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
Somapacitan (growth failure due to growth hormone deficiency, ≥ 3 to < 18 years; growth hormone deficiency in adults)

of 2 May 2024

At its session on 2 May 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. Annex XII shall be amended in alphabetical order to include the active ingredient Somapacitan as follows:

Somapacitan

Resolution of: 2 May 2024
Entry into force on: 2 May 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 24 July 2024):

Sogroya is indicated for the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD).

Therapeutic indication of the resolution (resolution of 2 May 2024):

Therapeutic indication according to marketing authorisation.

1. Extent of the additional benefit and significance of the evidence

Somapacitan is approved as a medicinal product for the treatment of rare diseases in accordance with Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan drugs. In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional medical benefit is considered to be proven through the grant of the marketing authorisation.

The Federal Joint Committee (G-BA) determines the extent of the additional benefit for the number of patients and patient groups for which there is a therapeutically significant additional benefit in accordance with Chapter 5 Section 12, paragraph 1, number 1, sentence 2 of its Rules of Procedure (VerfO) in conjunction with Section 5, paragraph 8 AM-NutzenV, indicating the significance of the evidence. This quantification of the additional benefit is based on the criteria laid out in Chapter 5 Section 5, paragraph 7, numbers 1 to 4 of the Rules of Procedure (VerfO).

a) Children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency

Extent of the additional benefit and significance of the evidence of somapacitan:

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

b) Adults with growth hormone deficiency (AGHD) for whom replacement of endogenous growth hormone (GH) is indicated

Extent of the additional benefit and significance of the evidence of somapacitan:

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

Study results according to endpoints:[1]

a) Children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency

Summary of results for relevant clinical endpoints

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

REAL 4 study: open-label, phase III study, somapacitan vs somatropin, 52 weeks

REAL 3 study: open-label, phase II study, somapacitan vs somatropin, 52 weeks and 104 weeks safety extension phase (at week 156)

Mortality

Endpoint Study	Somapacitan		Somatropin		Somapacitan vs somatropin
	N[a)]	Patients with event n (%)	N[a)]	Patients with event n (%)	Effect estimator [95% CI] p value
Overall mortality[b)]					
REAL 4	No deaths occurred.				
REAL 3	No deaths occurred.				

[1] Data from the dossier assessment of the G-BA (published on 1. February 2024), and from the amendment to the dossier assessment from 9 April 2024, unless otherwise indicated.

Morbidity

Endpoint Study	**Somapacitan**			**Somatropin**			**Somapacitan vs somatropin**
	N[c)]	Values Start of study MV (SD)	Amendment to start of study MV (SE)	N[c)]	Values Start of study MV (SD)	Amendment to start of study MV (SE)	MV difference [95% CI]; p value[d),e)]
Body height (z score)							
Change at week 52							
REAL 4	132	-2.99 (1.0)	1.25 (0.0)	68	-3.47 (1.5)	1.30 (0.1)	-0.05 [-0.18; 0.08]; 0.43
REAL 3	14	-3.84 (2.0)	1.42 (0.1)	14	-3.39 (1.1)	1.07 (0.1)	0.35 [0.05; 0.65]; 0.022
Change at week 156							
REAL 3	14	-3.84 (2.0)	2.66 (0.1)	14[f)]	-3.39 (1.1)	2.17 (0.1)	0.49 [0.13; 0.86]; 0.009

Endpoint **Study**	**Somapacitan**		**Somatropin**		**Somapacitan vs somatropin**
	N	Amendment to start of study MV (SE)	N	Amendment to start of study MV (SE)	Mean difference [95% CI]; p value
Annualized growth rate [cm/year] (presented additionally)					
Change at week 52					
REAL 4[g)]	132	11.2 (0.2)	68	11.7 (0.3)	-0.48 [-1.13; 0.18]; 0.15
REAL 3	14	11.7 (0.5)	14	9.9 (0.5)	1.80 [0.50; 3.09]; 0.008[h),i)]
Change at week 156					
REAL 3	14	8.5 (0.4)	11	7.6 (0.5)	0.84 [-0.45; 2.13] 0.20[h)]

