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: breast cancer, triple-negative, PD-L1 expression ≥ 10 (CPS), combination with chemotherapy)

of 5 May 2022

At its session on 5 May 2022, 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. 4 to the information on the benefit assessment of Pembrolizumab in accordance with the resolution of 5 May 2022 for the therapeutic indication "...indicated in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of locally advanced unresectable or metastatic carcinoma of the oesophagus or HER2-negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 (CPS ≥ 10)":

Pembrolizumab

Resolution of: 5 May 2022
Entry into force on: 5 May 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 October 2021):

Keytruda, in combination with chemotherapy, is indicated for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer in adults whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease.

Therapeutic indication of the resolution (resolution of 5 May 2022):

see the approved therapeutic indication

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

Adults with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease

Appropriate comparator therapy:

- Systemic therapy containing anthracyclines and/or taxanes, taking into account the marketing authorisation of the medicinal products

a) Extent and probability of the additional benefit of Pembrolizumab in combination with nab-paclitaxel or paclitaxel compared with nab-paclitaxel or paclitaxel:

Hint for a considerable additional benefit

b) Extent and probability of the additional benefit of Pembrolizumab in combination with chemotherapy other than nab-paclitaxel or paclitaxel compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease

a) Pembrolizumab in combination with nab-paclitaxel or paclitaxel

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑	Advantage in overall survival
Morbidity	↔	No relevant differences for the benefit assessment
Health-related quality of life	↔	No relevant differences for the benefit assessment.
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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

KEYNOTE 355:

- RCT, double-blind, phase III, data cut-off of 15.06.2021
- Pembrolizumab + chemotherapy (paclitaxel or nab-paclitaxel or gemcitabine/ carboplatin) vs placebo + chemotherapy (paclitaxel or nab-paclitaxel or gemcitabine/ carboplatin)

Sub-population whose tumour expresses PL1 (CPS ≥ 10) and allocation to taxane chemotherapy prior to randomisation

[1] Data from the dossier assessment of the IQWiG (A21-145) and from the addendum (A22-36), unless otherwise indicated.

Mortality

Endpoint	Pembrolizumab + paclitaxel or nab-paclitaxel [a]		Placebo + Paclitaxel or nab-paclitaxel [a]		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 Absolute difference (AD)[b]
Overall survival					
	96	29.7 [22.8; 38.3] *61 (63.5)*	47	16.1 [10.5; 20.8] *39 (83.0)*	0.56 [0.37; 0.84] 0.005 AD = +13.6 months

Morbidity

Endpoint	Pembrolizumab + paclitaxel or nab-paclitaxel [a]		Placebo + Paclitaxel or nab-paclitaxel [a]		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 Absolute difference (AD)[b]
Progression-free survival (PFS)[c]					
	96	9.9 [7.6; 19.7] *54 (56.3)*	47	5.4 [3.5; 7.4] *37 (78.7)*	0.48 [0.31; 0.75] 0.001 AD = + 4.5 months
Symptomatology (EORTC QLQ-C30), time to first deterioration[d]					
Exhaustion	94	1.4 [1.0; 2.6] *75 (79.8)*	45	2.1 [1.4; 4.9] *31 (68.9)*	1.14 [0.75; 1.73] 0.552
Nausea and vomiting	94	3.5 [1.5; 7.6] *56 (59.6)*	45	5.3 [1.4; 11.8] *22 (48.9)*	1.12 [0.68; 1.84] 0.658
Pain	94	3.9 [3.0; 7.6] *57 (60.6)*	45	3.5 [1.4; 3.9] *32 (71.1)*	0.72 [0.46; 1.11] 0.136
Dyspnoea	94	7.4 [5.5; 18.7] *44 (46.8)*	45	17.7 [9.0; n.c.] *12 (26.7)*	1.57 [0.83; 2.98] 0.169

