Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive (AM-RL):

Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Ipilimumab (New Therapeutic Indication: Non-small cell lung cancer (NSCLC), combination with nivolumab and platinum-based chemotherapy, first-line treatment)

of 3 June 2021

At its session on 3 June 2021, 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 on DD. Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of ipilimumab in accordance with the resolution of 15 August 2019:

Ipilimumab

Resolution of: 3 June 2021
Entry into force on: 3 June 2021
BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 5 November 2020):

Yervoy in combination with nivolumab and 2 cycles of platinum-based chemotherapy is indicated for the first-line treatment of metastatic non-small cell lung cancer in adults whose tumours do not have a sensitising EGFR mutation or ALK translocation.

Therapeutic indication of the resolution (resolution of 3 June 2021):

see new therapeutic indication according to marketing authorisation.

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

a) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of ≥ 50% (PD-L1 expression) and without EGFR-mutations or ALK translocations; first-line treatment

Appropriate comparator therapy:

- Pembrolizumab as monotherapy

Extent and likelihood of additional benefit of ipilimumab in combination with nivolumab and platinum-based chemotherapy compared with the appropriate comparator therapy:

An additional benefit is not proven.

b) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of <50% (PD-L1 expression) and without EGFR mutations or ALK translocations; first-line treatment

Appropriate comparator therapy:

- Cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed (except in the case of predominantly squamous histology))

or

- Carboplatin in combination with a third-generation cytostatic drug (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed (except in the case of predominantly squamous histology)) cf. Annex VI to Section K of the Pharmaceutical Directive

or

- Carboplatin in combination with nab-paclitaxel

or

- Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients with non-squamous histology)

or

- Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (only for patients with squamous histology)

Magnitude and likelihood of additional benefit of ipilimumab in combination with nivolumab and platinum-based chemotherapy versus platinum-based chemotherapy:

Hint for a minor additional benefit.

Study outcomes by endpoints:[1]

a) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of ≥ 50% (PD-L1 expression) and without EGFR-mutations or ALK translocations; first-line treatment

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

Summary of results of relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

[1] Data from the dossier assessment of the IQWiG (A20-116) and from the addendum (A21-56), unless otherwise indicated.

b) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of <50% (PD-L1 expression) and without EGFR mutations or ALK translocations; first-line treatment

Summary of results of relevant clinical endpoints

Endpoint category	Effect direction/ Risk of bias	Summary
Mortality	↑↑	Advantage in the endpoint overall survival
Morbidity	↑	Advantage in the endpoint health status
Health-related quality of life	∅	No data available.
Side effects	↓↓	Disadvantages in the endpoints SAE, severe AEs (CTCAE grade ≥3), discontinuation of therapy due to AEs, in detail in the endpoints immune-mediated AEs as well as further 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 a high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: There are no usable data for the benefit assessment.
n.a.: not assessable

CA209-9LA study: Ipilimumab + nivolumab + platinum-based chemotherapy[2] vs. platinum-based chemotherapy[2]

Study design: randomised, controlled, open-label

Data cut-off: 2. Data cut-off of 9/3/2020

[2] Platinum-based chemotherapy: Cisplatin or carboplatin in combination with permetrexed or carboplatin in combination with paclitaxel.

Mortality

Endpoint	Ipilimumab + nivolumab + platinum-based chemotherapy[a]		platinum-based chemotherapy[a]		Ipilimumab + nivolumab + platinum-based chemotherapy[a] vs platinum-based chemotherapy[a]
	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)[b]
Overall survival					
	262	16.16 [13.77; 20.53] 137 (52.3)	235	10.25 [8.67; 12.22] 167 (71.1)	0.61 [0.49; 0.77]; <0.001[c] AD= 5.9 months
Effect modification by the "brain metastases at the start of the study" feature					
yes	45	n. a. [12.39; n. c.] 20 (44.4)	35	7.82 [5.26; 10.74] 29 (82.9)	0.35 [0.19; 0.61] <0.001[c] AD: n.c.
no	217	15.44 [13.67; 20.53] 117 (53.9)	200	10.73 [8.97; 13.08] 138 (69.0)	0.68 [0.53; 0.87] 0.002 AD: n.c.
					Interaction[d]: 0.009

