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 Pralsetinib (lung cancer, non-small cell, RET fusion+)

of 16 June 2022

At its session on 16 June 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. Annex XII shall be amended in alphabetical order to include the active ingredient Pralsetinib as follows:

Pralsetinib

Resolution of: 16 June 2022
Entry into force on: 16 June 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 18 November 2021):

Gavreto is indicated as monotherapy for the treatment of adult patients with rearranged during transfection (RET) fusion-positive advanced non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.

Therapeutic indication of the resolution (resolution of 16 June 2022):

See therapeutic indication according to marketing authorisation.

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

a) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

Appropriate comparator therapy:

- Pembrolizumab as monotherapy

Extent and probability of the additional benefit of Pralsetinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

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 Pharmaceuticals Directive

or

- Carboplatin in combination with nab-paclitaxel

or

- Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients without EGFR or ALK-positive tumour mutations and with non-squamous histology)

or

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

or

- Monotherapy with gemcitabine or vinorelbine (only for patients with ECOG performance status 2 as an alternative to platinum-based combination treatment)

Extent and probability of the additional benefit of Pralsetinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

c) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with a PD-1/PD-L1 antibody as monotherapy

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 Pharmaceuticals Directive

or

- Carboplatin in combination with nab-paclitaxel

or

- Monotherapy with gemcitabine or vinorelbine (only for patients with ECOG performance status 2 as an alternative to platinum-based combination treatment)

Extent and probability of the additional benefit of Pralsetinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

d) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with cytotoxic chemotherapy

Appropriate comparator therapy:

- Docetaxel (only for patients with PD-L1 negative tumours)

or

- Pemetrexed (only for patients with PD-L1 negative tumours and except in cases of predominantly squamous histology)

or

- Nivolumab

or

- Pembrolizumab (only for patients with PD-L1 expressing tumours, PD-L1 expression ≥ 1% of tumour cells)

or

- Atezolizumab

or

- Docetaxel in combination with nintedanib (only for patients with PD-L1 negative tumours and adenocarcinoma histology)

Extent and probability of the additional benefit of Pralsetinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

e) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC); after first-line therapy with a PD-1/PD-L1 antibody in combination with platinum-containing chemotherapy or after sequential therapy with a PD-1/PD-L1 antibody and platinum-containing chemotherapy

Appropriate comparator therapy:

Patient-individual therapy with selection of:

- Afatinib
- Pemetrexed
- Erlotinib
- Docetaxel
- Docetaxel in combination with ramucirumab
- Docetaxel in combination with nintedanib
- Vinorelbine

taking into account the previous therapy and histology.

Extent and probability of the additional benefit of Pralsetinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-168) unless otherwise indicated.

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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

b) <u>Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy</u>

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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

c) <u>Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with a PD-1/PD-L1 antibody as monotherapy</u>

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.
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d) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with cytotoxic chemotherapy

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.
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e) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC); after first-line therapy with a PD-1/PD-L1 antibody in combination with platinum-containing chemotherapy or after sequential therapy with a PD-1/PD-L1 antibody and platinum-containing chemotherapy

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 ∅: 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

a) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

approx. 30 - 90 patients

b) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

approx. 85 - 220 patients

c) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with a PD-1/PD-L1 antibody as monotherapy

approx. 5 - 20 patients

d) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with cytotoxic chemotherapy

approx. 20 - 80 patients

e) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC); after first-line therapy with a PD-1/PD-L1 antibody in combination with platinum-containing chemotherapy or after sequential therapy with a PD-1/PD-L1 antibody and platinum-containing chemotherapy

approx. 30 - 100 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 Gavreto (active ingredient: pralsetinib) at the following publicly accessible link (last access: 4 April 2022):
https://www.ema.europa.eu/en/documents/product-information/gavreto-epar-product-information_en.pdf

Treatment with pralsetinib 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.

This medicinal product was authorised under "special conditions". This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

RET testing

The selection of patients for treatment of RET fusion-positive advanced NSCLC should be based on a validated test method.

