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)
Pembrolizumab (new therapeutic indication: non-small cell lung carcinoma, high risk of recurrence, neoadjuvant and adjuvant treatment, monotherapy or combination with platinum-based chemotherapy)

of 17 October 2024

At its session on 17 October 2024, 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 Pembrolizumab in accordance with the resolution of 17 October 2024 on the therapeutic indication: "adjuvant treatment of adults with non-small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum-based chemotherapy":**

Pembrolizumab

Resolution of: 17 October 2024
Entry into force on: 17 October 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 25 March 2024):

KEYTRUDA, in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults.

Therapeutic indication of the resolution (resolution of 17 October 2024):

See new therapeutic indication according to marketing authorisation.

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

a) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression ≥ 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

Appropriate comparator therapy:

Neoadjuvant treatment:

Nivolumab in combination with a platinum-based therapy

Followed by adjuvant treatment:

best supportive care

Extent and probability of the additional benefit of pembrolizumab in combination with platinum-based chemotherapy for neoadjuvant treatment followed by pembrolizumab as monotherapy for adjuvant treatment compared with the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression < 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

Appropriate comparator therapy:

Patient-individual therapy with selection of:

- preoperative (neoadjuvant) systemic chemotherapy with selection of
  - cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)

    and

- carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) and

▪ simultaneous radiochemotherapy with platinum-based (cisplatin or carboplatin) combination chemotherapy,

taking into account the tumour stage, the tumour histology, the presence of a Pancoast tumour and the feasibility of an R0 resection, as well as the prerequisites for the use of carboplatin.

Followed by adjuvant treatment:

best supportive care

Extent and probability of the additional benefit of pembrolizumab in combination with platinum-based chemotherapy for neoadjuvant treatment followed by pembrolizumab as monotherapy for adjuvant treatment compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression ≥ 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

An additional benefit is not proven.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

[1] Data from the dossier assessment of the IQWiG (A24-46) and from the addendum (A24-93), unless otherwise indicated.

b) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression < 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

An additional benefit is not proven.

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	↔	No relevant difference for the benefit assessment.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	↔	No relevant difference for the benefit assessment. In detail, disadvantages in specific AEs.

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

KEYNOTE 671 study: neoadjuvant phase: Pembrolizumab + platinum-based chemotherapy* versus platinum-based chemotherapy*; adjuvant phase: pembrolizumab (monotherapy) versus placebo

[* cisplatin + gemcitabine (for squamous histology) or cisplatin + pemetrexed (for non-squamous histology)].

Relevant sub-population: Patients with resectable NSCLC at a high risk of recurrence and tumour cell PD-L1 expression < 1%.

Mortality

Endpoint	Pembrolizumab + platinum-based chemotherapy[a] (neoadjuvant) + Pembrolizumab (adjuvant)		Platinum-based chemotherapy[a] (neoadjuvant) + Placebo (adjuvant)		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 (%)*	Hazard ratio [95% CI] p value[b]
Overall survival					
	138	n.r. [41.4; n.c.] 52 (37.7)[c]	151	47.5 [36.9; 53.7] 61 (40.4)[c]	0.91 [0.63; 1.32] 0.618

Morbidity

Endpoint	Pembrolizumab + platinum-based chemotherapy[a] (neoadjuvant) + Pembrolizumab (adjuvant)		Platinum-based chemotherapy[a] (neoadjuvant) + Placebo (adjuvant)		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 (%)*	Hazard ratio [95% CI] p value[b]
Failure of the curative approach (event-free survival, EFS)[d]					
	138	13.1 [8.3; 26.3] 85 (61.6)	151	12.8 [9.4; 17.9] 107 (70.9)	0.81 [0.61; 1.08] 0.150 RR [95% CI] p value 0.87 [0.74; 1.03] 0.100
Death	138	– 18 (13.0)	151	– 13 (8.6)	–[e]

Local progression that prevents the planned surgery	138	– 0 (0)	151	– 1 (0.7)	–[e]
No R0 surgery	138	– 7 (5.1)	151	– 16 (10.6)	–[e]
No surgery[f]	138	– 17 (12.3)	151	– 12 (7.9)	–[e]
Disease progression according to RECIST 1.1	138	– 6 (4.3)	151	– 6 (4.0)	–[e]
Recurrence	138	– 35 (25.4)	151	– 49 (32.5)	–[e]
Unresectable	138	– 2 (1.4)	151	– 10 (6.6)	–[e]
Symptomatology (EORTC QLQ-C30)					
No suitable data available.					
Symptomatology (EORTC QLQ-LC13)					
No suitable data available.					
Health status (EQ-5D VAS)					
No suitable data available.					

