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: limited-stage small cell lung cancer (LS-SCLC), following platinum-based chemoradiation therapy, monotherapy)

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 20 February 2025, last modified on 18 June 2025:**

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 12 March 2025):

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.

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 limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Appropriate comparator therapy for durvalumab as monotherapy:

- Best supportive care

Extent and probability of the additional benefit of durvalumab compared to the appropriate comparator therapy

Indication of a considerable additional benefit

Study results according to endpoints:[1]

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑↑	Advantage in overall survival.
Morbidity	↔	Advantage in the symptom scale "pain in the arm or shoulder" No relevant differences for the benefit assessment overall.
Health-related quality of life	↔	No statistically significant or relevant difference.
Side effects	↔	No statistically significant or relevant difference.

[1] Data from the dossier assessment of the IQWiG (A25-96) and from the addendum (G25-39), unless otherwise indicated.

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

ADRIATIC study:

- ongoing, randomised, controlled triple-arm study
- Durvalumab **versus** durvalumab + tremelimumab **versus** best supportive care
- Relevant study arms: Durvalumab **versus** + best supportive care

Mortality

Endpoint	**Durvalumab**		**Best supportive care**		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					
Overall survival	264	55.9 [37.3; n.c.] 115 (43.6)	266	33.4 [25.5; 39.9] 146 (54.9)	0.72 [0.56; 0.92] 0.008 AD: +22.5 months

Morbidity

Endpoint	**Durvalumab**		**Best supportive care**		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]
Progression-free survival (presented additionally)°					
	264	16.6 [10.2; 28.2] 139 (52.7)	266	9.2 [7.4; 12.9] 169 (63.5)	0.76 [0.61; 0.95] p = 0.0161
Symptomatology (time to first deterioration)					
EORTC-QLQ-C30[c]					

Fatigue	n.d.[d]	1.9 [1.8; 3.6] 159 (60.2[e])	n.d.[d]	2.7 [1.9; 3.6] 153 (57.5[e])	1.08 [0.86; 1.35] 0.530
Nausea and vomiting	n.d.[d]	14.7 [8.3; 23.9] 109 (41.3[e])	n.d.[d]	16.6 [11.0; 28.6] 96 (36.1[e])	1.09 [0.83; 1.45] 0.524
Pain	n.d.[d]	3.7 [2.9; 4.7] 155 (58.7[e])	n.d.[d]	2.8 [1.8; 5.5] 154 (57.9[e])	0.87 [0.70; 1.09] 0.261
Dyspnoea	n.d.[d]	4.5 [2.8; 5.6] 142 (53.8[e])	n.d.[d]	7.3 [3.7; 9.1] 125 (47.0[e])	1.16 [0.91; 1.47] 0.242
Insomnia	n.d.[d]	5.6 [4.5; 7.3] 134 (50.8[e])	n.d.[d]	8.3 [6.4; 12.9] 114 (42.9 [e])	1.24 [0.97; 1.60] 0.089
Appetite loss	n.d.[d]	5.6 [3.7; 9.2] 131 (49.6[e])	n.d.[d]	7.4 [4.6; 11.9] 115 (43.2[e])	1.11 [0.86; 1.43] 0.411
Constipation	n.d.[d]	11.9 [5.6; 17.6] 113 (42.8[e])	n.d.[d]	9.3 [6.5; 16.5] 105 (39.5[e])	0.97 [0.75; 1.28] 0.858
Diarrhoea	n.d.[d]	26.6 [14.7; 44.2] 87 (33.0[e])	n.d.[d]	22.0 [13.8; 32.2] 82 (30.8[e])	0.95 [0.70; 1.29] 0.738
EORTC-QLQ-LC13[c]					
Cough	n.d.[d]	2.7 [1.6; 5.5] 147 (55.7[e])	n.d.[d]	4.6 [2.7; 9.1] 128 (48.1[e])	1.14 [0.90; 1.45] 0.296
Haemoptysis	n.d.[d]	n.r. 60 (22.7[e])	n.d.[d]	n.r. 47 (17.7[e])	1.13 [0.77; 1.67] 0.527
Dyspnoea	n.d.[d]	1.1 [1.0; 1.4] 184 (69.7[e])	n.d.[d]	1.4 [0.9; 1.8] 167 (62.8[e])	1.16 [0.94; 1.43] 0.177
Chest pain	n.d.[d]	5.6 [2.8; 11.0] 129 (48.9[e])	n.d.[d]	5.5 [1.7; 11.0] 123 (46.2[e])	0.90 [0.70; 1.15] 0.420
Pain in the arm or shoulder	n.d.[d]	8.3 [5.6; 14.7] 125 (47.3[e])	n.d.[d]	4.5 [1.8; 6.4] 143 (53.8[e])	0.70 [0.55; 0.89] 0.004