4. Treatment costs

Annual treatment costs:

a) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pralsetinib	€ 115,979.85
Appropriate comparator therapy:	
Pembrolizumab	€ 99,714.53

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2022)

Costs for additionally required SHI services: not applicable

b) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

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

Designation of the therapy	Annual treatment costs/ patient
Pralsetinib	€ 115,979.85
Appropriate comparator therapy:	
Cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)	
Cisplatin + vinorelbine	
Cisplatin	€ 2,015.79 - € 2,494.46
Vinorelbine	€ 5,015.72 - € 6,261.22
Total	€ 7,031.51 - € 8,755.68
Additionally required SHI costs	€ 328.58 - € 421.62
Cisplatin + gemcitabine	
Cisplatin	€ 2,015.79 - € 2,494.46
Gemcitabine	€ 8,218.72
Total	€ 10,234.51 - € 10,713.18
Additionally required SHI costs	€ 328.58 - € 421.62
Cisplatin + docetaxel	
Cisplatin	€ 2,015.79
Docetaxel	€ 13,742.17
Total	€ 15,757.96
Additionally required SHI costs	€ 328.58 - € 421.62
Cisplatin + paclitaxel	
Cisplatin	€ 2,284.10
Paclitaxel	€ 17,485.96
Total	€ 19,770.05
Additionally required SHI costs	€ 537.68 - € 630.72
Cisplatin + pemetrexed	
Cisplatin	€ 2,015.79
Pemetrexed	€ 37,075.40
Total	€ 39,091.19
Additionally required SHI costs	€ 456.46 - € 597.96
Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)	
Carboplatin + vinorelbine	
Carboplatin	€ 8,074.47
Vinorelbine	€ 5,015.72 - € 6,261.22
Total	€ 13,090.19 - € 14,335.69

Designation of the therapy	Annual treatment costs/ patient
Carboplatin + gemcitabine	
Carboplatin	€ 8,074.47
Gemcitabine	€ 8,218.72
Total	€ 16,293.19
Carboplatin + docetaxel	
Carboplatin	€ 8,074.47
Docetaxel	€ 13,742.17
Total	€ 21,816.64
Carboplatin + paclitaxel	
Carboplatin	€ 8,074.47
Paclitaxel	€ 17,485.96
Total	€ 25,560.43
Additionally required SHI costs	€ 209.10
Carboplatin + pemetrexed	
Carboplatin	€ 8,074.47
Pemetrexed	€ 37,075.40
Total	€ 45,149.87
Additionally required SHI costs	€ 127.87 - € 176.34
Carboplatin in combination with nab-paclitaxel	
Carboplatin	€ 8,074.47
nab-paclitaxel	€ 39,113.46
Total	€ 47,187.93
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy[2]	
Pembrolizumab + pemetrexed + cisplatin	
Pembrolizumab	€ 99,714.53
Pemetrexed	€ 37,075.40
Cisplatin	€ 2,015.79
Total	€ 138,805.72
Additionally required SHI costs	€ 456.45 - € 597.96
Pembrolizumab + pemetrexed + carboplatin	
Pembrolizumab	€ 99,714.53
Pemetrexed	€ 37,075.40

[2] Only for patients without EGFR- or ALK-positive tumour mutations and with non-squamous histology

Designation of the therapy	Annual treatment costs/ patient
Carboplatin	€ 8,074.47
Total	€ 144,864.40
Additionally required SHI costs	€ 127.87 - € 176.34
Pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel[3]	
Pembrolizumab + carboplatin + paclitaxel	
Pembrolizumab	€ 99,714.53
Carboplatin	€ 8,074.47
Paclitaxel	€ 17,485.96
Total	€ 125,274.95
Additionally required SHI costs	€ 209.10
Pembrolizumab + carboplatin + nab-paclitaxel	
Pembrolizumab	€ 99,714.53
Carboplatin	€ 8,074.47
nab-paclitaxel	€ 39,113.46
Total	€ 146,902.46
Monotherapy with gemcitabine or vinorelbine[4]	
Gemcitabine	€ 7,166.25
Vinorelbine	€ 7,509.17 - € 9,373.83

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2022)

c) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with a PD-1/PD-L1 antibody as monotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pralsetinib	€ 115,979.85
Appropriate comparator therapy:	
Cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)	
Cisplatin + vinorelbine	
Cisplatin	€ 2,015.79 - € 2,494.46
Vinorelbine	€ 5,015.72 - € 6,261.22
Total	€ 7,031.51 - € 8,755.68

[3] only for squamous histology
[4] only for patients with ECOG performance status 2 as an alternative to platinum-based combination treatment

