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)
Sacituzumab govitecan (new therapeutic indication: breast cancer, HR+, HER2-, at least 3 prior therapies)

of 15 February 2024

At its session on 15 February 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. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Sacituzumab govitecan in accordance with the resolution of 19 May 2022:

Sacituzumab govitecan

Resolution of: 15 February 2024
Entry into force on: 15 February 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 26 July 2023):

Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting.

Therapeutic indication of the resolution (resolution from 15 February 2024):See new therapeutic indication according to the marketing authorisation.

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

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting

Appropriate comparator therapy:

- Capecitabine

  or

- Eribulin

  or

- Vinorelbine

  or

- an anthracycline or taxane-containing therapy (only for patients who have not yet received anthracycline and taxane-containing therapy or are eligible for renewed anthracycline or taxane-containing treatment).

Extent and probability of the additional benefit of sacituzumab govitecan over capecitabine or eribulin or vinorelbine

Indication of a considerable additional benefit

Study results according to endpoints:[1]

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑↑	Advantage in overall survival
Morbidity	↑	Advantages (fatigue, pain, dyspnoea) and disadvantages (diarrhoea and nausea and vomiting) in the symptomatology and an advantage in the health status
Health-related quality of life	↑	Advantages in physical, emotional and cognitive functioning, role functioning and global health status
Side effects	↓↓	Disadvantage for severe AEs as well as, in detail, advantages and disadvantages for 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
∅: No data available.
n.a.: not assessable

[1] Data from the dossier assessment of the IQWiG (A23-86) and from the addendum (A23-86), unless otherwise indicated.

TROPiCS-02 study: Sacituzumab govitecan vs**.** capecitabine or eribulin or vinorelbine or gemcitabine

EVER-132-002 study: Sacituzumab govitecan vs capecitabine or eribulin or vinorelbine or gemcitabine

Total: pooled data of patients from the TROPiCS-02 and the EVER-132-002 studies

Study design: open-label, randomised, controlled

Relevant sub-population: Patients to whom treatment with capecitabine, eribulin or vinorelbine was assigned prior to randomisation

Data cut-offs: TROPiCS-02 study: 1 December 2022

EVER-132-002 study: 30 April 2023

Mortality

Endpoint	**Sacituzumab govitecan**		**Capecitabine or eribulin or vinorelbine**		**Sacituzumab govitecan vs Capecitabine or eribulin or vinorelbine**
	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					
TROPiCS-02	205	14.4 [12.8; 16.0] 165 (80.5)	213	11.2 [10.1; 12.8] 176 (82.6)	0.85 [0.69; 1.05] 0.136[b]
EVER-132-002	160	21.1 [18.0; n.c.] 64 (40.0)	155	15.3 [13.2; 18.4] 85 (54.8)	0.64 [0.46; 0.88] 0.006[c]
Total	365	16.2 [14.7; 19.1] 229 (62.7)	368	12.8 [11.6; 14.9] 261 (70.9)	0.77 [0.64; 0.92] < 0.001[d] AD = + 3.4 months

Morbidity

Endpoint	Sacituzumab govitecan		Capecitabine or eribulin or vinorelbine		Sacituzumab govitecan vs Capecitabine or eribulin or vinorelbine
	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]
Progression-free survival (PFS)					
TROPiCS-02	205	4.7 [4.1; 6.4] 135 (65.9)	213	4.0 [2.8; 4.4] 142 (66.7)	0.673 [0.528; 0.859] 0.0014 AD = + 0.7 months
EVER-132-002	166	4.3 [4.1; 5.7] 122 (73.5)	165	4.2 [2.8; 4.2] 122 (73.9)	0.671 [0.517; 0.870] 0.0028 AD = + 0.1 months
Symptomatology (EORTC QLQ-C30 – time to 1st deterioration)[e]					
Fatigue					
TROPiCS-02	172	2.1 [1.6; 2.8] 121 (70.3)	162	1.3 [1.0; 1.8] 124 (76.5)	0.67 [0.52; 0.87] 0.002[b] AD = + 0.8 months
EVER-132-002	155	1.9 [1.5; 3.0] 99 (63.9)	147	1.7 [1.5; 2.6] 101 (68.7)	0.87 [0.65; 1.15] 0.300[c]
Total	327	2.0 [1.6; 2.8] 220 (67.3)	309	1.5 [1.4; 1.9] 225 (72.8)	0.75 [0.63; 0.91] 0.002[d] AD = + 0.5 months
Nausea and vomiting					
TROPiCS-02	173	2.4 [1.6; 3.9] 106 (61.3)	165	4.6 [2.9; 9.5] 77 (46.7)	1.26 [0.93; 1.69] 0.127[b]
EVER-132-002	154	2.0 [1.5; 2.8] 110 (71.4)	149	5.5 [2.8; n.c.] 68 (45.6)	1.63 [1.20; 2.23] 0.002[c]
Total	327	2.1 [1.7; 2.8]	314	5.5 [3.5; 7.2]	1.44

