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
Durvalumab (new therapeutic indication: muscle invasive bladder cancer (MIBC), neoadjuvant/ adjuvant therapy after cystectomy, combination with gemcitabine and cisplatin)

of 22 January 2026

At their session on 22 January 2026, 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 Durvalumab in accordance with the resolution of 22 January 2026 for the therapeutic indication: "IMFINZI as monotherapy is indicated for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.":**

S

Durvalumab

Resolution of: 22 January 2026
Entry into force on: 22 January 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 2 July 2025):

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC).

Therapeutic indication of the resolution (resolution of 22 January 2026):

See new therapeutic indication according to marketing authorisation.

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

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy

Appropriate comparator therapy:

A therapy regimen consisting of

- neoadjuvant treatment with cisplatin in combination with gemcitabine

followed by radical cystectomy and:

  - monitoring wait-and-see approach

    or

  - nivolumab (only suitable for patients with tumour cell PD-L1 expression ≥ 1% and at high risk of recurrence after radical resection)

Extent and probability of the additional benefit of durvalumab in combination with gemcitabine and cisplatin followed by durvalumab after radical cystectomy compared with gemcitabine in combination with cisplatin followed by monitoring wait-and-see approach after radical cystectomy:

Indication of a minor additional benefit.

Study results according to endpoints:[1]

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy

[1] Data from the dossier assessment of the IQWiG (A25-97) and from the addendum (A25-151), 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	↑↑	Advantage in avoiding the failure of the curative therapeutic approach (event rate and event-free survival) and in health status.
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

NIAGARA study:

- ongoing, open-label, randomised controlled trial
- Durvalumab + gemcitabine + cisplatin (neoadjuvant) followed by durvalumab after radical cystectomy (adjuvant) **versus** gemcitabine + cisplatin (neoadjuvant) followed by monitoring wait-and-see approach after radical cystectomy

Mortality

Endpoint	Durvalumab + gemcitabine + cisplatin/ durvalumab		Gemcitabine + cisplatin/ monitoring wait-and-see approach		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 (%)*	Effect estimator [95% CI] p value[a] Absolute difference (AD)[b]
Overall survival[c]					
	533	n.r. [n.r.; n.r.] 136 (25.5)	530	n.r. [n.r.; n.r.] 169 (31.9)	0.75 [0.59; 0.93] 0.0106

Morbidity

Endpoint	**Durvalumab + gemcitabine + cisplatin/ durvalumab**		**Gemcitabine + cisplatin/ monitoring wait-and-see approach**		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	Relative risk [95% CI] p value
Failure of the curative therapeutic approach					
Event rate	533	187 (35.1)	530	246 (46.4)	0.76 [0.65; 0.87]; < 0.001[d] AD: - 11.3%
Relapse after radical cystectomy	533	69 (12.9)	530	87 (16.4)	–
No cystectomy (medical reasons)	533	20 (3.8)	530	27 (5.1)	–
Not eligible for surgery	533	2 (0.4)	530	6 (1.1)	–
Progression of the disease	533	8 (1.5)	530	9 (1.7)	–
AE	533	6 (1.1)	530	7 (1.3)	–
Decision by the doctor	533	4 (0.8)	530	5 (0.9)	–
Refusal of cystectomy or intra-operative failure[e]	533	28 (5.3)	530	42 (7.9)	–
Refusal	533	1 (0.2)	530	5 (0.9)	–
Unsuccessful	533	1 (0.2)	530	0 (0)	–
Discontinuation of study participation	533	25 (4.7)	530	35 (6.6)	–
Death	533	1 (0.2)	530	2 (0.4)	–
Death	533	68 (12.8)[f]	530	85 (16.0)	–
	N	Median time to event in months:	N	Median time to event in months:	Hazard ratio[g] p value