Endpoint	Pembrolizumab + paclitaxel or nab-paclitaxel [a]		Placebo + Paclitaxel or nab-paclitaxel [a]		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 Absolute difference (AD)[b]
Insomnia	94	8.3 [3.7; 22.1] *44 (46.8)*	45	18.4 [5.6; n.c.] *14 (31.1)*	1.49 [0.81; 2.72] 0.199
Appetite loss	94	5.2 [3.5; 9.7] *56 (59.6)*	45	3.9 [3.0; 11.8] *24 (53.3)*	1.02 [0.63; 1.65] 0.935
Constipation	94	8.0 [4.9; 11.9] *48 (51.1)*	45	7.7 [4.9; n.c.] *16 (35.6)*	1.33 [0.75; 2.36] 0.325
Diarrhoea	94	4.0 [3.5; 8.3] *55 (58.5)*	45	18.4 [5.6; n.c.] *14 (31.1)*	1.98 [1.10; 3.58] 0.023 AD = - 14.4 months
Symptomatology (EORTC QLQ-BR23), time to first deterioration[d]					
Side effects of systemic therapy	94	1.4 [0.8; 1.4] *75 (79.8)*	45	1.4 [0.8; 2.1] *34 (75.6)*	1.07 [0.71; 1.61] 0.753
Chest symptoms	94	n.a. [12.6; n.c.] *26 (27.7)*	45	7.7 [3.5; n.c.] *18 (40.0)*	0.49 [0.27; 0.91] 0.023
Arm symptoms	94	7.6 [5.5; 12.0] *50 (53.2)*	45	3.9 [1.5; 7.7] *26 (57.8)*	0.83 [0.51; 1.33] 0.432
Burden due to hair loss	94	0.8 [0.8; 1.4] *70 (74.5)*	45	0.8 [0.7; 2.1] *34 (75.6)*	1.05 [0.69; 1.58] 0.826

Endpoint	Pembrolizumab + paclitaxel or nab-paclitaxel [a]		Placebo + Paclitaxel or nab-paclitaxel [a]		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 Absolute difference (AD)[b]
Health status (EQ-5D VAS)[e]					
≥ 7 points	94	3.0 [1.4; 3.5] *66 (70.2)*	45	2.1 [0.9; 5.6] *27 (60.0)*	1.13 [0.71; 1.78] 0.604
≥ 10 points	94	3.5 [1.9; 5.6] *61 (64.9)*	45	2.1 [1.4; 5.6] *27 (60.0)*	0.99 [0.62; 1.56] 0.952

Health-related quality of life

Endpoint	Pembrolizumab + paclitaxel or nab-paclitaxel [a]		Placebo + Paclitaxel or nab-paclitaxel [a]		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 Absolute difference (AD)[b]
EORTC QLQ-C30, time to first deterioration[f]					
Global health status	94	5.8 [3.6; 9.9] *55 (58.5)*	45	5.6 [3.5; 14.5] *22 (48.9)*	0.99 [0.60; 1.63] 0.969
Physical functioning	94	6.4 [3.8; 7.7] *63 (67.0)*	45	5.6 [3.4; 14.5] *23 (51.1)*	1.12 [0.69; 1.82] 0.651
Role functioning	94	3.4 [1.4; 5.6] *62 (66.0)*	45	4.9 [1.4; 9.7] *26 (57.8)*	1.21 [0.76; 1.92] 0.418
Emotional functioning	94	9.7 [5.8; 12.0] *47 (50.0)*	45	9.7 [4.5; n.c.] *19 (42.2)*	1.20 [0.70; 2.06] 0.505