Morbidity

Endpoint	Ipilimumab + nivolumab + platinum-based chemotherapy[a]		platinum-based chemotherapy[a]		Ipilimumab + nivolumab + platinum-based chemotherapy[a] vs platinum-based chemotherapy[a]
	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)[b]
Symptomatology (LCSS ASBI)[e]					
	262	n.a. 43 (16.4)	235	n. a. [16.33; n. c.] 29 (12.3)	0.78 [0.47; 1.29] 0.330[f]
Health status (EQ-5D VAS)[g]					
15 points	262	22.21 [20.14; n. a.]	235	17.81 [16.53; n. a.]	0.75 [0.52; 1.09]

Endpoint	Ipilimumab + nivolumab + platinum-based chemotherapy[a]		platinum-based chemotherapy[a]		Ipilimumab + nivolumab + platinum-based chemotherapy[a] vs platinum-based chemotherapy[a]
	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)[b]
		65 (24.8)		57 (24.3)	0.127[f]
10 points	262	17.51 [14.13; 19.48] 95 (36.3)	235	11.83 [9.26; n. a.] 82 (34.9)	0.70 [0.52; 0.95]; 0.023[f] AD= 5.7 months
7 points	262	15.87 [13.21; 19.29] 103 (39.3)	235	10.45 [9.03; 15.38] 89 (37.9)	0.68 [0.51; 0.91] 0.010[f] AD= 5.4 months
Progression-free survival[h]					
	262	6.74 [5.52; 7.26] 201 (76.7)	235	4.80 [4.27; 5.55] 209 (88.9)	0.65 [0.53; 0.79] < 0.001 AD= 1.9 months

Health-related quality of life

Endpoint	Ipilimumab + nivolumab + platinum-based chemotherapy[a]		platinum-based chemotherapy[a]		Ipilimumab + nivolumab + platinum-based chemotherapy[a] vs platinum-based chemotherapy[a]
	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)[b]
No usable data available.					

Side effects

Endpoint	Ipilimumab + nivolumab + platinum-based chemotherapy[a]		platinum-based chemotherapy[a]		Ipilimumab + nivolumab + platinum-based chemotherapy[a] vs platinum-based chemotherapy[a]
	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)[b]
Adverse events (presented additionally)					
	260	0.13 [0.13; 0.23] 259 (99.6)	227	0.20 [0.13; 0.30]; 222 (97.8)	-
Serious adverse events (SAE)[i]					
	260	5.09 [3.55; 7.26] 169 (65.0)	227	11.17 [6.80; n. a.] 98 (43.2)	1.52 [1.18; 1.95] 0.001[c] AD= 6.1 months
Severe adverse events (CTCAE grade 3 or 4)[i, j]					
	260	2.83 [1.94; 3.45] 201 (77.3)	227	3.71 [2.76; 5.59] 87 (38.3)	1.27 [1.02; 1.58] 0.031[c] AD= 0.9 months
Therapy discontinuation because of adverse events [i, k]					
	260	n.a. 82 (31.5)	227	n.a. 32 (14.1)	1.98 [1.31; 2.99]; <0.001[c] AD: n.c.
Specific adverse events					
Immune-mediated AE (presented additionally)					
	260	1.64 [1.02; 2.17]; 202 (77.7)	227	8.34 [5.26; 11.10]; 108 (47.6)	-
Immune-mediated SAEs					
	260	n.a. 57 (21.9)	227	n.a. 14 (6.2)	3.27 [1.82; 5.88]; <0.001[c] AD: n.c.