Event-free survival	533	n.r.	530	46.1 [32.2; n.c.]	0.68 [0.56; 0.82]; < 0.001

Endpoint	**Durvalumab + gemcitabine + cisplatin/ durvalumab**		**Gemcitabine + cisplatin/ monitoring wait-and-see approach**		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 (%)*	Effect estimator [95% CI] p value[a] Absolute difference (AD)[b]
Symptomatology (time to first deterioration)					
EORTC QLQ-C30[h,i]					
Fatigue	n.d.[j]	1.0 [1.0; 1.0] 385 (72.2[k])	n.d.[j]	1.0 [1.0; 1.1] 360 (67.9[k])	1.12 [0.97; 1.30]; 0.140
Nausea and vomiting	n.d.[j]	1.8 [1.1; 1.8] 322 (60.4[k])	n.d.[j]	1.8 [1.1; 1.8] 296 (55.8[k])	1.09 [0.93; 1.28]; 0.304
Pain	n.d.[j]	2.9 [2.7; 3.6] 309 (58.0[k])	n.d.[j]	2.7 [1.9; 3.6] 310 (58.5[k])	0.94 [0.81; 1.11]; 0.469
Dyspnoea	n.d.[j]	2.8 [2.7; 2.9] 290 (54.4[k])	n.d.[j]	2.8 [2.7; 3.2] 252 (47.5[k])	1.04 [0.87; 1.23]; 0.688
Insomnia	n.d.[j]	3.7 [2.9; 3.8] 259 (48.6[k])	n.d.[j]	3.8 [3.6; 4.6] 239 (45.1[k])	1.07 [0.90; 1.28]; 0.455
Appetite loss	n.d.[j]	1.8 [1.8; 1.9] 319 (59.8[k])	n.d.[j]	1.8 [1.6; 1.8] 309 (58.3[k])	0.97 [0.83; 1.14]; 0.678
Constipation	n.d.[j]	1.9 [1.8; 2.7] 287 (53.8[k])	n.d.[j]	1.8 [1.8; 2.4] 290 (54.7[k])	0.90 [0.76; 1.06]; 0.222
Diarrhoea	n.d.[j]	4.7 [4.5; 5.7] 220 (41.3[k])	n.d.[j]	5.5 [4.6; 6.0] 198 (37.4[k])	1.13 [0.93; 1.37]; 0.239
PGIS[i, l]	n.d.[j]	4.8 [3.7; 5.7] 182 (34.1[k])	n.d.[j]	4.9 [3.6; 5.7] 185 (34.9[k])	0.96 [0.78; 1.18]; 0.689
Health status (time to first deterioration)					
EQ-5D VAS[i, m]	n.d.[j]	3.7 [2.9; 4.3] 256 (48.0[k])	n.d.[j]	2.9 [2.7; 3.7] 239 (45.1[k])	0.97 [0.81; 1.16]; 0.707
PGIC[n]	n.d.[j]	5.3 [4.6; 7.3] 227 (42.6[k])	n.d.[j]	4.2 [2.9; 5.0] 246 (46.4[k])	0.82 [0.69; 0.99]; 0.037

Health-related quality of life

EORTC QLQ-C30 (time to first deterioration[i, o])					
Global health status	n.d.[j]	1.8 [1.8; 1.9] 326 (61.2[k])	n.d.[j]	1.8 [1.8; 1.9] 312 (58.9[k])	1.01 [0.86; 1.18]; 0.943
Physical functioning	n.d.[j]	2.7 [1.9; 2.7] 346 (64.9[k])	n.d.[j]	1.9 [1.8; 2.7] 339 (64.0[k])	0.96 [0.82; 1.12]; 0.598
Role functioning	n.d.[j]	1.8 [1.1; 1.8] 356 (66.8[k])	n.d.[j]	1.8 [1.8; 1.8] 337 (63.6[k])	1.05 [0.90; 1.22]; 0.543
Emotional functioning	n.d.[j]	3.8 [3.6; 4.7] 251 (47.1[k])	n.d.[j]	4.0 [3.6; 4.6] 243 (45.8[k])	1.00 [0.83; 1.19]; 0.965
Cognitive functioning	n.d.[j]	2.3 [1.8; 2.8] 320 (60.0[k])	n.d.[j]	2.7 [2.0; 2.9] 280 (52.8[k])	1.16 [0.99; 1.36]; 0.079
Social functioning	n.d.[j]	1.9 [1.8; 2.7] 322 (60.4[k])	n.d.[j]	1.9 [1.8; 2.8] 313 (59.1[k])	1.00 [0.86; 1.17]; 0.991

