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
Olaparib (new therapeutic indication: prostate cancer, metastatic, castration-resistant chemotherapy not clinically indicated, combination with abiraterone and/or prednisone)

of 6 July 2023

At its session on 6 July 2023, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Olaparib in accordance with the resolution of 20 April 2023:

Olaparib

Resolution of: 6 July 2023
Entry into force on: 6 July 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 16 December 2022):

Lynparza is indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with mCRPC in whom chemotherapy is not clinically indicated

Therapeutic indication of the resolution (resolution of 6 July 2023):

See new therapeutic indication according to marketing authorisation.

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

a) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have not received prior therapy for mCRPC

Appropriate comparator therapy:

- abiraterone acetate in combination with prednisone or prednisolone (only for patients whose disease is progressive during or after docetaxel-containing chemotherapy; only for patients with asymptomatic or mildly symptomatic disease after failure of androgen deprivation therapy, in whom chemotherapy is not yet clinically indicated)

  or

- enzalutamide (only for patients whose disease progresses during or after chemotherapy with docetaxel; only for patients with asymptomatic or mildly symptomatic disease after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated)

  or

- olaparib as monotherapy (only for patients with BRCA1/2 mutations (germline and/or somatic) whose disease is progressive after previous treatment that included a new hormonal agent)

  or

- best supportive care (only for patients with reduced general condition (ECOG performance status ≥ 2))

Extent and probability of the additional benefit of Olaparib in combination with abiraterone acetate and prednisone or prednisolone versus abiraterone acetate in combination with prednisone or prednisolone:

a1) Adults with BRCA mutation

Hint for a considerable additional benefit.

a2) Adults without BRCA mutation (BRCA wild type)

An additional benefit is not proven.

b) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have received prior therapy for mCRPC

Appropriate comparator therapy:

Patient-individual therapy with selection of:

- abiraterone acetate in combination with prednisone or prednisolone (only for patients whose disease is progressive during or after docetaxel-containing chemotherapy),
- enzalutamide (only for patients whose disease progresses during or after chemotherapy with docetaxel) and
- olaparib as monotherapy (only for patients whose disease is progressive after previous treatment that included a new hormonal agent),

taking into account the previous therapy/ therapies and the BRCA1/2 mutational status.

Extent and probability of the additional benefit of Olaparib in combination with abiraterone acetate and prednisone or prednisolone compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have not received prior therapy for mCRPC

a1) Adults with BRCA mutation

[1] Data from the dossier assessment of the IQWiG (A23-03) and from the addendum (A23-47), unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑	Advantage in overall survival.
Morbidity	↑	Advantages for symptomatic skeletal-related events, impairment due to pain.
Health-related quality of life	↑	Advantage (FACT-P total score).
Side effects	↓	Disadvantages in severe AEs and discontinuation due to AEs. In detail, disadvantages for each of the specific AEs.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

a2) <u>Adults without BRCA mutation (BRCA wild type)</u>

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	There is no relevant difference for the benefit assessment.
Morbidity	↔	There are no relevant differences for the benefit assessment.
Health-related quality of life	↔	There are no relevant differences for the benefit assessment.
Side effects	↓	Disadvantages for severe AEs, discontinuation due to AEs and SAEs. In detail, disadvantages for each of the specific AEs.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

PROpel study: Olaparib in combination with abiraterone and predniso(lo)ne **vs** placebo + abiraterone in combination with predniso(lo)ne

Randomised, controlled, double-blind, multicentre phase III study

3rd data cut-off from 12.10.2022

Mortality

Endpoint	**Olaparib + abiraterone and predniso(lo)ne**		**Abiraterone + predniso(lo)ne**		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI]; p value Absolute difference (AD)[a]
Overall survival					
	399	42.1 [38.4; n.c.] 176 (44.1)	397	34.7 [31.0; 39.3] 205 (51.6)	0.82 [0.67; 1.00][b]; 0.054[c] AD: 7.4 months
Effect modification by the characteristic BRCA mutational status					
BRCA-mutated	47	n.r. 13 (27.7)	38	23.0 [17.8; 34.2] 25 (65.8)	0.29 [0.14; 0.56]; <0.001
BRCA wild type	343	39.6 [35.9; n.c.] 158 (46.1)	350	37.9 [32.2; 43.7] 176 (50.3)	0.91 [0.73; 1.13]; 0.386
				Interaction[d]:	0.001