Health-related quality of life

Endpoint Study	**Somapacitan**		**somatropin**		**Somapacitan vs somatropin**
	N	Patients with event n (%)[j)]	N	Patients with event n (%)[j)]	RR [95% CI] p value[k),l)]
Growth Hormone Deficiency - Child Impact Measure (GHD-CIM) ObsRO[m)]					
Total score, improvement at week 52 by ≥ 15 points					
REAL 4	127[n),o)]	30 (23.6)	63[n),o)]	17 (27.0)	0.88 [0.52; 1.46]; 0.74
REAL 3	14	6 (42.9)	14[p)]	3 (21.4)	2.00 [0.62; 6.45]; 0.27
Meta-analysis	141[n)]	36 (25.5)	77[n)]	20 (26.0)	0.98 [0.61; 1.57]; 0.94
Total score, improvement at week 156 by ≥ 15 points					
REAL 3	14	5 (35.7)	14[q)]	2 (14.3)	2.50 [0.58; 10.80]; 0.24

Endpoint **Study**	**Somapacitan**		**somatropin**		**Somapacitan vs somatropin**
	N	MV (SE)	N	MV (SE)	Mean difference [95% CI][r),s),t)]; p value *Hedges' g [95% CI]*
Growth Hormone Deficiency – Child Treatment Burden Measure (GHD-CTB) ObsRO (presented additionally)					
Total score at week 52[u)]					
REAL 4	112[n)]	10.7 (1.0)	57[n)]	13.1 (1.4)	-2.39 [-5.69; 0.91]; 0.16
REAL 3	14	3.5 (2.4)	11	10.4 (2.7)	-6.88 [-14.07; 0.31]; 0.06
Meta-analysis	126[n)]	9.6 (0.8)	68[n)]	13.0 (1.4)	-3.35 [-6.65; -0.05]; 0.047 *-0.25 [-0.55; 0.04]*
Total score at week 156					
REAL 3	13	5.4 (2.6)	11	14.3 (2.9)	-8.87 [-16.74; -1.01]; 0.028 *-0.75 [-1.59; 0.08]*
Physical domain at week 52					

Endpoint Study	Somapacitan		somatropin		Somapacitan vs somatropin
	N	MV (SE)	N	MV (SE)	Mean difference [95% CI][r),s),t)]; p value *Hedges' g [95% CI]*
REAL 4	116[n)]	11.6 (1.1)	57[n)]	14.5 (1.6)	-2.89 [-6.80; 1.02]; 0.15
REAL 3	14	4.7 (3.0)	13	14.3 (3.1)	-9.59 [-18.21; -0.96]; 0.030 *-0.70 [-1.48; 0.08]*
Meta-analysis	130[n)]	10.4 (0.9)	70[n)]	14.5 (1.8)	-4.05 [-8.08; -0.01]; 0.0495 *-0.30 [-0.59; -0.01]*
Physical domain at week 156					
REAL 3	13	3.6 (3.0)	11	18.8 (3.2)	-15.17 [-24.09; -6.25]; 0.001 *-1.18 [-2.05; -0.31]*
Emotional domain at week 52					
REAL 4	112[n)]	15.4 (1.8)	58[n)]	18.9 (2.4)	-3.53 [-9.49; 2.43]; 0.24
REAL 3	14	6.2 (4.2)	11	15.8 (4.7)	-9.62 [-22.30; 3.05]; 0.13
Meta-analysis	126[n)]	14.0 (1.5)	69[n)]	18.8 (2.6)	-4.86 [-10.81; 1.08]; 0.11
Emotional domain at week 156					
REAL 3	13	5.3 (4.2)	11	16.2 (4.6)	-10.93 [-23.59; 1.72]; 0.09
Impairment at week 52					
REAL 4	117[n)]	5.2 (0.8)	59[n)]	6.4 (1.1)	-1.28 [-3.88; 1.33]; 0.33
REAL 3	14	-0.06 (2.3)	13	10.4 (2.4)	-10.45 [-17.10; -3.80]; 0.003 *-0.98 [-1.78; -0.18]*
Meta-analysis	131[n)]	-[v)]	72[n)]	-[v)]	-[v)]
Impairment at week 156					
REAL 3	13	6.7 (2.5)	11	11.0 (2.6)	-4.32 [-11.60; 2.97]; 0.24