Immune-mediated severe AEs[j]					
	260	n.a. 75 (28.8)	227	n.a. 21 (9.3)	2.94 [1.81; 4.79]; <0.001[c] AD: n.c.
other specific adverse events					
Anaemia (PT, severe AE[j])	260	n.a. 22 (8.5)	227	n.a. 39 (17.2)	0.46 [0.27; 0.78] 0.003[c] AD: n.c.
Lipase elevated (PT, severe AE[j])	260	n.a. 21 (8.1)	227	n.a. 3 (1.3)	4.75 [1.40; 16.05] 0.006[c] AD: n.c.
Amylase elevated (PT, severe AE[j])	260	n.a. 10 (3.8)	227	n.a. 0 (0)	n. c.[l]; 0.006[c] AD: n.c.
Hepatobiliary disorders (SOC, severe AE[j]	260	n.a. 18 (6.9)	227	n.a. 0 (0)	n. c.[l]; <0.001[c] AD: n.c.
Skin and subcutaneous tissue disorders (SOC, severe AE[j])	260	n.a. 17 (6.5)	227	n.a. 3 (1.3)	4.80 [1.40; 16.40] 0.006[c] AD: n.c.
Endocrine disorders (SOC, severe AE[j])	260	n.a. 11 (4.2)	227	n.a.	n. c.[l]; 0.006[c] AD: n.c.

[a] cisplatin or carboplatin in combination with pemetrexed and carboplatin in combination with paclitaxel
[b] Data on absolute difference (AD) only in the case of statistically significant difference; own calculation
[c] effect and CI: presumably unstratified Cox-Proportional-Hazards-Model log-log transformation (according to Brookmeyer and Crowley); p-value: presumably unstratified log-rank test
[d] Interaction: from unstratified Cox proportional hazards model with treatment group, subgroup, and treatment group*subgroup interaction terms
[e] Time to permanent deterioration; defined as an increase in score of ≥ 15 points with no improvement below the response threshold in any of the following surveys
[f] effect and CI: presumably unstratified Cox-Proportional-Hazards-Model log-log transformation (according to Brookmeyer and Crowley) with values at baseline as covariates; p-value: presumably unstratified log-rank test
[g] Time to permanent deterioration; defined as a decrease in score of ≥ 15, 10, or 7 points with no improvement below the response threshold on any of the following surveys
[h] Data from: Dossier on Nivolumab Module 4A dated 2.12.2020
[i] without detection of progression of the underlying disease
operationalised as CTCAE grade ≥ 3
[k] operationalised as discontinuation of at least 1 combination of active ingredients
[l] Because no deaths occurred in one study arm, HR cannot be meaningfully estimated.
Abbreviations used:
AD = absolute difference; ASBI = Average Symptom Burden Index; CTCAE = Common Terminology Criteria for Adverse Events; EQ-5D = European Quality of Life Questionnaire - 5 Dimensions; HR = hazard ratio; CI = confidence interval; LCSS = Lung Cancer Symptom Scale; N = number of patients evaluated; n = number of patients with (at least one) event; n. b. = not calculable; n. e. = not achieved; PT = preferred term; SOC = system organ class; SAE = serious adverse event; AE = adverse event; VAS = visual analogue scale; vs = versus.

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

a) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of ≥ 50% (PD-L1 expression) and without EGFR-mutations or ALK translocations; first-line treatment

approx. 3,710 to 4,680 patients

b) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of <50% (PD-L1 expression) and without EGFR mutations or ALK translocations; first-line treatment

approx. 10,630 to 11,500 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 Opdivo (active ingredient: ipilimumab) at the following publicly accessible link (last access: 28 April 2021):

https://www.ema.europa.eu/documents/all-authorised-presentations/yervoy-epar-all-authorised-presentations_de.pdf

Treatment with ipilimumab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology and specialists in internal medicine and pneumology or specialists participating in the Oncology Agreement who are experienced in the treatment of adult patients with non-small cell lung cancer.

According to the requirements for risk minimisation activities in the EPAR (European Public Assessment Report), the pharmaceutical company must provide a patient card.

Data from elderly patients (≥ 75 years) from the CA209-9LA study are limited. In these patients, ipilimumab in combination with nivolumab and chemotherapy should be used with caution after careful consideration of the potential benefit/risk in each individual case.