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI costs	€ 328.58 - € 421.62
Cisplatin + gemcitabine	
Cisplatin	€ 2,015.79 - € 2,494.46
Gemcitabine	€ 8,218.72
Total	€ 10,234.51 - € 10,713.18
Additionally required SHI costs	€ 328.58 - € 421.62
Cisplatin + docetaxel	
Cisplatin	€ 2,015.79
Docetaxel	€ 13,742.17
Total	€ 15,757.96
Additionally required SHI costs	€ 328.58 - € 421.62
Cisplatin + paclitaxel	
Cisplatin	€ 2,284.10
Paclitaxel	€ 17,485.96
Total	€ 19,770.05
Additionally required SHI costs	€ 537.68 - € 630.72
Cisplatin + pemetrexed	
Cisplatin	€ 2,015.79
Pemetrexed	€ 37,075.40
Total	€ 39,091.19
Additionally required SHI costs	€ 456.45 - € 597.96
Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)	
Carboplatin + vinorelbine	
Carboplatin	€ 8,074.47
Vinorelbine	€ 5,015.72 - € 6,261.22
Total	€ 13,090.19 - € 14,335.69
Carboplatin + gemcitabine	
Carboplatin	€ 8,074.47
Gemcitabine	€ 8,218.72
Total	€ 16,293.19
Carboplatin + docetaxel	
Carboplatin	€ 8,074.47
Docetaxel	€ 13,742.17

Designation of the therapy	Annual treatment costs/ patient
Total	€ 21,816.64
Carboplatin + paclitaxel	
Carboplatin	€ 8,074.47
Paclitaxel	€ 17,485.96
Total	€ 25,560.43
Additionally required SHI costs	€ 209.10
Carboplatin + pemetrexed	
Carboplatin	€ 8,074.47
Pemetrexed	€ 37,075.40
Total	€ 45,149.87
Additionally required SHI costs	€ 127.87 - € 176.34
Carboplatin in combination with nab-paclitaxel	
Carboplatin	€ 8,074.47
nab-paclitaxel	€ 39,113.46
Total	€ 47,187.93
Monotherapy with gemcitabine or vinorelbine[5]	
Gemcitabine	€ 7,166.25
Vinorelbine	€ 7,509.17 - € 9,373.83

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2022)

d) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC) after first-line therapy with cytotoxic chemotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pralsetinib	€ 115,979.85
Appropriate comparator therapy:	
Docetaxel (only for patients with PD-L1 negative tumours)	
Docetaxel	€ 13,742.17
Pemetrexed[6]	
Pemetrexed	€ 37,075.40
Additionally required SHI costs	€ 127.87 - € 176.34
Nivolumab	

[5] only for patients with ECOG performance status 2 as an alternative to platinum-based combination treatment
[6] only for patients with PD-L1 negative tumours and except in the case of predominantly squamous cell histology

Designation of the therapy	Annual treatment costs/ patient
Nivolumab	€ 76,217.74
Pembrolizumab	
Pembrolizumab	€ 99,714.53
Atezolizumab	
Atezolizumab	€ 68,139.62
Docetaxel in combination with nintedanib[7]	
Docetaxel	€ 13,742.17
Nintedanib	€ 32,010.08
Total	€ 45,752.26

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2022)

e) Adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC); after first-line therapy with a PD-1/PD-L1 antibody in combination with platinum-containing chemotherapy or after sequential therapy with a PD-1/PD-L1 antibody and platinum-containing chemotherapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pralsetinib	€ 115,979.85
Appropriate comparator therapy:	
Patient-individual therapy, taking into account previous therapy and histology with selection of afatinib, pemetrexed, erlotinib, docetaxel, docetaxel in combination with ramucirumab, docetaxel in combination with nintedanib and vinorelbine	
Afatinib	
Afatinib	€ 30,935.18
Pemetrexed	
Pemetrexed	€ 37,075.40
Additionally required SHI costs	€ 127.87 - € 176.34
Erlotinib	
Erlotinib	€ 9,851.84
Docetaxel in combination with ramucirumab	
Docetaxel	€ 13,742.17
Ramucirumab	€ 56,850.15
Total	€ 70,592.32

[7] only for patients with PD-L1 negative tumours and adenocarcinoma histology

Designation of the therapy	Annual treatment costs/ patient
Docetaxel in combination with nintedanib	
Docetaxel	€ 13,742.17
Nintedanib	€ 32,010.08
Total	€ 45,752.26
Vinorelbine	
Vinorelbine	€ 7,509.17 - € 9,373.83

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2022)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number / patient/ year	Costs/ patient/ year
Appropriate comparator therapy:					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Docetaxel (monotherapy or combination therapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Gemcitabine (combination therapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2,818.80
Gemcitabine (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	39	€ 3,159.00
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	52.2	€ 4,228.20

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number / patient/ year	Costs/ patient/ year
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	26.1	€ 1,853.10
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	8.7 - 17.4	€ 617.70 - € 1,235.40
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Ramucirumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Vinorelbine (combination therapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2,818.80
Vinorelbine (monotherapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	52.1	€ 4,220.10

II. Entry into force

1. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 June 2022.
2. The period of validity of the resolution is limited to 31 December 2027.

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

Berlin, 16 June 2022

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

Prof. Hecken