		216 (66.1)		145 (46.2)	[1.17; 1.78] 0.002[d] AD = - 3.4 months
Pain					
TROPiCS-02	169	3.8 [2.8; 6.1] 95 (56.2)	159	3.2 [2.2; 4.3] 90 (56.6)	0.83 [0.62; 1.12] 0.212[b]
EVER-132-002	154	5.6 [3.3; 7.7] 79 (51.3)	145	2.9 [2.3; 4.1] 88 (60.7)	0.67 0.49; 0.92] 0.010[c]
Total	323	4.8 [3.5; 6.1] 174 (53.1)	304	3.0 [2.7; 3.9] 178 (58.8)	0.75 [0.61; 0.93] 0.020[d] AD = + 1.8 months
Dyspnoea					
TROPiCS-02	170	n.d.[f] 80 (47.1)	161	3.9 [2.4; 7.5] 84 (52.2)	n.d.[f]
EVER-132-002	152	23.3 [6.1; n.c.] 59 (38.8)	148	5.6 [3.9; 11.2] 66 (44.6)	0.71 [0.50; 1.02] 0.060[c]
Total	322	7.2 [5.8; 18.2] 139 (43.2)	309	4.5 [3.1; 6.9] 150 (48.5)	0.67 [0.53; 0.85] < 0.001[d] AD = + 2.7 months
Insomnia					
TROPiCS-02	160	8.7 [6.0; 18.9] 68 (42.5)	150	3.6 [2.3; n.c.] 69 (46.0)	0.67 [0.48; 0.95] 0.021[b] AD = + 5.1 months
EVER-132-002	150	7.4 [4.2; 11.0] 69 (46.0)	144	5.6 [4.3; n.c.] 59 (41.0)	1.00 [0.70; 1.42] 1.000[c]
Total	310	7.7 [5.9; 12.5] 137 (44.2)	294	5.3 [3.6; 8.3] 128 (43.5)	0.81 [0.64; 1.03] 0.200[d]
Appetite loss					
TROPiCS-02	167	3.3 [1.7; 5.9] 97 (58.1)	156	3.7 [2.3; 5.4] 78 (50.0)	1.08 [0.79; 1.46] 0.633[b]

EVER-132-002	151	2.9 [2.0; 4.2] 95 (62.9)	148	4.2 [2.7; n.c.] 71 (48.0)	1.17 [0.86; 1.60] 0.300[c]
Total	318	3.0 [2.2; 4.2] 192 (60.4)	304	4.1 [2.8; 5.4] 149 (49.0)	1.12 [0.90; 1.39] 0.600[d]
Constipation					
TROPiCS-02	170	5.4 [3.2; 9.1] 83 (48.8)	158	4.8 [3.2; 8.2] 70 (44.3)	1.01 [0.73; 1.40] 0.942[b]
EVER-132-002	153	7.0 [4.2; n.c.] 64 (41.8)	146	8.5 [4.4; n.c.] 51 (34.9)	1.08 [0.73; 1.58] 0.700[c]
Total	323	7.0 [4.2; 11.2] 147 (45.5)	304	5.7 [4.2; n.c.] 121 (39.8)	1.04 [0.82; 1.33] 0.100[d]
Diarrhoea					
TROPiCS-02	172	2.0 [1.6; 3.4] 104 (60.5)	164	8.2 [5.8; n.c.] 55 (33.5)	2.41 [1.72; 3.37] < 0.001[b] AD = - 6.2 months
EVER-132-002	154	2.9 [1.9; 4.8] 95 (61.7)	149	9.6 [5.8; n.c.] 45 (30.2)	2.23 [1.55; 3.20] < 0.001[c] AD = - 6.7 months
Total	326	2.5 [1.8; 3.6] 199 (61.0)	313	9.6 [5.9; n.r.] 100 (31.9)	2.29 [1.79; 2.92] < 0.001[d] AD = - 7.1 months
Health status (EQ-5D VAS – time to 1st deterioration)[g]					
TROPiCS-02	168	11.8 [6.9; n.c.] 63 (37.5)	162	7.0 [4.6; 12.7] 64 (39.5)	0.72 [0.51; 1.03] 0.073[b]
EVER-132-002	155	n.d. 49 (31.6)	149	n.d. 54 (36.2)	0.68 [0.46; 1.01] 0.050[h]
Total	323	12.3 [8.5; n.c.] 112 (34.7)	311	6.9 [5.3; 12.7] 118 (37.9)	0.71 [0.54; 0.92] 0.010[d] AD = + 5.4 months