Side effects

Endpoint Study	**Somapacitan**		**somatropin**		**Somapacitan vs somatropin**
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
Total adverse events (presented additionally)					
REAL 4	132	94 (71.2)	68	41 (60.3)	-
REAL 3	14	13 (92.9)	14	13 (92.9)	-
Meta-analysis	146	107 (73.3)	82	54 (65.9)	-
Severe adverse events[w)]					
Events until week 52					
REAL 4	132	4 (3.0)	68	1 (1.5)	2.06 [0.23; 18.08]; 0.62
REAL 3	14	0 (0)	14	0 (0)	-
Meta-analysis	146	-	82	-	-
Events until week 156					
REAL 3	14	0 (0)	14	1 (7.1)	0.33 [0.01; 7.55]; 0.52
Serious adverse events (SAE)					
Events until week 52					
REAL 4	132	6 (4.5)	68	2 (2.9)	1.55 [1.32; 7.45]; 0.62
REAL 3	14	1 (7.1)	14	1 (7.1)	1.00 [0.07; 14.45]; n.d.
Meta-analysis	146	7 (4.8)	82	3 (3.7)	1.31 [0.35; 4.93]; 0.69
Events until week 156					
REAL 3	14	2 (14.3)	14	2 (14.3)	1.00 [0.16; 6.14]; n.d.
Therapy discontinuation due to adverse events					
Events until week 52					
REAL 4	132	0 (0)	68	0 (0)	-
REAL 3	14	0 (0)	14	2 (14.3)	0.20 [0.01; 3.82]; 0.22
Meta-analysis	146	-	82	-	-

Endpoint Study	Somapacitan		somatropin		Somapacitan vs somatropin
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
Events until week 156					
REAL 3	14	0 (0)	14	2 (14.3)	0.20 [0.01; 3.82]; 0.22
Severe adverse events according to MedDRA[w)] (with incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No severe AEs ≥ 5%					
SAEs according to MedDRA (with incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No SAEs ≥ 5%					
Adverse events of special interest (with statistically significant difference between the treatment arms)					
No significant differences					

a) Safety population
b) Fatalities were recorded using safety.
c) Full Analysis Set
d) REAL 3 study: MMRM with treatment, age group, sex, region and interaction term sex x age group as factors and baseline value of body height (z score) as covariate.
e) REAL 4 study: ANCOVA with treatment, age group, sex, region, highest measured GH concentration in the stimulation test and interaction term sex x age group x region as factors and baseline value of body height (z score) as covariate.
f) Number of subjects at baseline N = 14 and at week 156 N = 11.
g) In the REAL 4 study, a non-inferiority test of treatment with somapacitan versus somatropin was performed using a non-inferiority threshold of -1.8 cm/year and a one-sided t-test for 2 groups at the 2.5% significance level.
h) REAL 3 study: MMRM with treatment, age group, sex, region and interaction term sex x age group as factors and baseline value of body height as covariate.
i) REAL 4 study: ANCOVA with treatment, age group, sex, region, highest measured GH concentration in the stimulation test and interaction term sex x age group x region as factors and baseline value of body height as covariate.
j) Missing values were imputed as non-responders.
k) RR with 95% CI was calculated using non-parametric analysis.
l) Meta-analysis calculated post hoc: Model with fixed effects; unadjusted two-sided p value using Wald test.
m) Scale from 0 to 100 points; higher values mean higher disease burden.
n) A total of 10 subjects from the REAL 4 study (at study sites in Latvia, Poland, Serbia and Spain) did not take part in the questionnaire survey because no linguistically validated translation of the questionnaire was available and were not enrolled in the FAS.
o) Number of subjects at baseline: N = 98 in the somapacitan arm and N = 53 in the somatropin arm; number of subjects at week 52: N = 113 in the somapacitan arm and N = 55 in the somatropin arm.
p) Number of subjects at baseline N = 13 and at week 52 N = 14.
q) Number of subjects at baseline N = 13 and at week 156 N = 11.
r) REAL 3 study: MMRM with treatment, age group, sex, region and interaction term sex x age group as factors that were hierarchically nested within the "week" factor.