Side effects

Endpoint	**Durvalumab + gemcitabine + cisplatin/ durvalumab**		**Gemcitabine + cisplatin/ monitoring wait-and-see approach**		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 (%)*	Hazard ratio [95% CI] p value[l] Absolute difference (AD)[b]
Total adverse events (presented additionally)					
	530	0.1 [0.1; 0.1] 527 (99.4)	526	0.1 [0.1; 0.2] 525 (99.8)	–
Serious adverse events (SAE)					
	530	5.3 [4.7; 6.1] 326 (61.5)	526	6.0 [5.1; 8.2] 287 (54.6)	1.10 [0.93; 1.29] 0.263
Severe adverse events (CTCAE grade ≥ 3)					
	530	3.3 [2.7; 3.8] 380 (71.7)	526	2.7 [2.3; 3.5] 365 (69.4)	0.95 [0.82; 1.10] 0.500
Therapy discontinuation due to adverse events					
	No suitable data[p]				
PRO-CTCAE					

	No suitable data[q]				
Specific adverse events					
Immune-mediated AEs (presented additionally)	530	9.9 [8.0; 13.9] 262 (49.4)	526	n.r. 139 (26.4)	–
Immune-mediated SAEs	530	n.r. 24 (4.5)	526	n.r. 5 (1.0)	4.48 [1.85; 13.31] < 0.001
Immune-mediated severe AEs[r]	530	n.r. 23 (4.3)	526	n.r. 7 (1.3)	3.11 [1.40; 7.85] 0.006
Skin and subcutaneous tissue disorders (SOC, AEs)	530	14.5 [10.6; n.c.] 237 (44.7)	526	n.r. 157 (29.8)	1.55 [1.27; 1.91] < 0.001
Pulmonary embolism (PT, SAEs)	530	n.r. 18 (3.4)	526	n.r. 5 (1.0)	3.50 [1.40; 10.59] 0.008
Anaemia (PT, SAEs)	530	n.r. 5 (0.9)	526	n.r. 17 (3.2)	0.28 [0.09; 0.72] 0.008
Cardiac disorders (SOC, severe AEs[r])	530	n.r. 23 (4.3)	526	n.r. 10 (1.9)	2.16 [1.06; 4.76] 0.038

[a] HR and CI from Cox proportional hazards model; p value from log-rank test. In each case stratified by clinical tumour status (T2N0 vs > T2N0a), renal function (adequate renal function vs borderline renal function) and tumour PD-L1 expression status (high vs low/ negative).

[b] Data on absolute difference (AD) only in the case of statistically significant difference; own calculation.

[c] Results from the dossier of the pharmaceutical company.

[d] Own calculation, unconditional exact test.

[e] In addition to the listed events, the events for medically unjustified partial cystectomy and failure to perform a delayed cystectomy are included in the overall rate.

[f] Discrepancies between Module 4 and the study report.

[g] HR and CI from Cox proportional hazards model, p value from log-rank test. In each case stratified by clinical tumour status [T2N0 vs > T2N0a], renal function [adequate renal function vs borderline renal function] and tumour PD-L1 expression status [high vs low/ negative]).

[h] 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).