Health-related quality of life

Endpoint	Sacituzumab govitecan		Capecitabine or eribulin or vinorelbine		Sacituzumab govitecan vs Capecitabine or eribulin or vinorelbine
	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]
EORTC QLQ-C30 – time to 1st deterioration[i]					
Global health status					
TROPiCS-02	173	4.9 [3.0; 6.7] 95 (54.9)	164	2.6 [2.0; 3.5] 103 (62.8)	0.66 [0.50; 0.88] 0.004[b] AD = + 2.3 months
EVER-132-002	154	3.8 [2.8; 4.7] 89 (57.8)	147	2.8 [2.1; 4.1] 86 (58.5)	0.87 [0.64; 1.18] 0.400[c]
Total	327	4.1 [3.2; 5.0] 184 (56.3)	311	2.8 [2.2; 3.5] 189 (60.8)	0.76 [0.62; 0.93] 0.020[d] AD = + 1.3 months
Physical functioning					
TROPiCS-02	174	5.6 [3.1; 8.3] 88 (50.6)	164	3.4 [2.2; 4.6] 87 (53.0)	0.72 [0.53; 0.97] 0.029[b] AD = + 2.2 months
EVER-132-002	154	4.5 [2.9; 9.9] 79 (51.3)	149	2.8 [2.1; 4.2] 91 (61.1)	0.64 [0.47; 0.88] 0.005[c] AD = + 1.7 months
Total	328	5.6 [3.5; 8.4] 167 (50.9)	313	3.0 [2.6; 3.9] 178 (56.9)	0.68 [0.55; 0.84] 0.001[d] AD = + 2.6 months
Role functioning					
TROPiCS-02	171	2.8 [1.7; 4.3] 111 (64.9)	159	2.2 [1.5; 2.9] 102 (64.2)	0.77 [0.58; 1.01] 0.055[b]

EVER-132-002	152	4.1 [2.8; 6.9] 83 (54.6)	149	2.7 [1.7; 3.5] 94 (63.1)	0.73 [0.54; 0.99] 0.040[c] AD = + 1.4 months
Total	323	3.0 [2.6; 4.4] 194 (60.1)	308	2.5 [1.8; 2.8] 196 (63.6)	0.76 [0.62; 0.93] 0.005[d] AD = + 0.5 months
Emotional functioning					
TROPiCS-02	169	n.d.[j] 62 (36.7)	164	4.5 [3.4; 9.5] 75 (45.7)	n.d.[j]
EVER-132-002	154	9.9 [4.1; n.c.] 61 (39.6)	149	5.3 [6.1; n.c.] 64 (43.0)	0.75 [0.52; 1.08] 0.100[c]
Total	323	11.1 [7.2; n.c.] 123 (38.1)	313	4.7 [4.2; 7.2] 139 (44.4)	0.69 [0.54; 0.89] 0.010[d] AD = + 6.4 months
Cognitive functioning					
TROPiCS-02	174	5.2 [3.0; 11.1] 86 (49.4)	164	n.d.[k] 68 (41.5)	n.d.[k]
EVER-132-002	155	3.8 [2.8; 4.7] 88 (56.8)	148	2.7 [1.7; 2.9] 95 (64.2)	0.63 [0.47; 0.85] 0.002[c] AD = + 1.1 months
Total	329	4.0 [3.2; 5.6] 174 (52.9)	312	3.2 [2.8; 4.2] 163 (52.2)	0.80 [0.64; 0.99] < 0.001[d] AD = + 0.8 months
Social functioning					
TROPiCS-02	170	2.4 [1.7; 4.3] 101 (59.4)	157	3.5 [2.6; 4.3] 88 (56.1)	0.99 [0.74; 1.33] 0.958[b]
EVER-132-002	152	4.2 [2.9; 7.2] 87 (57.2)	146	3.0 [2.1; 4.4] 82 (56.2)	0.78 [0.57; 1.06] 0.100[c]
Total	322	3.5 [2.7; 4.3] 188 (58.4)	303	3.1 [2.1; 4.2] 170 (56.1)	0.90 [0.73; 1.11] 0.400[d]