Endpoint	Pembrolizumab + paclitaxel or nab-paclitaxel [a]		Placebo + Paclitaxel or nab-paclitaxel [a]		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 Absolute difference (AD)[b]
Cognitive functioning	94	3.5 [2.6; 5.5] *66 (70.2)*	45	3.9 [1.4; 7.6] *27 (60.0)*	1.11 [0.71; 1.74] 0.646
Social functioning	94	3.5 [1.6; 3.8] *65 (69.1)*	45	3.5 [1.4; 11.8] *27 (60.0)*	1.03 [0.65; 1.61] 0.906
EORTC QLQ-BR23, time to first deterioration[f]					
Body image	94	5.6 [3.5; 8.9] *50 (53.2)*	45	3.5 [1.4; 5.6] *27 (60.0)*	0.71 [0.44; 1.14] 0.160
Sexual activity	94	n.a. [5.6; n.c.] *34 (36.2)*	45	22.7 [3.6; n.c.] *17 (37.8)*	0.80 [0.44; 1.44] 0.460
Sexual pleasure	No usable data available				
Future prospects	94	11.3 [6.3; n.c.] *38 (40.4)*	45	25.3 [4.9; n.c.] *17 (37.8)*	1.07 [0.60; 1.91] 0.815

Side effects

Endpoint	Pembrolizumab + paclitaxel or nab-paclitaxel [a]		Placebo + Paclitaxel or nab-paclitaxel [a]		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 Absolute difference (AD)[b]
Adverse events (presented additionally)[g]					
	95	0.3 [0.1; 0.3] *93 (97.9)*	47	0.3 [0.1; 0.4] *45 (95.7)*	-
Serious adverse events (SAE)[g]					
	95	29.5 [20.5; n.c.] *28 (29.5)*	47	n.a. [19.3; n.c.] *7 (14.9)*	1.86 [0.81; 4.26] 0.144
Severe adverse events [g, h]					
	95	5.7 [4.2; 10.3] *61 (64.2)*	47	6.5 [2.8; n.c.] *23 (48.9)*	1.20 [0.74; 1.94] 0.459
Discontinuation due to AEs[i, j]					
	95	n.a. [23.5; n.c.] *24 (25.3)*	47	n.a. [19.9; n.c.] *4 (8.5)*	2.43 [0.84; 7.02] 0.101
Specific adverse events					
Immune-mediated SAEs [g]	95	n.a. 4 (4.2)	47	n.a. 0 (0.0)	n.c. 0.165
Immune-mediated severe AEs [g, h]	95	n.a. 8 (8.4)	47	n.a. 0 (0)	n.c. 0.067
Diarrhoea (PT, AEs)	95	13.3 [7.6; n.c.] *41 (43.2)*	47	21.2 [17.3; n.c.] *7 (14.9)*	2.81 [1.26; 6.28] 0.012 AD = -7.9 months
Dysgeusia (PT, AEs)	95	n.a. *12 (12.6)*	47	n.a. *0 (0.0)*	n.c. 0.017
Gastrointestinal disorders (SOC, SAEs)	95	n.a. *8 (8.4)*	47	n.a. *0 (0.0)*	n.c. 0.044

a. Evaluated sub-population
b. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation
c. Information from the dossier of the pharmaceutical company
d. Time to first deterioration an increase in score by ≥ 10 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0-100).
e. Time to first deterioration
f. Time to first deterioration A decrease in score by ≥ 10 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0-100).
g. Without recording of the progression of the underlying disease
h. Operationalised as CTCAE grade ≥ 3
i. Without recording of the progression of the underlying disease
j. Operationalised as discontinuation of at least 1 active ingredient component

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; EORTC QLQ-BR23 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Breast Cancer 23; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.a. = not achieved; PT = preferred term; SOC = system organ class; SAE = serious adverse event; AE: adverse event; VAS = visual analogue scale; vs = versus

b) Pembrolizumab in combination with chemotherapy other than nab-paclitaxel or paclitaxel

No 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	∅	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

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

Adults with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease

approx. 260 – 270 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 Keytruda (active ingredient: pembrolizumab) at the following publicly accessible link (last access: 17 March 2022):

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 as well as specialists in obstetrics and gynaecology and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of adults with breast cancer.