Morbidity

Endpoint	**Olaparib + abiraterone and predniso(lo)ne**		**Abiraterone + predniso(lo)ne**		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 (%)*	HR [95% CI]; p value Absolute difference (AD)[a]
Progression-free survival[2]					
Radiological progression-free survival (rPFS)	399	25 [n.d.] 219 (54.9)	397	16.5 [n.d.] 277 (69.8)	0.68 [0.57; 0.81]; <0.0001 AD: 8.5 months

2 Data from the pharmaceutical company's statement of 08.05.2023

Endpoint	Olaparib + abiraterone and predniso(lo)ne		Abiraterone + predniso(lo)ne		Intervention vs control
	N	Median time to event [95% CI] *Patients with event n (%)*	N	Median time to event [95% CI] *Patients with event n (%)*	HR [95% CI]; p value Absolute difference (AD)[a]
Symptomatic skeletal-related events					
Symptomatic skeletal-related events	398[g]	n.r. 46 (11.6[g])	395[g]	n.r. 51 (12.9[g])	0.82 [0.55; 1.22][b]; 0.321[c]
Effect modification by the characteristic BRCA mutational status					
BRCA-mutated	47	n.r. 8 (17.0)	38	19.7 [12.7; n.c.] 11 (28.9)	0.31 [0.12; 0.78]; 0.013
BRCA wild type	343	n.r. 37 (10.8)	350	n.r. 40 (11.4)	0.89 [0.57; 1.40]; 0.623
				Interaction[d]	0.042
Endpoint components					
Radiotherapy to prevent or alleviate skeletal symptoms	398[g]	n.r. 31 (7.8[g])	395[g]	n.r. 42 (10.6[g])	0.67 [0.42; 1.06][b]; 0.104[c]
New symptomatic pathological bone fracture	398[g]	n.r. 17 (4.3[g])	395[g]	n.r. 16 (4.1[g])	0.91 [0.46; 1.83][b]; 0.776[c]
Occurrence of spinal cord compression	398[g]	n.r. 3 (0.8[g])	395[g]	n.r. 9 (2.3[g])	0.28 [0.06; 0.94][b]; 0.045[c]
Orthopaedic surgery due to bone metastases	398[g]	n.r. 2 (0.5[g])	395[g]	n.r. 6 (1.5[g])	0.27 [0.04; 1.19][b]; 0.099[c]
Pain (BPI-SF)					
Worst pain (BPI-SF item 3)[h]	330[i]	n.r. 97 (29.4[i])	333[i]	n.r. 89 (26.7[i])	1.00 [0.75; 1.34][b]; 0.945[c]
Pain intensity (BPI-SF items 3-6)[h] (presented additionally)	330[i]	*n.r.* 69 (20.9[d])	333[i]	*n.r.* 63 (18.9[i])	*0.98 [0.70; 1.39][b]; 0.910[c]*
Impairment due to pain (BPI-SF item 9a-g)[j]	330[i]	n.r. 76 (23.0[i])	333[i]	n.r. 82 (24.6[i])	0.84 [0.61; 1.15][b]; 0.299[c]

Effect modification by the characteristic BRCA mutational status					
BRCA-mutated	47[k]	n.r. 6 (12.8)	38[k]	n.r. 8 (21.1)	0.29 [0.10; 0.84]; 0.023
BRCA wild type	343[k]	n.r. 69 (20.1)	350[k]	n.r. 74 (21.1)	0.95 [0.68; 1.32]; 0.764
				Interaction[d]	0.037
Health status (EQ-5D VAS)					
	No suitable data available.				