Side effects

Endpoint	Sacituzumab govitecan		Capecitabine or eribulin or vinorelbine		Sacituzumab govitecan vs Capecitabine or eribulin or vinorelbine
	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]
Total adverse events (presented additionally)					
TROPiCS-02	201	0.1 [0.1; 0.1] 201 (100.0)	194	0.2 [0.1; 0.2] 185 (95.4)	-
EVER-132-002	160	n.d. 160 (100.0)	155	n.d. 155 (100.0)	-
Serious adverse events (SAE)					
TROPiCS-02	201	n.r. [17.9; n.c.] 55 (27.4)	194	n.r. 34 (17.5)	1.42 [0.93; 2.19] 0.107[b]
EVER-132-002	160	n.r. [12.8; n.c.][l] 36 (22.5)	155	n.r.[l] 31 (20.0)	0.95 [0.59; 1.55] 0.846[c,l]
Total	361	n.r. [17.9; n.c.] 91 (25.2)	349	n.r. 65 (18.6)	1.20 [0.87; 1.66] 0.400[d]
Severe adverse events (CTCAE grade ≥ 3)					
TROPiCS-02	201	0.8 [0.7; 1.0] 151 (75.1)	194	2.4 [1.1; 3.7] 110 (56.7)	1.49 [1.17; 1.91] 0.002[b] AD = - 1.6 months
EVER-132-002	160	0.7 [0.5; 0.8][l] 131 (81.9)	155	0.7 [0.5; 1.2][l] 109 (70.3)	1.08 [0.83; 1.39] 0.565[c,l]
Total	361	0.7 [0.6; 0.9] 282 (78.1)	349	1.2 [0.8; 2.0] 219 (62.8)	1.29 [1.08; 1.53] < 0.001[d] AD = - 0.5 months
Therapy discontinuation due to adverse events					
TROPiCS-02	201	n.r. 14 (7.0)	194	n.r. 6 (3.1)	1.70 [0.64; 4.53] 0.282[b]
EVER-132-002	160	n.r.[l]	155	n.r.[l]	0.78

		5 (3.1)		5 (3.2)	[0.22; 2.77] 0.703[c,l]
Total	361	n.r. 19 (5.3)	349	n.r. 11 (3.2)	1.26 [0.60; 2.68] 0.300[d]
PRO-CTCAE					
TROPiCS-02	No suitable data[n]				
EVER-132-002	No suitable data[n]				
Specific adverse events					
Hand-foot syndrome[o]					
TROPiCS-02	201	n.r. 4 (2.0)	194	n.r. 14 (7.2)	0.19 [0.05; 0.65] 0.003[b]
EVER-132-002	159	n.r. 2 (1.3)	156	n.r. 4 (2.6)	0.45 [0.08; 2.49] 0.350[c]
Total					0.25 [0.09; 0.69] 0.008[p]
Gastrointestinal toxicity[q]					
TROPiCS-02	201	n.r. 31 (15.4)	194	n.r. 11 (5.7)	2.63 [1.32; 5.24] 0.004[b]
EVER-132-002	159	n.r. 19 (11.9)	156	n.r. 5 (3.2)	3.25 [1.20; 8.82] 0.015[c]
Total					2.81 [1.60; 4.96] < 0.001[p]
Neutropenia[r]					
TROPiCS-02	201	1.6 [1.0; 4.6] 111 (55.2)	194	9.6 [4.3; n.c.] 77 (39.7)	1.55 [1.15; 2.08] 0.003[b] AD = - 8 months
EVER-132-002	159	0.9 [0.7; 1.1] 112 (70.4)	156	1.1 [0.6; 1.9] 99 (63.5)	1.05 [0.80; 1.38] 0.722[c]
Total					1.26 [1.03; 1.54] 0.025[p]
Other specific AEs					
TROPiCS-02	No suitable data[s]				
EVER-132-002	No suitable data[s]				