4. Treatment costs

Annual treatment costs:

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

a) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of ≥ 50% (PD-L1 expression) and without EGFR-mutations or ALK translocations; first-line treatment

Name of therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Ipilimumab	€ 63,175.22
+ nivolumab	€ 84,077.15
Total:	€ 147,252.37
+2 cycles of platinum-based chemotherapy consisting of cisplatin or carboplatin in combination with a third-generation cytostatic agent	
Cisplatin + pemetrexed	
Cisplatin	€ 230.74
Pemetrexed	€ 8,608.48
Total:	€ 8,839.22
Ipilimumab + nivolumab + cisplatin + pemetrexed	€ 156,091.59
Additionally required SHI costs	€150.79 - €169.61
Carboplatin + pemetrexed	
Carboplatin	€ 943.60
Pemetrexed	€ 8,608.48
Total:	€ 9,552.08
Ipilimumab + nivolumab + carboplatin + pemetrexed	€ 156,804.45
Additionally required SHI costs	€ 38.62 - € 45.93
Carboplatin + Paclitaxel	
Carboplatin	€ 943.60
Paclitaxel	€ 2008.48
Total:	€ 2,952.08
Ipilimumab + nivolumab + carboplatin + paclitaxel	€ 150,204.45
Additionally required SHI costs	€ 65.08
Appropriate comparator therapy:	
Pembrolizumab monotherapy	
Pembrolizumab	€ 99,706.18

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 May 2021).

Other SHI benefits:

Name of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ Patient/ Year	Costs/ Patient/ Year
Medicinal product to be assessed:					
Ipilimumab	Preparation for parenteral solutions with monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Nivolumab	Preparation for parenteral solutions with monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	2	€ 162.00
Cisplatin	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	2	€ 162.00
Paclitaxel	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	2	€ 162.00
Pemetrexed	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	2	€ 162.00

Appropriate comparator therapy:					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40

b) Adult patients with metastatic non-small cell lung cancer (NSCLC) with a tumour proportion score [TPS] of <50% (PD-L1 expression) and without EGFR mutations or ALK translocations; first-line treatment

Name of therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Ipilimumab	€ 63,175.22
+ nivolumab	€ 84,077.15
Total:	€ 147,252.37
+2 cycles of platinum-based chemotherapy consisting of cisplatin or carboplatin in combination with a third-generation cytostatic agent	
Cisplatin + pemetrexed	
Cisplatin	€ 230.74
Pemetrexed	€ 8,608.48
Total:	€ 8,839.22
Ipilimumab + nivolumab + cisplatin + pemetrexed	€ 156,091.59
Additionally required SHI costs	€ 150.79 - € 169.61
Carboplatin + pemetrexed	
Carboplatin	€ 943.60
Pemetrexed	€ 8,608.48
Total:	€ 9,552.08
Ipilimumab + nivolumab + carboplatin + pemetrexed	€ 156,804.45
Additionally required SHI costs	€ 38.62 - € 45.93
Carboplatin + Paclitaxel	
Carboplatin	€ 943.60
Paclitaxel	€ 2008.48
Total:	€ 2,952.08
Ipilimumab + nivolumab + carboplatin + paclitaxel	€ 150,204.45

Name of therapy	Annual treatment costs/patient
Additionally required SHI costs	€ 65.08
Appropriate comparator therapy:	
Cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed (except in the case of predominantly squamous histology))	
Cisplatin + docetaxel	
Cisplatin	€ 2,007.44
Docetaxel	€ 21,230.61
Total:	€ 23,238.05
Additionally required SHI costs	€ 328.58 - € 421.62
Cisplatin + gemcitabine	
Cisplatin	€2,007.44- €2486.11
Gemcitabine	€ 8,193.66
Total:	€ 10,201.10- € 10,679.77
Additionally required SHI costs	€328.58 - €421.62
Cisplatin + Paclitaxel	
Cisplatin	€ 2,271.74
Paclitaxel	€ 17,473.78
Total:	€ 19,745.52
Additionally required SHI costs	€ 582.64 - € 675.68
Cisplatin + pemetrexed	
Cisplatin	€ 2,007.44
Pemetrexed	€ 74,893.78
Total:	€ 76,901.22
Additionally required SHI costs	€ 455.26 - € 595.83
Cisplatin + Vinorelbine	
Cisplatin	€ 2,007.44- € 2486.11
Vinorelbine	€ 4,742.20 - € 5,987.34
Total:	€ 6,749.64- € 8,473.45
Additionally required SHI costs	€ 328.58 - € 421.62
Carboplatin in combination with a third-generation cytostatic drug (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed (except in the case of predominantly squamous histology)) cf. Annex VI to Section K of the Pharmaceutical Directive	
Carboplatin + Docetaxel	
Carboplatin	€ 8,209.32

