PD-L1 expression < 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

The following medicinal products with new active ingredients that can be used in a combination therapy with durvalumab in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredient and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

Tremelimumab (tremelimumab AstraZeneca), tremelimumab (Imjudo)

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. In Annex XIIa of the Pharmaceuticals Directive, the following information shall be added in alphabetical order:

Active ingredient of the assessed medicinal product

Durvalumab

Resolution according to Section 35a paragraph 3 SGB V from

5 October 2023

Therapeutic indication of the resolution

Imfinzi in combination with tremelimumab and platinum-based chemotherapy y is indicated for the first-line treatment of adults with metastatic NSCLC with no sensitising EGFR mutations or ALK positive mutations.

Patient group a

Adults with metastatic NSCLC with PD-L1 expression ≥ 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Tremelimumab (tremelimumab AstraZeneca), tremelimumab (Imjudo)

Period of validity of the designation (since... or from... to)

Since 5 October 2023

Patient group b

Adults with metastatic NSCLC with PD-L1 expression < 50% with no genomic EGFR or ALK tumour mutations, first-line therapy

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names)

Tremelimumab (tremelimumab AstraZeneca), tremelimumab (Imjudo)

Period of validity of the designation (since... or from... to)

Since 5 October 2023"

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 5 October 2023.

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

Berlin, 5 October 2023

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

Prof. Hecken