[a] Indication of absolute difference (AD) only in case of statistically significant difference; own calculation
[b] Effect and CI from stratified Cox regression model, p value from stratified log-rank test; stratified by number of previous chemotherapy regimens in metastatic stage (2 vs 3 or 4), visceral metastases (yes vs no) and endocrine-based therapy in metastatic stage for ≥ 6 months (yes vs no)
[c] Effect and CI from stratified Cox regression model, p value from stratified log-rank test; stratified by number of previous chemotherapy regimens in the metastatic stage (2 vs 3 or 4), visceral metastases (yes vs no) and previous CDK4/6 inhibitor therapy in the metastatic stage (yes vs no)
[d] IPD meta-analysis: Effect and CI from stratified Cox regression model, p value from stratified log-rank test; stratified by number of previous chemotherapy regimens in the metastatic stage (2 vs 3 or 4), visceral metastases (yes vs no), treatment and study are included in the model as covariates
[e] An increase in score by ≥ 10 points compared to the start of study is considered a clinically relevant deterioration (scale range 0 to 100).
[f] Between the data cut-off from 01.07.2022 and the data cut-off from 01.12.2022, an event occurred in 2 other subjects. Effect estimate [95% CI] is not available for the data cut-off from 01. 12.2022. At the data cut-off from 01.07.2022, the hazard ratio was 0.66 (95% CI: [0.48; 0.90].
[g] A decrease in score by ≥ 15 points compared to the start of study is considered a clinically relevant deterioration (scale range 0 to 100)
[h] Effect and CI from unstratified Cox regression; p value from unstratified log-rank test
[g] A decrease in score by ≥ 10 points compared to the study design is considered a clinically relevant deterioration (scale range 0 to 100).
[j] Between the data cut-off from 01.07.2022 and the data cut-off from 01.12.2022, an event occurred in 1 other subject. Effect estimate [95% CI] is not available for the data cut-off from 01.12.2022. At the data cut-off from 01.07.2022, the hazard ratio was 0.65 (95% CI: [0.46; 0.91]).
[k] Between the data cut-off from 01.07.2022 and the data cut-off from 01.12.2022, an event occurred in 1 other subject. Effect estimate [95% CI] is not available for the data cut-off from 01.12.2022. At the data cut-off from 01.07.2022, the hazard ratio was 1.02 (95% CI: [0.74; 1.41]).
[l] Information refers to the safety population, which includes all patients who received (at least) 1 dose of the study medications (159 vs 156 patients)
[n] No suitable data available; see dossier assessment A23-86 and Addendum for justification
[o] Operationalised as palmar-plantar erythrodysaesthesia syndrome (PT, AEs)
[p] Meta-analysis: fixed-effect model; inverse variance method
[q] Operationalised as gastrointestinal disorders (SOC, severe AEs)
[r] Operationalised as a combination of the PTs neutropenia, decreased neutrophil count and febrile neutropenia (each severe AEs) predefined by the pharmaceutical company
[s] No suitable data available; a specific AE selection based on meta-analytically summarised results is not possible

Abbreviations used:
AD = absolute difference; CDK = cyclin-dependent kinase; CTCAE = Common Terminology Criteria for Adverse Events; EORTC = European Organisation for Research and Treatment of Cancer; HR = hazard ratio; IPD = individual patient data; n.d.: no data available; 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; PRO-CTCAE: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events; PT = preferred term; QLQ-C30: Quality of Life Questionnaire-Core 30; SOC: system organ class; SAE = serious adverse event; RCT = randomised controlled trial; AE = adverse event; VAS = visual analogue scale; vs = versus

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

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting

approx. 2,480 – 8,240 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 Trodelvy (active ingredient: sacituzumab govitecan) at the following publicly accessible link (last access: 01 November 2023):

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

Treatment with sacituzumab govitecan should only be initiated and monitored by specialists in internal medicine, haematology, and oncology who are experienced in the treatment of patients with breast cancer, as well as specialists in obstetrics and gynaecology, and other specialists participating in the Oncology Agreement.

4. Treatment costs

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

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Sacituzumab govitecan	€ 163,722.86
Appropriate comparator therapy:	
Capecitabine monotherapy	
Capecitabine	€ 2,450.78
Eribulin monotherapy	
Eribulin	€ 39,889.33
Vinorelbine monotherapy	
Vinorelbine	€ 7,062.10 - € 8,513.56
Taxanes	
Docetaxel	€ 15,412.05
nab-paclitaxel	€ 35454.24
Paclitaxel	
Paclitaxel	€ 15,537.68
Additionally required SHI services	€ 256.25
Anthracyclines	
Doxorubicin	€ 1,920.85 - € 2,882.88
Liposomal pegylated doxorubicin	€ 36548.85

Designation of the therapy	Annual treatment costs/ patient
Epirubicin	€ 4,678.80 - € 5140.32

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

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Sacituzumab govitecan	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy:					
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Doxorubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	5 - 11	€ 500 - € 1,100
Pegylated liposomal doxorubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
Epirubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	10 - 16	€ 1,000 - € 1,600
Eribulin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	34.8	€ 3,480
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1740
nab-paclitaxel	Surcharge for production of a parenteral	€ 100	1	17.4	€ 1,740

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	preparation containing cytostatic agents				
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	52.1	€ 5,210

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:

Adults with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative breast cancer who have received endocrine-based therapy, and at least two additional systemic therapies in the advanced setting

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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.

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III. The resolution will enter into force on the day of its publication on the website of the G-BA on 15 February 2024.

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

Berlin, 15 February 2024

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

Prof. Hecken