GBA
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
Zolbetuximab (new assessment of an orphan drug after exceeding the EUR 30 million limit:
Gastric or gastro-oesophageal junction (GEJ) adenocarcinoma, Claudin (CLDN) 18.2 positive, HER2-negative, first-line, combination with fluoropyrimidine- and platinum-containing chemotherapy)

of 5 November 2026

At their session on 5 November 2026, the Federal Joint Committee (GBA) 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 information on the active ingredient zolbetuximab in the version of the resolution of 17 April 2025 (Federal Gazette, BAnz AT 21.05.2025 B3) shall be replaced by the following information:**

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Zolbetuximab

Resolution of: 5 November 2026
Entry into force on: 5 November 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 19 September 2024):

Vyloy, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.

Therapeutic indication of the resolution (resolution of 5 November 2026):

See therapeutic indication according to marketing authorisation.

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

a) Adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression ≥ 1 (Combined Positive Score; CPS); first-line treatment

Appropriate comparator therapy:

- nivolumab in combination with fluoropyrimidine and platinum-based combination chemotherapy (only for tumours with PD-L1 expression (CPS) ≥ 5)

or

- pembrolizumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy

Extent and probability of the additional benefit of zolbetuximab in combination with capecitabine and oxaliplatin (CAPOX) compared with the appropriate comparator therapy

An additional benefit is not proven.

b) Adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression < 1 (Combined Positive Score; CPS); first-line treatment

Appropriate comparator therapy:

- cisplatin + capecitabine

or

- oxaliplatin + capecitabine

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or

– cisplatin + S-1 (tegafur/ gimeracil/ oteracil)

or

– cisplatin + 5-fluorouracil (only for patients with oesophageal adenocarcinoma)

or

– cisplatin + 5-fluorouracil + folinic acid (only for patients with oesophageal adenocarcinoma)

or

– epirubicin + cisplatin + capecitabine

or

– epirubicin + cisplatin + 5-fluorouracil

or

– epirubicin + oxaliplatin + capecitabine

or

– docetaxel + cisplatin + 5-fluorouracil

or

– 5-fluorouracil + oxaliplatin + epirubicin (only for patients with oesophageal adenocarcinoma)

Extent and probability of the additional benefit of zolbetuximab in combination with capecitabine and oxaliplatin (CAPOX) compared to CAPOX

Hint of a minor additional benefit.

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Study results according to endpoints:[1]

a) Adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression ≥ 1 (Combined Positive Score; CPS); first-line treatment

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 ∅: no data available n.a.: not assessable		

b) Adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression < 1 (Combined Positive Score; CPS); first-line treatment

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-52), unless otherwise indicated.

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GLOW study:

- Multicentre, double-blind, placebo-controlled phase III study
- Zolbetuximab in combination with capecitabine and oxaliplatin (CAPOX) versus placebo in combination with CAPOX
- Final data cut-off: 12 January 2024 (final OS analysis)
- Relevant sub-population: Patients harbouring tumours with PD-L1 expression < 1 (Combined Positive Score [CPS])

Mortality

Endpoint	**Zolbetuximab + CAPOX**		**CAPOX**		**Zolbetuximab vs CAPOX**
	N	Median survival time in months [95% CI][a] *Patients with event n (%)*	N	Median survival time in months [95% CI][a] *Patients with event n (%)*	Effect estimator [95% CI][b] p value[c] Absolute difference (AD)[f]
Overall survival					
	84	15.5 [11.8; 19.3] 54 (64.3)	88	12.1 [7.8; 15.4] 67 (76.1)	0.68 [0.47; 0.99] 0.045 AD: +3.4 months

Morbidity

Endpoint	**Zolbetuximab + CAPOX**		**CAPOX**		**Zolbetuximab vs CAPOX**
	N	Median survival time in months [95% CI][a] *Patients with event n (%)*	N	Median survival time in months [95% CI][a] *Patients with event n (%)*	Effect estimator [95% CI][b] p value[c] Absolute difference (AD)[f]
Progression-free survival (PFS) (presented additionally)					
	84	8.8 [7.0; 12.0] 50 (59.5)	88	7.3 [6.1; 8.5] 62 (70.5)	0.686 [0.460; 1.021] 0.0628
Symptomatology					
Symptomatology (EORTC QLQ-C30 – Time to 1st deterioration)[d]					
Fatigue	84	1.5 [1.0; 2.8] 58 (69.0)	88	1.5 [0.9; 3.5] 56 (63.6)	1.02 [0.69; 1.50] 0.885
Nausea and vomiting	No suitable data				
Pain	84	4.4	88	3.5	0.79