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:

Adults with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease

a) Pembrolizumab in combination with nab-paclitaxel or paclitaxel

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pembrolizumab in combination with nab-paclitaxel or paclitaxel	
1) Pembrolizumab + nab-paclitaxel	
Pembrolizumab	€ 99,714.53
nab-paclitaxel	€ 29,222.70
Total	€ 128,937.23
2) Pembrolizumab + paclitaxel	
Pembrolizumab	€ 99,714.53
Paclitaxel	€ 19,749.99
Total	€ 119,464.52
Additionally required SHI services	€ 256.88
Appropriate comparator therapy:	
Anthracycline and/or taxane-containing systemic therapy	€ 2,082.75 - € 62,071.00[2]

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2022)

Costs for additionally required SHI services:

Designation of the therapy	Annual treatment costs/ patient
Appropriate comparator therapy:	
Paclitaxel	€ 256.88

[2] The cost range results from the low-cost therapy of doxorubicin and the high-cost therapy of liposomal doxorubicin + cyclophosphamide.

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	8.7 - 17.4	€ 617.70 - € 1235.40
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	39	€ 3,159.00
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Doxorubicin (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	5 - 11	€ 405 - € 891
Doxorubicin (in combination with docetaxel or with paclitaxel)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	9 - 11	€ 729 - € 891

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Doxorubicin (in combination with cyclophosphamide)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	7 - 9	€ 567 - € 729
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Doxorubicin pegylated, liposomal	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	13	€ 1,053.00
Doxorubicin, liposomal	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Epirubicin (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	10 - 16	€ 810 - € 1,296.00
Epirubicin (in combination with cyclophosphamide)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	13 - 15	€ 1,053.00 - € 1,215.00
Epirubicin (in combination with paclitaxel)	Surcharge for production of a parenteral preparation	€ 81	1	15 - 16	€ 1,215.00 - € 1,296.00

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Epirubicin (in combination with docetaxel)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	12 - 13	€ 972 - € 1,053.00
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2818.80

b) Pembrolizumab in combination with chemotherapy other than nab-paclitaxel or paclitaxel

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pembrolizumab in combination with chemotherapy other than nab-paclitaxel or paclitaxel	
Pembrolizumab	€ 99,714.53
Chemotherapy other than nab-paclitaxel or paclitaxel[3]	Not determinable
Appropriate comparator therapy:	
Anthracycline and/or taxane-containing systemic therapy	€ 2,082.75 - € 62,071.00[4]

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2022)

Costs for additionally required SHI services:

Designation of the therapy	Annual treatment costs/ patient
Appropriate comparator therapy:	

[3] The marketing authorisation of pembrolizumab in combination with chemotherapy is not restrictive with regard to the chemotherapy component. Thus, a variety of different chemotherapies and treatment regimens may be considered with respect to the chemotherapy component.
[4] The cost range results from the low-cost therapy of doxorubicin and the high-cost therapy of liposomal doxorubicin + cyclophosphamide

Designation of the therapy	Annual treatment costs/ patient
Paclitaxel	€ 256.88

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	8.7 - 17.4	€ 617.70 - € 1235.40
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	39	€ 3,159.00
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Doxorubicin (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	5 - 11	€ 405 - € 891
Doxorubicin (in combination with docetaxel or with paclitaxel)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	9 - 11	€ 729 - € 891

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
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Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Doxorubicin pegylated, liposomal	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	13	€ 1,053.00
Doxorubicin, liposomal	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Epirubicin (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	10 - 16	€ 810 - € 1,296.00
Epirubicin (in combination with cyclophosphamide)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	13 - 15	€ 1,053.00 - € 1,215.00
Epirubicin (in combination with paclitaxel)	Surcharge for production of a parenteral preparation	€ 81	1	15 - 16	€ 1,215.00 - € 1,296.00

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Epirubicin (in combination with docetaxel)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	12 - 13	€ 972 - € 1,053.00
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2818.80

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 5 May 2022.

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

Berlin, 5 May 2022

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

Prof. Hecken