Endpoint Study	Somapacitan		somatropin		Somapacitan vs somatropin
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
s) REAL 4 study: MMRM with treatment, age group, sex, region, highest measured GH concentration in the stimulation test and interaction term sex x age group x region as factors that were hierarchically nested within the "week" factor. t) Meta-analysis: MMRM with treatment, study, age group, sex, region, highest measured GH concentration in the stimulation test and interaction term sex x age group x region as factors that were hierarchically nested within the "week" factor. u) Scale from 0 to 100 points; higher values mean higher burden of therapy. v) Due to the high heterogeneity, the results of the meta-analysis are not reported. w) The study's own criteria were used for severity grading. Abbreviations: ANCOVA: analysis of covariance; AWG: therapeutic indication; n.d.: no data available; CI: confidence interval; MMRM: Mixed Model for Repeated Measures; MV: mean value; ObsRO: Observer-Reported Outcome; RR: relative risk; SD: standard deviation; SE: standard error; SAE: serious adverse event; AE: adverse event.					

b) Adults with growth hormone deficiency (AGHD) for whom replacement of endogenous growth hormone (GH) is indicated

Hint for a non-quantifiable additional benefit since the scientific data does not allow quantification.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant differences for the benefit assessment.
Morbidity	n.a.	There are no assessable data.
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 ∅: No data available. n.a.: not assessable		

REAL 1 study: open-label, phase III study, somapacitan vs somatropin vs placebo, 34 weeks

REAL 2 study: open-label, phase III study, somapacitan vs somatropin, 26 weeks

JP study: open-label, phase III study, somapacitan vs somatropin, 52 weeks

Mortality

Endpoint Study	**Somapacitan**		**somatropin**		**Somapacitan vs somatropin**
	N[a)]	Patients with event n (%)	N[a)]	Patients with event n (%)	RR [95% CI] p value
Overall mortality[b)]					
REAL 1	No deaths occurred.				
REAL 2	No deaths occurred.				
REAL JP	No deaths occurred.				

Morbidity

Endpoint Study	**Somapacitan**			**Somatropin**			**Somapacitan vs somatropin**
	N	Values Start of study MV (SD)	Change from baseline MV (SE)	N	Values Start of study MV (SD)	Change from baseline MV (SE)	MV difference [95% CI]; p value[c)]
Change in truncal fat percentage at week 34 (presented additionally)							
REAL 1	120	39.11 (8.81)	-1.06 (n.d.)	119	38.10 (9.65)	-2.23 (n.d.)	4.99 [1.84; 8.14]; 0.002[d)]

Quality of life

Endpoint Study	**Somapacitan**			**Somatropin**			**Somapacitan vs somatropin**
	N[e)]	Values Start of study MV (SD)	Change from baseline MV (SE)	N[e)]	Values Start of study MV (SD)	Change from baseline MV (SE)	MV difference [95% CI]; p value[f)]
Treatment Related Impact Measure (TRIM) – Adult Growth Hormone Deficiency (AGHD) – total value[g)]							
Change at week 34							

Endpoint Study	Somapacitan			Somatropin			Somapacitan vs somatropin
	N[e)]	Values Start of study MV (SD)	Change from baseline MV (SE)	N[e)]	Values Start of study MV (SD)	Change from baseline MV (SE)	MV difference [95% CI]; p value[f)]
REAL 1	119	46.62 (18.19)	-5.71 (12.69)	118	46.00 (15.94)	-9.99 (13.64)	4.99 [1.84; 8.14]; 0.002
SF36[h)]							
Change at week 34							
REAL 1	117	44.79 (11.70)	2.70 (9.29)	118	44.32 (11.56)	4.09 (10.19)	-1.70 [-3.93; 0.53]; 0.13