Health-related quality of life

Endpoint	**Pembrolizumab + platinum-based chemotherapy[a] (neoadjuvant) + Pembrolizumab (adjuvant)**		**Platinum-based chemotherapy[a] (neoadjuvant) + Placebo (adjuvant)**		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 (%)*	Hazard ratio [95% CI] p value[b]
EORTC QLQ-C30					
No suitable data available.					

Side effects

Endpoint	Pembrolizumab + platinum-based chemotherapy[a] (neoadjuvant) + Pembrolizumab (adjuvant)		Platinum-based chemotherapy[a] (neoadjuvant) + Placebo (adjuvant)		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	Relative risk [95% CI][g] p value[h]
Total adverse events (presented additionally)					
	138	137 (99.3)	151	148 (98.0)	–
Serious adverse events (SAE)					
	138	58 (42.0)	151	48 (31.8)	1.32 [0.97; 1.79] 0.074
Severe adverse events (CTCAE grade ≥ 3)					
	138	89 (64.5)	151	87 (57.6)	1.12 [0.93; 1.35] 0.256
Therapy discontinuation due to adverse events					
	138	37 (26.8)	151	26 (17.2)	1.56 [0.998; 2.43] 0.0505
Specific adverse events					
Immune-mediated SAEs (PT collection)[i]					
	138	9 (6.5)	151	2 (1.3)	4.92 [1.08; 22.39] 0.022
Immune-mediated severe AEs (PT collection; CTCAE grade ≥ 3)[i]					
	138	8 (5.8)	151	3 (2.0)	2.92 [0.79; 10.78] 0.096
Oedema, peripheral (PT; AE)					
	138	19 (13.8)	151	7 (4.6)	2.97 [1.29; 6.85] 0.007
General disorders and administration site conditions (SOC, SAE)					
	138	11 (8.0)	151	2 (1.3)	6.02 [1.36; 26.67] 0.007

a. Cisplatin + gemcitabine (for squamous histology) or cisplatin + pemetrexed (for non-squamous histology)
b. Effect, CI and p value: Cox proportional hazards model; it is unclear whether stratification was also used here as described in Module 4 of the pharmaceutical company (stratification factors: tumour stage [II vs III], PD-L1 status [TPS < 50% vs TPS ≥ 50%], histology [squamous vs non-squamous] and region [East Asia vs non-East Asia], with pre-specified summary [depending on endpoint, see Module 4 of the pharmaceutical company] of manifestations due to a small number of events); p value: Wald test
c. This includes 1 patient in each one of the two arms who had withdrawn consent before death; it is unclear why these two patients were included in the evaluation.
d. Operationalised via event-free survival. Includes the events: radiological disease progression according to RECIST 1.1 that prevents planned surgery; local progression (primary tumour or regional lymph nodes) that prevents planned surgery; no surgery (for patients who moved to the adjuvant phase without surgery); unresectable tumour; not disease-free after surgery (patients with R1 or R2 resection); local recurrence or distant recurrence (for patients who are disease-free after surgery [R0 resection]); death from any cause.
e. The effect estimations for the individual components are not shown since only the qualifying events for the EFS are specified for the individual components.
f. Reasons for not having a surgery are: Physician's decision, adverse event, withdrawal of consent or refusal by the patient, disease progression according to RECIST 1.1, clinical progression and new cancer therapy not included in the study
g. Calculation of RR and CI (asymptotic) by IQWiG
h. IQWiG calculation (unconditional exact test, CSZ method[2])
i. Illustrated in Module 4 A using a list of predefined PTs. The same definition is assumed for the subsequently submitted documents.