Health-related quality of life

Endpoint	**Olaparib + abiraterone and predniso(lo)ne**		**Abiraterone + predniso(lo)ne**		Intervention vs control
	N	Median time to event [95% CI] *Patients with event n (%)*	N	Median time to event [95% CI] *Patients with event n (%)*	HR [95% CI]; p value Absolute difference (AD)[a]
FACT-P					
Total score[l]	278[i]	n.r. 91 (32.7[i])	295[i]	n.r. 98 (33.2[i])	0.95 [0.71; 1.26][b]; 0.701[c]
Effect modification by the characteristic BRCA mutational status					
BRCA-mutated	47[k]	n.r. 9 (19.1)	38[k]	17.4 [6.4; n c.] 12 (36.1)	0.36 [0.15; 0.85]; 0.020
BRCA wild type	343[k]	n.r. 79 (23.0)	350[k]	n.r. 84 (24.0)	1.04 [0.77; 1.42]; 0.790
				Interaction[c]	0.022
Endpoint components (presented additionally)					
Physical well-being[m]	*278[i]*	*11.9 [9.1; 19.3]* *152 (54.7[i])*	*295[i]*	*17.4 [13.7; 24.8]* *140 (47.5[i])*	*1.29 [1.03; 1.63][b]*
Social / family well-being[m]	*278[i]*	*11.1 [8.2; 21.1]* *141 (50.7[i])*	*295[i]*	*15.6 [9.1; 37.7]* *142 (48.1[i])*	*1.04 [0.82; 1.32][b]*

Emotional well-being[n]	*278[i]*	*n.r.* *114 (41.0[j])*	*295[i]*	*24.8 [21.1; 34.0]* *125 (42.4[j])*	*0.95 [0.74; 1.23][b]*
Functional well-being[m]	*278[i]*	*15.6 [11.0; 23.0]* *144 (51.8[j])*	*295[i]*	*11.1 [9.1; 19.3]* *159 (53.9[j])*	*0.89 [0.71; 1.11][b]*
Prostate cancer-specific subscale[o]	*278[i]*	*35.8 [24.8; n.c.]* *100 (36.0[j])*	*295[i]*	*35.8 [21.1; n.c.]* *102 (34.6[j])*	*0.96 [0.73; 1.27][b]*

Side effects

Endpoint	**Olaparib + abiraterone and predniso(lo)ne**		**Abiraterone + predniso(lo)ne**		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 (%)*	HR [95% CI]; p value Absolute difference (AD)[a]
Adverse events (presented additionally)					
	398	0.5 [0.5; 0.8] 389 (97.7)	396	1.0 [0.8; 1.2] 380 (96.0)	
Serious adverse events (SAEs)					
	398	31.7 [25.8; n.c.] 161 (40.5)	396	39.5 [32.3; n.c.] 126 (31.8)	1,23 [0,98; 1,56]; 0.079[p]
Effect modification by the characteristic BRCA mutational status					
BRCA-mutated	47	n.r. 14 (29.8)	38	20.2 [13.6; n.c.] 12 (31.6)	0.58 [0.27; 1.29]; 0.178
BRCA wild type	342	27.7 [25.2; 33.9] 144 (42.1)	350	39.5 [32.3; n.c.] 112 (32.0)	1.34 [1.04; 1.71]; 0.021 AD: 11.8 months
				Interaction[d]:	0.0497
Severe adverse events (CTCAE grade 3 or 4)					
	398	19.2 [14.1; 24.0] 222 (55.8)	396	27.8 [21.4; 35.4] 171 (43.2)	1,31 [1,08; 1,61]; 0.007[p] AD: 8.6 months
Therapy discontinuation due to adverse events					
	398	n.r. 71 (17.8)	396	n.r. 43 (10.9)	1,57 [1,08; 2,30]; 0.019[p]
Specific adverse events					