Pain in other parts of the body	n.d.[d]	4.6 [3.6; 7.3] 135 (51.1[e])	n.d.[d]	2.8 [1.6; 6.4] 136 (51.1[e])	0.91 [0.72; 1.16] 0.454
Wounded mouth	n.d.[d]	15.6 [8.3; 29.4] 106 (40.2[e])	n.d.[d]	18.5 [8.2; 30.3] 100 (37.6[e])	0.97 [0.74; 1.28] 0.841
Dysphagia	n.d.[d]	27.5 [15.7; n.c.] 92 (34.8[e])	n.d.[d]	31.3 [18.4; n.c.] 84 (31.6[e])	0.99 [0.73; 1.33] 0.930
Peripheral neuropathy	n.d.[d]	6.5 [5.5; 10.1] 127 (48.1[e])	n.d.[d]	6.5 [4.5; 10.1] 129 (48.5[e])	0.89 [0.69; 1.14] 0.356
Alopecia	n.d.[d]	18.3 [12.8; 33.2] 100 (37.9[e])	n.d.[d]	22.2 [12.8; n.c.] 87 (32.7)	1.08 [0.81; 1.44] 0.632
PGIS					
PGIS[f]	n.d.[d]	3.7 [1.9; 7.3] 132 (50.0[e])	n.d.[d]	5.5 [3.6; 5.5] 127 (47.7[e])	1.09 [0.85; 1.39] 0.569
Health status					
EQ-5D-5L VAS[g]	n.d.[d]	11.0 [9.1; 16.5] 111 (42.0[e])	n.d.[d]	18.3 [7.4; 31.2] 90 (33.8[e])	1.17 [0.88; 1.55] 0.295

Health-related quality of life

Endpoint	**Durvalumab**		**Best supportive care**		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]
Global health status	n.d.[d]	3.6 [2.7; 4.5] 143 (54.2[e])	n.d.[d]	4.5 [2.7; 8.2] 130 (48.9[e])	1.08 [0.85; 1.38] 0.498
Physical functioning	n.d.[d]	5.5 [3.6; 7.4] 134 (50.8[e])	n.d.[d]	8.3 [5.5; 11.0] 123 (46.2[e])	1.17 [0.91; 1.49] 0.228
Role functioning	n.d.[d]	4.7 [2.8; 7.4] 138 (52.3[e])	n.d.[d]	3.8 [2.7; 6.4] 139 (52.3[e])	0.83 [0.66; 1.06] 0.142

Cognitive functioning	n.d.[d]	4.7 [3.6; 6.4] 140 (53.0[e])	n.d.[d]	5.5 [3.7; 8.2] 136 (51.1[e])	0.98 [0.77; 1.24] 0.880
Emotional functioning	n.d.[d]	8.2 [5.5; 11.9] 125 (47.3[e])	n.d.[d]	7.3 [3.6; 10.2] 124 (46.6[e])	0.91 [0.70; 1.16] 0.451
Social functioning	n.d.[d]	4.6 [3.6; 7.3] 140 (53.0[e])	n.d.[d]	5.6 [3.7; 8.3] 132 (49.6[e])	1.03 [0.81; 1.31] 0.792