Abbreviations used:
CTCAE = Common Terminology Criteria for Adverse Events; EFS = event-free survival; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30; EORTC QLQ-LC13 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Lung Cancer 13; EQ-5D = European Quality of Life-5 Dimensions; HR = hazard ratio; CI = confidence interval; N = number of evaluated patients; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PD-L1 = Programmed Death-Ligand-1; PT = preferred term; RECIST = Response Evaluation Criteria In Solid Tumours; RR = relative risk; SOC = system organ class; SAE = serious adverse event; TPS = Tumour Proportion Score; AE = adverse event; VAS = visual analogue scale

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

a) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression ≥ 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

Approx. 3,240 to 3,680 patients

b) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression < 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

Approx. 1,850 to 2,100 patients

[2] Martín Andrés A, Silva Mato A. Choosing the optimal unconditioned test for comparing two independent proportions. Computat Stat Data Anal 1994; 17(5): 555-574. https://doi.org/10.1016/0167-9473(94)90148-1.

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 Keytruda (active ingredient: pembrolizumab) at the following publicly accessible link (last access: 8 October 2024):

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

Treatment with pembrolizumab 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 carcinoma, as well as specialists in internal medicine and pulmonology or specialists in pulmonary medicine and other doctors from specialist groups participating in the Oncology Agreement.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients. The training material contains, in particular, instructions on the management of immune-mediated side effects potentially occurring with pembrolizumab as well as on infusion-related reactions.

4. Treatment costs

Annual treatment costs:

a) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression ≥ 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed: Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab (monotherapy) (adjuvant treatment)	
Neoadjuvant treatment:	
Pembrolizumab + platinum-based chemotherapy	
Pembrolizumab + cisplatin + gemcitabine	
Pembrolizumab	€ 20,701.60
Cisplatin	€ 456.12
Gemcitabine	€ 1,435.68
Total	€ 22,593.40
Additionally required SHI services	€ 129.45 - € 134.57
Pembrolizumab + cisplatin + pemetrexed	
Pembrolizumab	€ 20,701.60
Cisplatin	€ 456.12

Designation of the therapy	Annual treatment costs/ patient
Pemetrexed	€ 4,313.76
Total	€ 25,471.48
Additionally required SHI services	€ 188.98 - € 208.56
Adjuvant treatment:	
Pembrolizumab (monotherapy)	
Pembrolizumab	€ 67,280.20 - € 72,455.60
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Patient population a)	
Neoadjuvant treatment:	
Nivolumab + platinum-based chemotherapy	
Nivolumab + carboplatin + paclitaxel	
Nivolumab	€ 13,139.19
Carboplatin	€ 1,088.28 - € 1,295.70
Paclitaxel	€ 2,867.07 - € 3,210.09
Total	€ 17,094.54 - € 17,644.98
Additionally required SHI services	€ 81.22
Nivolumab + cisplatin + pemetrexed	
Nivolumab	€ 13,139.19
Cisplatin	€ 342.09
Pemetrexed	€ 3,235.32
Total	€ 16,716.60
Additionally required SHI services	€ 155.02 - € 184.41
Nivolumab + cisplatin + gemcitabine	
Nivolumab	€ 13,139.19
Cisplatin	€ 342.09
Gemcitabine	€ 1,076.76 - € 1,389.00
Total	€ 14,558.04 - € 14,870.28
Additionally required SHI services	€ 114.52 - € 129.45
Adjuvant treatment:	
best supportive care	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2024)

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: Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab (monotherapy) (adjuvant treatment)					
Neoadjuvant treatment:					
Pembrolizumab + platinum-based chemotherapy					
Pembrolizumab + cisplatin + gemcitabine					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2 - 4	€ 200 - € 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	8	€ 800
Pembrolizumab + cisplatin + pemetrexed					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2 - 4	€ 200 - € 400
Cisplatin	Surcharge for production of a parenteral preparation	€ 100	1	4	€ 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Adjuvant treatment:					
Pembrolizumab (monotherapy)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	7 - 13	€ 700 - € 1,300
Appropriate comparator therapy:					
Patient population a)					
Neoadjuvant treatment:					
Nivolumab + platinum-based chemotherapy					
Nivolumab + paclitaxel + carboplatin					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	3	€ 300
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Paclitaxel	Surcharge for production of a	€ 100	1	3	€ 300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral preparation containing cytostatic agents				
Nivolumab + cisplatin + pemetrexed					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	3	€ 300
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Nivolumab + cisplatin + gemcitabine					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	3	€ 300
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Gemcitabine	Surcharge for production of a parenteral preparation	€ 100	2	6	€ 600