Side effects

Endpoint Study	Somapacitan		Somatropin		Somapacitan vs Somatropin
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[i),k)]
Total adverse events (presented additionally)					
REAL 1	120	87 (72.5)	119	95 (79.8)	-
REAL 2	61	53 (86.9)	31	21 (67.7)	-
REAL JP	46	43 (93.5)	16	11 (68.8)	-
Severe adverse events[j)]					
REAL 1	120	7 (5.8)	119	9 (7.6)	0.77 [0.30; 2.00]; 0.68
REAL 2	61	5 (8.2)	31	2 (6.5)	1.27 [0.26; 6.18]; 1.00
REAL JP	46	0 (0)	16	0 (0)	-
Serious adverse events (SAE)					
REAL 1	120	7 (5.8)	119	11 (9.2)	0.63 [0.25; 1.57]; 0.41
REAL 2	61	4 (6.6)	31	2 (6.5)	1.02 [0.20; 5.25]; 1.00
REAL JP	46	4 (8.7)	16	0 (0)	3.26 [0.18; 57.33]; 0.25
Therapy discontinuation due to adverse events					
REAL 1	120	0 (0)	119	4 (3.4)	0.11 [0.01; 2.02]; 0.045
REAL 2	61	1 (1.6)	31	1 (3.2)	0.51 [0.03; 7.85]; 0.74
REAL JP	46	0 (0)	16	1 (6.3)	0.12 [0.01; 2.82]; 0.11

Endpoint Study	Somapacitan		Somatropin		Somapacitan vs Somatropin
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value[i),k)]
Severe adverse events according to MedDRA (with incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No severe AEs ≥ 5%					
SAEs according to MedDRA (with incidence ≥ 5% in one study arm and statistically significant difference between the treatment arms; SOC and PT)					
No SAEs ≥ 5%					
Adverse events of special interest (with statistically significant difference between the treatment arms)					
No significant differences					

a) Safety population
b) Fatalities were collected using safety.
c) ANCOVA model with treatment, occurrence of growth hormone deficiency (in adulthood or childhood), sex, region, diabetes status and interaction between sex, region and diabetes status as factors and the baseline value of truncal fat percentage as a covariate.
d) According to the study protocol, only the effect was to be calculated. No hypothesis testing was carried out.
e) Full Analysis Set
f) Change from baseline to week 25 and week 34 using MMRM with treatment, onset of GHD disease, sex, region, diabetes status and interaction of sex, region and diabetes status as factors and the respective instrument-specific baseline value as covariate.
g) Scale from 0 to 100 points; higher values mean higher disease burden.
h) Scale from 0 to 100 points; higher values correspond to better quality of life.
i) RR with 95% CI was calculated using non-parametric analysis.
j) The study's own criteria were used for severity grading.
k) Calculation of the G-BA

Abbreviations:
GHD: growth hormone deficiency; n.d.: no data available CI: confidence interval; MMRM: Mixed Model for Repeated Measures; MV: mean value; PT: preferred term; RR: relative risk; SD: standard deviation; SE: standard error; SF-36: Short-Form-36 Health Survey; SOC: SOC system organ class; AE: adverse event;

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

a) Children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency

approx. 6,700 – 8,200 patients

b) Adults with growth hormone deficiency (AGHD) for whom replacement of endogenous growth hormone (GH) is indicated

approx. 2,450 – 3,400 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 Sogroya (active ingredient: somapacitan) at the following publicly accessible link (last access: 11 March 2024):

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

Treatment with somapacitan should only be initiated and monitored by doctors experienced in treating children and adolescents with growth hormone deficiency (paediatric GHD) and adults with growth hormone deficiency (adult GHD).

4. Treatment costs

Annual treatment costs:

a) Children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Somapacitan	€ 27,649.89 – € 54,719.90

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

Costs for additionally required SHI services: not applicable

b) Adults with growth hormone deficiency (AGHD) for whom replacement of endogenous growth hormone (GH) is indicated

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Somapacitan	€ 81,789.81

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

Costs for additionally required SHI services: not applicable

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) Children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency
   - 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 growth hormone deficiency (AGHD) for whom replacement of endogenous growth hormone (GH) is indicated
   - 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.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 2 May 2024.

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

Berlin, 2 May 2024

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

Prof. Hecken