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		[3.7; 9.0] 45 (53.6)		[2.1; 5.8] 51 (58.0)	[0.52; 1.22] 0.288
Dyspnoea	84	6.8 [4.2; 19.7] 38 (45.2)	88	5.3 [4.2; 10.8] 40 (45.5)	0.96 [0.61; 1.53] 0.887
Insomnia	84	5.4 [3.0; 13.9] 40 (47.6)	88	4.2 [2.6; 7.8] 39 (44.3)	0.94 [0.59; 1.49] 0.797
Appetite loss	84	3.4 [1.5; 5.0] 44 (52.4)	88	3.0 [2.2; 6.3] 48 (54.5)	1.05 [0.68; 1.61] 0.842
Constipation	84	5.5 [4.4; n.c.] 34 (40.5)	88	4.9 [3.5; 9.2] 41 (46.6)	0.76 [0.47; 1.24] 0.268
Diarrhoea	84	6.7 [3.2; 27.2] 35 (41.7)	88	2.9 [2.3; 18.9] 42 (47.7)	0.79 [0.49; 1.26] 0.309
Symptomatology (EORTC QLQ-OG25 – Time to 1st deterioration)[d]					
Dysphagia	84	3.9 [1.6; 8.0] 46 (54.8)	88	6.4 [3.5; 11.7] 40 (45.5)	1.17 [0.74; 1.82] 0.494
Dietary restrictions	84	7.6 [3.4; 22.7] 38 (45.2)	88	7.9 [5.0; 27.2] 36 (40.9)	1.03 [0.64; 1.67] 0.902
Reflux	84	3.6 [2.0; 6.5] 45 (53.6)	88	4.8 [3.4; 9.2] 40 (45.5)	1.16 [0.73; 1.84] 0.502
Odynophagia	84	7.4 [4.7; n.c.] 31 (36.9)	88	5.1 [2.6; 9.2] 42 (47.7)	0.66 [0.40; 1.08] 0.092
Pain and discomfort	84	7.3 [4.3; 15.7] 39 (46.4)	88	4.6 [2.6; 6.7] 44 (50.0)	0.69 [0.44; 1.09] 0.111
Anxiety states	84	3.3 [1.5; 5.1] 44 (52.4)	88	3.4 [2.1; 6.3] 40 (45.5)	1.12 [0.70; 1.77] 0.646
Eating in front of others	84	15.8 [7.6; 17.7] 31 (36.9)	88	9.2 [6.4; n.c.] 28 (31.8)	0.96 [0.56; 1.64] 0.856
Dry mouth	84	4.9 [2.6; 22.6] 39 (46.4)	88	3.0 [2.1; 6.6] 44 (50.0)	0.81

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					[0.52; 1.28] 0.361
Taste disorders	84	3.5 [2.8; 4.5] 49 (58.3)	88	3.0 [1.5; 5.3] 50 (56.8)	1.01 [0.66; 1.53] 0.949
Body image	84	6.7 [3.3; 16.4] 36 (42.9)	88	5.0 [2.7; 11.7] 40 (45.5)	0.87 [0.54; 1.40] 0.587
Difficulty swallowing saliva	84	11.3 [4.9; 19.8] 36 (42.9)	88	18.9 [14.8; n.c.] 23 (26.1)	1.69 [0.98; 2.92] 0.056
Choking episodes when swallowing	84	15.5 [6.9; n.c.] 26 (31.0)	88	n.c. [9.17; n.c.] 23 (26.1)	1.05 [0.59; 1.88] 0.855
Coughing difficulties	84	9.5 [5.1; 13.5] 38 (45.2)	88	14.1 [10.0; 19.7] 29 (33.0)	1.46 [0.88; 2.42] 0.145
Difficulty speaking	84	12.4 [7.4; n.c.] 30 (35.7)	88	14.8 [6.4; n.c.] 26 (29.5)	1.15 [0.67; 1.97] 0.617
Weight loss	84	6.9 [3.2; 17.0] 38 (45.2)	88	6.3 [2.2; n.c.] 36 (40.9)	0.90 [0.56; 1.44] 0.678
Hair loss	84	23.0 [4.6; n.c.] 10 (11.9)	88	6.7 [1.5; n.c.] 8 (9.1)	0.41 [0.13; 1.26] 0.108
Pain intensity (NRS – Time to 1st deterioration[f])	84	6.4 [3.0; 9.2] 47 (56.0)	88	9.2 [4.2; n.c.] 34 (38.6)	1.36 [0.86; 2.16] 0.179
Health status (EQ-5D VAS – Time to 1st deterioration[g])	84	13.9 [7.2; 20.8] 32 (38.1)	88	6.5 [4.2; n.c.] 35 (39.8)	0.81 [0.49; 1.35] 0.418