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				

b) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression < 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed: Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab (monotherapy) (adjuvant treatment)	
Neoadjuvant treatment:	
Pembrolizumab + platinum-based chemotherapy	
Pembrolizumab + cisplatin + gemcitabine	
Pembrolizumab	€ 20,701.60
Cisplatin	€ 456.12
Gemcitabine	€ 1,435.68
Total	€ 22,593.40
Pembrolizumab + cisplatin + pemetrexed	
Pembrolizumab	€ 20,701.60
Cisplatin	€ 456.12
Pemetrexed	€ 4,313.76
Total	€ 25,471.48
Adjuvant treatment:	
Pembrolizumab (monotherapy)	
Pembrolizumab	€ 67,280.20 - € 72,455.60
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Patient population b)	
Neoadjuvant treatment:	
Patient-individual therapy with selection of preoperative (neoadjuvant) systemic chemotherapy with selection of	
Cisplatin + vinorelbine	
Cisplatin	€ 390.84
Vinorelbine	€ 1,077.12
Total	€ 1,467.96

Designation of the therapy	Annual treatment costs/ patient
Cisplatin + paclitaxel	
Cisplatin	€ 210.82
Paclitaxel	€ 1,911.38
Total	€ 2,122.20
Cisplatin + gemcitabine	
Cisplatin	€ 342.09 - € 390.84
Gemcitabine	€ 1,389.00
Total	€ 1,731.09 - € 1,779.84
Cisplatin + docetaxel	
Cisplatin	€ 390.84
Docetaxel	€ 1,469.52
Total	€ 1,860.36
Cisplatin + pemetrexed	
Cisplatin	€ 342.09
Pemetrexed	€ 3,235.32
Total	€ 3,577.41
Carboplatin + vinorelbine	
Carboplatin	Not calculable
Vinorelbine	Not calculable
Total	Not calculable
Carboplatin + paclitaxel	
Carboplatin	€ 1,088.28
Paclitaxel	€ 2,867.07
Total	€ 3,955.35
Carboplatin + gemcitabine	
Carboplatin	€ 1,182.93
Gemcitabine	€ 1,076.76
Total	€ 2,259.69
Carboplatin + docetaxel	
Carboplatin	€ 1,295.70
Docetaxel	€ 1,469.52
Total	€ 2,765.22
Carboplatin + pemetrexed	
Carboplatin	€ 1,727.60
Pemetrexed	€ 4,313.76

Designation of the therapy	Annual treatment costs/ patient
Total	€ 6,041.36
Simultaneous radiochemotherapy	
Radiotherapy	€ 3,430.39 - € 4,003.24
Chemotherapy	Not calculable
Total	Not calculable
Adjuvant treatment:	
best supportive care	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2024)

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: Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab (monotherapy) (adjuvant treatment)					
Neoadjuvant treatment:					
Pembrolizumab + platinum-based chemotherapy					
Pembrolizumab + cisplatin + gemcitabine					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2 - 4	€ 200 - € 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation	€ 100	1	8	€ 800

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Pembrolizumab + cisplatin + pemetrexed					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2 - 4	€ 200 - € 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Adjuvant treatment:					
Pembrolizumab (monotherapy)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	7 - 13	€ 700 - € 1,300
Appropriate comparator therapy:					
Patient population b)					
Patient-individual therapy with selection of preoperative (neoadjuvant) systemic chemotherapy with selection of					
Cisplatin + vinorelbine					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	6	€ 600
Cisplatin + paclitaxel					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2	€ 200
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	2	€ 200
Cisplatin + gemcitabine					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	6	€ 600
Cisplatin + docetaxel					
Cisplatin	Surcharge for production of a	€ 100	1	3	€ 300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral preparation containing cytostatic agents				
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Cisplatin + pemetrexed					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Carboplatin + paclitaxel					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Carboplatin + gemcitabine					
Carboplatin	Surcharge for production of a parenteral preparation	€ 100	1	3	€ 300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	6	€ 600
Carboplatin + docetaxel					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Carboplatin + pemetrexed					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400

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 resectable non-small cell lung carcinoma with tumour cell PD-L1 expression ≥ 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with resectable non-small cell lung carcinoma with tumour cell PD-L1 expression < 1% at high risk of recurrence; neoadjuvant and adjuvant treatment

- No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 17 October 2024.

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

Berlin, 17 October 2024

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

Prof. Hecken