Name of therapy	Annual treatment costs/patient
Docetaxel	€ 21,230.61
Total:	€29,439.93
Carboplatin + gemcitabine	
Carboplatin	€ 8,209.32
Gemcitabine	€ 8,193.66
Total:	€ 16,402.98
Carboplatin + Paclitaxel	
Carboplatin	€ 8,209.32
Paclitaxel	€ 17,473.78
Total:	€ 25,683.10
Additionally required SHI costs	€ 254.06
Carboplatin + pemetrexed	
Carboplatin	€ 8,209.32
Pemetrexed	€ 74,893.78
Total:	€ 83,103.10
Additionally required SHI costs	€ 126.68 - € 174.21
Carboplatin + Vinorelbine	
Carboplatin	€ 8,209.32
Vinorelbine	€ 4,742.20 - € 5,987.34
Total:	€ 12,951.52 - € 14,196.66
Carboplatin in combination with nab-paclitaxel	
Carboplatin	€ 8,209.32
nab-paclitaxel	€ 39,088.40
Total	€ 47,297.72
Additionally required SHI costs	
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients with non-squamous histology)	
Pembrolizumab + pemetrexed + cisplatin	
Pembrolizumab	€ 99,706.18
Pemetrexed	€ 74,893.78
Cisplatin	€ 2,007.44
Total:	€ 176,607.40
Additionally required SHI costs	€ 455.26 - € 595.83
Pembrolizumab + pemetrexed + carboplatin	

Name of therapy	Annual treatment costs/patient
Pembrolizumab	€ 99,706.18
Pemetrexed	€ 74,893.78
Carboplatin	€ 8,209.32
Total:	€ 182,809.28
Additionally required SHI costs	€ 126.68 - € 174.21
Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (only for patients with squamous histology)	
Pembrolizumab + carboplatin + paclitaxel	
Pembrolizumab	€ 99,706.18
Carboplatin	€ 8,209.32
Paclitaxel	€ 17,473.78
Total:	€ 125,389.28
Additionally required SHI costs	€ 254.06
Pembrolizumab + carboplatin + nab-paclitaxel	
Pembrolizumab	€ 99,706.18
Carboplatin	€ 8,209.32
nab-paclitaxel	€ 39,088.40
Total:	€ 147,003.90

Costs after deduction of legally prescribed rebates (status Lauer-Taxe: 15 May 2021).

Other SHI benefits:

Name of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ Patient/ Year	Costs/ Patient/ Year
Medicinal product to be assessed:					
Ipilimumab	Preparation for parenteral solutions with monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Nivolumab	Preparation for parenteral solutions with monoclonal antibodies	€ 71	1	17.4	€ 1,235.40

Name of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ Patient/ Year	Costs/ Patient/ Year
Carboplatin	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	2	€ 162.00
Cisplatin	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	2	€ 162.00
Paclitaxel	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	2	€ 162.00
Pemetrexed	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	2	€ 162.00
Appropriate comparator therapy:					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Carboplatin	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	17.4	€ 1,409.40

Name of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ Patient/ Year	Costs/ Patient/ Year
Cisplatin	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	17.4	€ 1,409.40
Vinorelbine	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	2	34.8	€ 2,818.80
Gemcitabine	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	2	34.8	€ 2,818.80
Docetaxel	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	17.4	€ 1,409.40
Paclitaxel	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	17.4	€ 1,409.40
Pemetrexed	Surcharge for the preparation of a parenteral preparation containing cytostatics	€ 81	1	17.4	€ 1,409.40
nab-paclitaxel	Surcharge for the preparation of a parenteral preparation	€ 81	1	52.2	€ 4,228.20

Name of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ Patient/ Year	Costs/ Patient/ Year
	containing cytostatics				

II. The resolution will enter into force on the day of its publication on the internet on the G-BA website on 3 June 2021.

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

Berlin, 3 June 2021

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

Prof. Hecken