MDS (PT, AEs)	398	n.r. 2 (0.5)	396	n.r. 0 (0)	n.c.; 0.197[p, r]
AML (PT, AEs)	398	n.r. 0 (0)	396	n.r. 0 (0)	–
Pneumonitis (AEs)[q]	398	n.r. 5 (1.3)	396	n.r. 3 (0.8)	1,62 [0,40; 7,89]; 0.506[p]
Diarrhoea (PT, AEs)	398	n.r. 82 (20.6)	396	n.r. 42 (10.6)	1.88 [1.30; 2.75]; <0.001[p]
Nausea (PT, AEs)	398	n.r. 122 (30.7)	396	n.r. 57 (14.4)	2.36 [1.73; 3.25]; <0.001[p]
Loss of appetite (PT, AEs)	398	n.r. 66 (16.6)	396	n.r. 31 (7.8)	2.10 [1.38; 3.25]; <0.001[p]
Injury, poisoning and procedural complications (SOC, SAEs)	398	n.r. 20 (5.0)	396	n.r. 8 (2.0)	2,24 [1,02; 5,42]; 0.048[p]
Pulmonary embolism (PT, severe AEs)	398	n.r. 29 (7.3)	396	n.r. 9 (2.3)	3,06 [1,51; 6,87]; 0.002[p]
Anaemia (PT, severe AEs)	398	n.r. 64 (16.1)	396	n.r. 13 (3.3)	4.99 [2.85; 9.48]; <0.001[p]

[a] Data on absolute difference (AD) only in the case of statistically significant difference; own calculation
[b] HR and CI: Cox proportional hazards model adjusted for metastases (bone only vs visceral vs other) and docetaxel treatment of mHSPC (yes vs no)
[c] p value: Log-rank test stratified by metastases (bone only vs visceral vs other) and docetaxel treatment of mHSPC (yes vs no)
[d] p value from interaction test based on likelihood ratio test
[e] HR with associated 95% CI is estimated by a Cox proportional hazards model adjusted for the stratification variables. The stratification variables considered for adjustment are "metastases (bone only vs visceral vs other)" and "docetaxel treatment of mHSPC (yes vs no)". Ties were managed using the Efron method.
[f] The p value is based on a stratified log-rank test. Ties were handled using the Breslow method.
[g] IQWiG calculation; information refers to patients who were included in the analysis
[h] Time to first deterioration. An increase by ≥ 2 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0 to 10).
[i] IQWiG calculation; information refers to patients who have a baseline value and at least one follow-up value.
[j] Time to first deterioration. An increase by ≥ 1.5 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0 to 10).
[k] Unclear percentage of patients without baseline or follow-up value in the subgroups that are not included in the evaluation.
[l] Time to first deterioration. A decrease by ≥ 23.4 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–156).

[m] Time to first deterioration. A decrease by ≥ 4.2 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–28).
[n] Time to first deterioration. A decrease by ≥ 3.6 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–24).
[o] Time to first deterioration. A decrease by ≥ 7.2 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–48).
[p] HR, 95% CI and p value: Cox proportional hazards model with associated log-rank test.
[q] AESI defined by the pharmaceutical company. PTs that occurred were pneumonitis, interstitial lung disease and radiation-induced pneumonitis.
[r] For the p value, the information from the analysis for the combined endpoint MDS / AML was used, as only 2 MDS events were observed in this analysis as well. Identical censoring and event times is assumed for both endpoints.