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Health-related quality of life

Endpoint	Zolbetuximab + CAPOX		CAPOX		Zolbetuximab vs CAPOX
	N	Median survival time in months [95% CI][a] *Patients with event n (%)*	N	Median survival time in months [95% CI][a] *Patients with event n (%)*	Effect estimator [95% CI][b] p value[c]
EORTC QLQ-C30 – Time to 1st deterioration[d]					
Global health status	84	6.3 [3.2; 10.6] 47 (56.0)	88	5.0 [3.0; 7.2] 46 (52.3)	0.96 [0.62; 1.48] 0.876
Physical functioning	84	3.9 [2.2; 5.5] 50 (59.5)	88	5.3 [2.9; 9.2] 42 (47.7)	1.31 [0.85; 2.00] 0.213
Role functioning	84	2.2 [1.6; 4.5] 55 (65.5)	88	3.2 [1.5; 4.9] 49 (55.7)	1.14 [0.76; 1.70] 0.529
Emotional functioning	84	6.8 [3.7; 10.9] 43 (51.2)	88	5.8 [3.2; 7.9] 47 (53.4)	0.97 [0.62; 1.52] 0.889
Cognitive functioning	84	3.2 [1.6; 5.9] 51 (60.7)	88	5.1 [4.0; 8.9] 42 (47.7)	1.33 [0.86; 2.03] 0.185
Social functioning		4.4 [1.5; 8.5] 47 (56.0)		4.4 [2.5; 6.0] 47 (53.4)	0.91 [0.60; 1.39] 0.677

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Side effects

Endpoint	Zolbetuximab + CAPOX		CAPOX		Zolbetuximab vs CAPOX
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI][h] p value[i]
Total adverse events (presented additionally)					
	83	82 (98.8)	87	84 (96.6)	-
Serious adverse events (SAEs)					
	83	45 (54.2)[j]	87	45 (51.7)[c]	1.05 [0.79; 1.39] 0.794
Severe adverse events[k]					
	83	64 (77.1)	87	57 (65.5)	1.18 [0.97; 1.43] 0.106
Therapy discontinuation due to adverse events[l]					
	83	26 (31.3)[j]	87	22 (25.3)[j]	1.24 [0.77; 2.01] 0.530
Specific adverse events					
Vomiting (PT, AE)	No suitable data				
Nausea (PT, AE)	No suitable data				
Decreased appetite (PT, severe AE)	83	5 (6.0)	87	0 (0)	11.52 [0.64; 205.20] 0.021[e]

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a	Brookmeyer–Crowley method
b	HR and 95% CI: Cox regression model stratified by region (Asia vs non-Asia), number of organs with metastases (0–2 vs ≥ 3) and previous gastrectomy (yes vs no)
c	Stratified log-rank test
d	An increase in score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
e	Discrepancy between p value (exact) and CI (asymptotic) due to different calculation methods
f	Own calculation
g	Discrepancy between p value (exact) and CI (asymptotic) due to different calculation methods
h	Calculation using the fourfold table: in the case of 0 events in a study arm, the correction factor 0.5 was used in both study arms when calculating effect and CI.
i	IQWiG calculation, unconditional exact test (CSZ method)
j	In the GLOW study, progression of the underlying disease was not to be documented. It is unclear why individual events were still documented as SAEs or discontinuation due to AEs. However, given the low number of events, it is not expected that this will have any impact on the results.
k	Operationalised as CTCAE grade ≥ 3
l	Discontinuation of at least one component

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; 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; RR = relative risk; SOC = system organ class; SAE = serious adverse event; AE= adverse event; vs = versus

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

a) Adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression ≥ 1 (Combined Positive Score; CPS); first-line treatment

Approximately 470 to 1,340 patients

b) Adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression < 1 (Combined Positive Score; CPS); first-line treatment

Approximately 620 to 1,700 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

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product characteristics, SmPC) for Vyloy (active ingredient: zolbetuximab) at the following publicly accessible link (last access: 15 July 2026):

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

Treatment with zolbetuximab must only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with gastric or gastro-oesophageal junction carcinomas, as well as specialists in internal medicine and gastroenterology and other specialists from other specialist groups participating in the Oncology Agreement.