[i] Patients for whom no analysable assessment or baseline data were available at the time of evaluation were censored on day 1. Patients who did not show deterioration and died within 2 visits of the last survey were censored at the time of the last survey. In the case of ≥ 2 missed visits (regardless of whether deterioration or death occurred thereafter), censoring was performed at the time of the last survey before the 2 missed visits. Patients who could not deteriorate due to a baseline value that was too low are included in the reason for censoring - no deterioration.[j] Patients without a baseline value or without a value during the course of the study were censored on day 1 and were therefore not included in the evaluations. They account for around 20%.

[k] Percentage refers to the number of patients randomised into this arm.

[l] An increase by ≥ 1 point compared to the start of the study is considered as clinically relevant deterioration (6-point scale).

[m] A decrease in score by ≥ 15 points compared to the start of study is considered as clinically relevant deterioration (scale range: 0 to 100).

[n] Deterioration to the levels 'Slightly worse (-1)', 'Somewhat worse (-2)' or 'Significantly worse (-3) compared to day 1 of the 1st cycle:

[o] A decrease in score by ≥ 10 points compared to the start of study is considered as clinically relevant deterioration (scale range: 0 to 100).

[p] Therapy discontinuations in the comparator arm can only occur in the neoadjuvant phase, as there is only one further observation at the study visits in the adjuvant phase.

[q] Effect estimate cannot be interpreted.

[r] Operationalised as CTCAE grade ≥ 3.

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; EORTC = European Organisation for Research and Treatment of Cancer; 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; PD-L1 = Programmed Cell Death-Ligand 1; PGIC = Patient Global Impression of Change; PGIS: Patient Global Impression of Severity; PRO-CTCAE = Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events; pU = pharmaceutical company; QLQ-C30 = Quality of Life Questionnaire - Core 30; RCT = randomised controlled trial; RR = relative risk; SAE = serious adverse event; AE = adverse event; VAS = visual analogue scale; vs = versus.

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

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy

Approx. 4,310 to 5,730 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 Imfinzi (active ingredient: durvalumab) at the following publicly accessible link (last access: 17 September 2025):

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

Treatment with durvalumab should only be initiated and monitored by specialists in internal medicine, haematology and oncology as well as specialists in urology and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of patients with bladder cancer.

4. Treatment costs

Annual treatment costs:

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Neoadjuvant treatment: Durvalumab in combination with cisplatin and gemcitabine	
Durvalumab	€ 23,596.08
Cisplatin	€ 463.72
Gemcitabine	€ 2,159.04
Total:	€ 26,218.84
Adjuvant treatment: Durvalumab (monotherapy)	
Durvalumab	€ 47,192.16
Appropriate comparator therapy:	
Neoadjuvant treatment: Cisplatin in combination with gemcitabine	
Cisplatin	€ 347.79 - € 463.72
Gemcitabine	€ 1,619.28 - € 2,159.04

Designation of the therapy	Annual treatment costs/ patient
Total:	€ 1,967.07 - € 2,622.76
Adjuvant treatment: Monitoring wait-and-see approach or nivolumab	
Monitoring wait-and-see approach	Not calculable
Nivolumab	€ 75,571.60

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 November 2025)

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:					
Neoadjuvant treatment: Durvalumab in combination with cisplatin and gemcitabine					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4	€ 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	12	€ 1,200
Adjuvant treatment: Durvalumab (monotherapy)					
Durvalumab	Surcharge for the preparation of a parenteral	€ 100	1	8	€ 800

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	solution containing monoclonal antibodies				
Appropriate comparator therapy:					
Neoadjuvant treatment: Cisplatin in combination with gemcitabine					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3 - 4	€ 300 - € 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	9 - 12	€ 900 - € 1,200
Adjuvant treatment: Nivolumab (monotherapy)					
Nivolumab (1st and subsequent year)	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13 - 26	€ 1,300 – € 2,600

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 resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy

– 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 22 January 2026.

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

Berlin, 22 January 2026

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

Prof. Hecken