Abbreviations used:
AD = absolute difference; AML = acute myeloid leukaemia; BICR = Blinded Independent Central Review; BPI-SF = Brief Pain Inventory-Short Form; CTCAE = Common Terminology Criteria for Adverse Events; FACT-P = Functional Assessment of Cancer Therapy - Prostate; mHSPC = metastatic hormone-sensitive prostate cancer; MDS = myelodysplastic syndrome; HR = hazard ratio; n.d. = no data; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PT = preferred term; SOC = system organ class; AE = adverse event; VAS = visual analogue scale; vs = versus

b) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have received prior therapy for mCRPC

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
∅: Data available.
n.a.: not assessable

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

a) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have not received prior therapy for mCRPC

and

b) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have received prior therapy for mCRPC

approx. 9,400 to 12,200 patients in total

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 Lynparza (active ingredient: olaparib) at the following publicly accessible link (last access: 22 June 2023):

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

Treatment with olaparib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology as well as specialists in urology and further doctors from other professional groups participating in the Oncology Agreement who are experienced in the treatment of patients with prostate cancer.

Medicinal castration with a GnRH agonist or antagonist should be continued during the treatment of patients who have not been surgically castrated.

4. Treatment costs

Annual treatment costs:

The costs for the first year of treatment are shown for the cost representation in the resolution.

a) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have not received prior therapy for mCRPC

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Olaparib + abiraterone acetate + prednisone or prednisolone + GnRH analogue	
Olaparib	€ 58,205.77
Abiraterone acetate	€ 1,456.59
Prednisone or prednisolone	€ 55.74 - € 67.20
GnRH analogue	€ 1,283.62 - € 2,139.00
Total	€ 61,001.72 - € 61,868.56
Appropriate comparator therapy:	
Abiraterone acetate + prednisone or prednisolone + GnRH analogue	
Abiraterone acetate	€ 1,456.59
Prednisone or prednisolone	€ 55.74 - € 67.20

Designation of the therapy	Annual treatment costs/ patient
GnRH analogue	€ 1,283.62 - € 2,139.00
Total	€ 2,795.95 - € 3,662.79
Enzalutamide + GnRH analogue	
Enzalutamide	€ 39,933.35
GnRH analogue	€ 1,283.62 - € 2,139.00
Total	€ 41,216.97 - € 42,072.35
Olaparib monotherapy + GnRH analogue	
Olaparib	€ 58,205.77
GnRH analogue	€ 1,283.62 - € 2,139.00
Total	€ 59,489.39 - € 60,344.77
Best supportive care	
Best supportive care [3]	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 June 2023

b) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have received prior therapy for mCRPC

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Olaparib + abiraterone acetate + prednisone or prednisolone + GnRH analogue	
Olaparib	€ 58,205.77
Abiraterone acetate	€ 1,456.59
Prednisone or prednisolone	€ 55.74 - € 67.20
GnRH analogue	€ 1,283.62 - € 2,139.00
Total	€ 61,001.72 - € 61,868.56
Appropriate comparator therapy:	
Abiraterone acetate + prednisone or prednisolone + GnRH analogue	
Abiraterone acetate	€ 1,456.59
Prednisone or prednisolone	€ 55.74 - € 67.20
GnRH analogue	€ 1,283.62 - € 2,139.00
Total	€ 2,795.95 - € 3,662.79
Enzalutamide + GnRH analogue	
Enzalutamide	€ 39,933.35
GnRH analogue	€ 1,283.62 - € 2,139.00

3 When comparing olaparib in combination with abiraterone acetate and prednisone/ prednisolone versus best supportive care, the costs of best supportive care must also be additionally considered for the medicinal product assessed.

Designation of the therapy	Annual treatment costs/ patient
Total	€ 41,216.97 - € 42,072.35
Olaparib monotherapy + GnRH analogue	
Olaparib	€ 58,205.77
GnRH analogue	€ 1,283.62 - € 2,139.00
Total	€ 59,489.39 - € 60,344.77

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 June 2023

Costs for additionally required SHI services: not applicable

5. 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 Olaparib

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients which, on the basis of the marketing authorisation under Medicinal Products Act, can be used in a combination therapy with olaparib for the treatment of adult patients with mCRPC in whom chemotherapy is not clinically indicated:

a) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have not received prior therapy for mCRPC

   – No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who have received prior therapy for mCRPC

   – No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 6 July 2023.

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

Berlin, 6 July 2023

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

Prof. Hecken