Eligible patients must have a CLDN18.2-positive tumour status, defined as ≥ 75% of tumour cells with moderate to strong membranous CLDN18 immunohistochemical staining, tested by a CE-marked in vitro diagnostic device (IVD) with an appropriate intended use. If a CE-marked IVD is not available, an alternative validated test must be used.

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 locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression ≥ 1 (Combined Positive Score; CPS); first-line treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Zolbetuximab in combination with oxaliplatin, folinic acid and fluorouracil (mFOLFOX6)	
Zolbetuximab	€ 106,211.70 - € 108,583.52
Oxaliplatin	€ 9,825.08
Folinic acid	€ 11,588.97
Fluorouracil (5-FU)	€ 1,213.39
Total	€ 128,839.14 - € 131,210.96
Zolbetuximab in combination with oxaliplatin and capecitabine (CAPOX)	
Zolbetuximab	€ 106,211.70 - € 108,583.52
Oxaliplatin	€ 8,322.08
Capecitabine	€ 2,105.96
Total	€ 116,639.74 - € 119,011.56
Appropriate comparator therapy:	
Pembrolizumab in combination with cisplatin and 5-fluorouracil (5-FU)	
Pembrolizumab	€ 79,663.81

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Designation of the therapy	Annual treatment costs/ patient
Cisplatin	€ 11,751.96
5-FU	€ 1,966.20
Total	€ 93,381.97
Additionally required SHI services	€ 271.70 - € 326.88
Pembrolizumab in combination with oxaliplatin and capecitabine	
Pembrolizumab	€ 79,663.81
Oxaliplatin	€ 8,322.08
Capecitabine	€ 2,105.96
Total	€ 90,091.85
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (FOLFOX-4) (only for tumours with PD-L1 expression (CPS ≥ 5))	
Nivolumab	€ 74,557.26
5-FU	€ 796.57 - € 1,179.72
Folinic acid	€ 12,353.44
Oxaliplatin	€ 9,825.08
Total	€ 97,532.35 - € 97,915.50
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (mod. FOLFOX-6) (only for tumours with PD-L1 expression (CPS ≥ 5))	
Nivolumab	€ 74,557.26
5-FU	€ 398.29 - € 815.10
Folinic acid	€ 11,588.97
Oxaliplatin	€ 9,825.08
Total	€ 96,369.60 - € 96,786.41
Nivolumab in combination with capecitabine and oxaliplatin (XELOX) (only for tumours with PD-L1 expression (CPS ≥ 5))	
Nivolumab	€ 74,557.26
Capecitabine	€ 2,105.96
Oxaliplatin	€ 8,322.08
Total	€ 84,985.30

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 September 2026)

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:					

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Zolbetuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
				or	
				26.1	€ 2,610
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
				or	
				26.1	€ 2,610
Folinic acid	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
5-FU *Bolus*	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
5-FU *22 h infusion*	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Appropriate comparator therapy					
Pembrolizumab in combination with cisplatin and 5-FU					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 - 17.4	€ 870 - € 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Pembrolizumab in combination with oxaliplatin and capecitabine					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 - 17.4	€ 870 - € 1,740
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (FOLFOX-4)					

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(only for tumours with PD-L1 expression (CPS ≥ 5))					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 – 26.1	€ 1,740 - € 2,610
5-FU Bolus	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	52.2	€ 5,220
5-FU 22 h infusion	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	52.2	€ 5,220
Folinic acid	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	52.2	€ 5,220
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Nivolumab in combination with 5-fluorouracil (5-FU) + folinic acid + oxaliplatin (FOLFOX-6) (only for tumours with PD-L1 expression (CPS ≥ 5))					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 – 26.1	€ 1,740 - € 2,610
5-FU Bolus	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
5-FU 22 h infusion	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Folinic acid	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Nivolumab in combination with capecitabine and oxaliplatin (XELOX) (only for tumours with PD-L1 expression (CPS ≥ 5))					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740

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Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740