Side effects

Endpoint	**Durvalumab**		**Best supportive care**		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[i]
Adverse events					
	262	247 (94.3)	265	234 (88.3)	–
Serious adverse events (SAE)					
	262	78 (29.8)	265	64 (24.2)	1.23 [0.93; 1.64] 0.152
Severe adverse events (CTCAE grade 3 or 4)[k,l]					
	262	69 (26.3)	265	68 (25.7)	1.03 [0.77; 1.37] 0.898
Therapy discontinuation due to adverse events					
	262	43 (16.4)	265	28 (10.6)	1.55 [1.00; 2.42] 0.051
Specific adverse events					
Immune-mediated AEs (presented additionally)					
Immune-mediated AEs (presented additionally)	262	134 (51.1)	265	73 (27.5)	–
Immune-mediated SAEs	262	25 (9.5)	265	8 (3.0)	3.16 [1.45; 6.88] 0.002

Immune-mediated severe AEs[k,m]	262	16 (6.1)	265	4 (1.5)	4.05 [1.37; 11.94] 0.006
Pneumonitis (AEs)[n]	262	100 (38.2)	265	80 (30.2)	1.26 [1.00; 1.61] 0.055

a HR and CI: Cox proportional hazards model; p value: Log-rank test; each stratified according to TNM classification (I/II vs III) and receipt of PCI (yes vs no), each from data in the IVRS; for patient-reported endpoints, censoring was performed as follows: if neither deterioration nor death occurred, at the time of the last survey or on day 1 if no surveys or no baseline value were available during the course of the study; if deterioration or death occurred after 2 missed visits, at the time of the last survey before the 2 missed visits; if death without prior deterioration occurred within 2 visits after the last survey, at the time of death. The pharmaceutical company do not describe how they proceeded with a baseline value that does not allow a deterioration by 10 or 15 points. It is assumed that there was no censoring on day 1, but that the same rules were applied as in other cases without deterioration.

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

c An increase by ≥ 10 points compared to the start of the study is considered a clinically relevant deterioration (scale range: 0 to 100).

d According to the pharmaceutical company, all randomised patients were included in the evaluation. At the same time, the pharmaceutical company states that patients with no baseline value or no value in the course of the study were censored on day 1. Thus, de facto no times of these patients were included in the evaluation.

e Percentage refers to the number of patients randomised into this arm.

f An increase by ≥ 1 point compared to the start of the study is considered a clinically relevant deterioration (6-point scale).

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

h A decrease by ≥ 10 points compared to the start of the study is considered a clinically relevant deterioration (scale range: 0 to 100).

i Own calculation of RR, CI (asymptotic) and p value (unconditional exact test, CSZ method according to Martín Andrés and Silva Mato A., 1994)

k The pharmaceutical company operationalise severe AEs in Module 4 A as CTCAE grade ≥ 3. Based on the information in the study documents, it is clear that these are operationalised as CTCAE grade 3 or 4.

l 5 (1.9%) vs 4 (1.5%) patients experienced a grade 5 event.

m 1 (0.4%) vs 0 patients experienced a grade 5 event.

n operationalised via the GT "pneumonitis or radiation pneunomitis"

o Information from the dossier of the pharmaceutical company

Abbreviations used:
AD = Absolute Difference; CTCAE = Common Terminology Criteria for Adverse Events; GT = grouped term; HR = hazard ratio; 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; RR = relative risk; SAE = serious adverse event; AE = adverse event; vs = versus

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

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Approx. 670 – 1,750 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: 28 October 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 who are experienced in the treatment of patients with small cell lung cancer, as well as specialists in internal medicine and pulmonology or specialists in pulmonary medicine and other doctors from other specialist groups participating in the Oncology Agreement.

4. Treatment costs

Annual treatment costs:

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Durvalumab	€ 76,687.26
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Best supportive care	Different from patient to patient

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:					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0	€ 1,300

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 limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation 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