b) Adults with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive with a PD-L1 expression < 1 (Combined Positive Score; CPS); first-line treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Zolbetuximab in combination with oxaliplatin, folinic acid and fluorouracil (mFOLFOX6)	
Zolbetuximab	€ 106,211.70 - € 108,583.52
Oxaliplatin	€ 9,825.08
Folinic acid	€ 11,588.97
Fluorouracil (5-FU)	€ 1,213.39
Total	€ 128,839.14 - € 131,210.96
Zolbetuximab in combination with oxaliplatin and capecitabine (CAPOX)	
Zolbetuximab	€ 106,211.70 - € 108,583.52
Oxaliplatin	€ 8,322.08
Capecitabine	€ 2,105.96
Total	€ 116,639.74 - € 119,011.56
Appropriate comparator therapy:	
Cisplatin in combination with capecitabine	
Cisplatin	€ 2,350.39
Capecitabine	€ 2,105.96
Total	€ 4,456.35
Additionally required SHI services	€ 271.70 - € 326.88
Oxaliplatin in combination with capecitabine	
Oxaliplatin	€ 8,322.08
Capecitabine	€ 2,105.96
Total	€ 10,428.04
Cisplatin + S-1 (tegafur/ gimeracil/ oteracil)	
Cisplatin	€ 704.82
S-1 (tegafur/ gimeracil/ oteracil)	€ 7,013.31
Total	€ 7,718.13
Additionally required SHI services	€ 114.86 - € 134.91
Cisplatin in combination with 5-fluorouracil (5-FU)	

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Designation of the therapy	Annual treatment costs/ patient
(only for patients with oesophageal adenocarcinoma)	
Cisplatin	€ 2,350.39
5-FU	€ 2,655.24
Total	€ 5,005.63
Additionally required SHI services	€ 271.70 - € 326.88
Cisplatin in combination with 5-fluorouracil (5-FU) and folinic acid (only for patients with oesophageal adenocarcinoma)	
Cisplatin	€ 2,350.39
5-FU	€ 2,655.24
Folinic acid	€ 7,725.98
Total	€ 12,731.61
Additionally required SHI services	€ 271.70 - € 326.88
Epirubicin in combination with cisplatin and capecitabine	
Epirubicin	€ 4,978.31
Cisplatin	€ 1,874.15
Capecitabine	€ 2,305.46
Total	€ 9,157.92
Additionally required SHI services	€ 271.70 - € 326.88
Epirubicin in combination with cisplatin and 5-fluorouracil (5-FU)	
Epirubicin	€ 4,978.31
Cisplatin	€ 1,874.15
5-FU	€ 4,723.10
Total	€ 11,575.56
Additionally required SHI services	€ 271.70 - € 326.88
Epirubicin in combination with oxaliplatin and capecitabine	
Epirubicin	€ 4,978.31
Oxaliplatin	€ 8,322.08
Capecitabine	€ 2,305.46
Total	€ 15,605.85
Epirubicin in combination with oxaliplatin and 5-fluorouracil (5-FU) (only for patients with oesophageal adenocarcinoma)	
Epirubicin	€ 4,978.31
Oxaliplatin	€ 8,322.08
5-FU	€ 4,723.10
Total	€ 18,023.49
Docetaxel in combination with cisplatin and 5-fluorouracil (5-FU)	

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Annual treatment costs/ patient
(only for patients with oesophageal adenocarcinoma)	
Docetaxel	€ 4,328.77
Cisplatin	€ 2,350.39
5-FU	€ 2,655.24
Total	€ 9,334.40
Additionally required SHI services	€ 271.70 - € 326.88

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 September 2026)

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:					
Zolbetuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
				or	
				26.1	€ 2,610
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
				or	
				26.1	€ 2,610
Folinic acid	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
5-FU *Bolus*	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
5-FU *22 h infusion*	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Appropriate comparator therapy					
Cisplatin in combination with capecitabine					

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Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Oxaliplatin in combination with capecitabine					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin in combination with S-1 (tegafur/ gimeracil/ oteracil)					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin in combination with 5-fluorouracil (5-FU) (only for patients with oesophageal adenocarcinoma)					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	87.0	€ 1,870
Cisplatin in combination with 5-fluorouracil (5-FU) and folinic acid (only for patients with oesophageal adenocarcinoma)					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	87.0	€ 1,870
Folinic acid	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Epirubicin in combination with cisplatin and capecitabine					
Epirubicin	Surcharge for production of a parenteral preparation	€ 100	1	17.4	€ 1,740

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	containing cytostatic agents				
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Epirubicin in combination with cisplatin and 5-fluorouracil (5-FU)					
Epirubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	36.5	€ 36,500
Epirubicin in combination with oxaliplatin and capecitabine					
Epirubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Epirubicin in combination with oxaliplatin and 5-fluorouracil (5-FU)					
Epirubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	365.0	€ 36,500

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Docetaxel in combination with cisplatin and 5-fluorouracil (5-FU) (only for patients with oesophageal adenocarcinoma)					
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	8.7	€ 8,700

II. The resolution will enter into force on the day of its publication on the GBA website on 5 November 2026.

The justification for this resolution will be published on the GBA website at www.g-ba.de.

Berlin, 5 November 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk

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