

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: non-small cell lung
cancer (NSCLC), EGFR/ALK negative, neoadjuvant/ adjuvant
therapy, combination with platinum-based chemotherapy)

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 on the therapeutic indication "in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy for the treatment of adults with resectable muscle invasive bladder cancer (MIBC)"**

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 31 March 2025):

IMFINZI in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy as adjuvant treatment, is indicated for the treatment of adults with resectable NSCLC at high risk of recurrence and no EGFR mutations or ALK rearrangements.

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 NSCLC at high risk of recurrence and no EGFR mutations or ALK rearrangements; neoadjuvant and adjuvant therapy

Appropriate comparator therapy:

- Neoadjuvant treatment with nivolumab in combination with platinum-based therapy followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression $\geq 1\%$)

or

- Neoadjuvant treatment with pembrolizumab in combination with platinum-based therapy followed by adjuvant treatment with pembrolizumab

Extent and probability of the additional benefit of durvalumab in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by durvalumab as monotherapy compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:¹

Adults with resectable NSCLC at high risk of recurrence and no EGFR mutations or ALK rearrangements; neoadjuvant and adjuvant therapy

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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		

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

Adults with resectable NSCLC at high risk of recurrence and no EGFR mutations or ALK rearrangements; neoadjuvant and adjuvant therapy

Approx. 4,540 – 4,660 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: 09 January 2026):

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 non-small cell lung cancer, as well as specialists in internal medicine and pulmonology or

¹ Data from IQWiG's dossier assessment (A25-98).

specialists in pulmonary medicine and other doctors from other specialist groups participating in the Oncology Agreement.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (including patient identification card).

The training material contains, in particular, information and warnings about immune-mediated side effects as well as infusion-related reactions.

4. Treatment costs

Treatment costs:

Adults with resectable NSCLC at high risk of recurrence and no EGFR mutations or ALK rearrangements; neoadjuvant and adjuvant therapy

Designation of the therapy	Treatment costs/ patient
Medicinal product to be assessed:	
Durvalumab + platinum-based chemotherapy (neoadjuvant treatment) followed by durvalumab as monotherapy (adjuvant treatment)	
Neoadjuvant treatment:	
Durvalumab + platinum-based chemotherapy	
Durvalumab	€ 23,596.08
Carboplatin	€ 1,452.80 - € 1,707.12
Cisplatin	€ 463.72 - € 573.76
Docetaxel	€ 1,960.28
Gemcitabine	€ 1,859.36
Paclitaxel	€ 3,823.88
Pemetrexed	€ 4,280.80
Vinorelbine	€ 1,153.28 - € 1,439.84
Total (durvalumab + platinum-based chemotherapy; neoadjuvant)	€ 25,213.08 - € 29,584.00 ²
Adjuvant treatment:	
Durvalumab (monotherapy)	
Durvalumab	€ 70,788.24
Appropriate comparator therapy:	
Nivolumab + platinum-based chemotherapy (neoadjuvant treatment) followed by monitoring wait-and-see approach	

² The lower limit of the range results for durvalumab in combination with cisplatin and vinorelbine. The upper limit of the range results for durvalumab in combination with carboplatin and pemetrexed.

Designation of the therapy	Treatment costs/ patient
Neoadjuvant treatment:	
Nivolumab + platinum-based chemotherapy	
Nivolumab	€ 17,439.60
Carboplatin	€ 1,452.80 - € 1,707.12
Cisplatin	€ 463.72 - € 573.76
Docetaxel	€ 1,960.28
Gemcitabine	€ 1,859.36
Paclitaxel	€ 3,823.88
Pemetrexed	€ 4,280.80
Vinorelbine	€ 1,153.28 - € 1,439.84
Total (nivolumab + platinum-based chemotherapy; neoadjuvant)	€ 19,056.60 - € 23,427.52 ³
Monitoring wait-and-see approach	
Not calculable	
Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab as monotherapy (adjuvant treatment)	
Neoadjuvant treatment:	
Pembrolizumab + platinum-based chemotherapy	
Pembrolizumab	€ 18,721.56
Carboplatin	€ 1,452.80 - € 1,707.12
Cisplatin	€ 463.72 - € 573.76
Docetaxel	€ 1,960.28
Gemcitabine	€ 1,859.36
Paclitaxel	€ 3,823.88
Pemetrexed	€ 4,280.80
Vinorelbine	€ 1,153.28 - € 1,439.84
Total (pembrolizumab + platinum-based chemotherapy; neoadjuvant)	€ 20,338.56 - € 24,709.48 ⁴
Adjuvant treatment:	
Pembrolizumab (monotherapy)	
Pembrolizumab	€ 60,845.07 - € 65,525.46

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

³ The lower limit of the range results for nivolumab in combination with cisplatin and vinorelbine. The upper limit of the range results for nivolumab in combination with carboplatin and pemetrexed.

⁴ The lower limit of the range results for pembrolizumab in combination with cisplatin and vinorelbine. The upper limit of the range results for pembrolizumab in combination with carboplatin and pemetrexed.

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 + platinum-based chemotherapy (neoadjuvant treatment) followed by durvalumab as monotherapy (adjuvant treatment)					
Neoadjuvant treatment:					
Durvalumab + platinum-based chemotherapy					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4	€ 400
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8	€ 800
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8	€ 800
Adjuvant treatment:					
Durvalumab (monotherapy)					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	12	€ 1,200
Appropriate comparator therapy:					
Nivolumab + platinum-based chemotherapy (neoadjuvant treatment) followed by monitoring wait-and-see approach					
Neoadjuvant treatment:					
Nivolumab + platinum-based chemotherapy					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4	€ 400
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Cisplatin	Surcharge for production of a parenteral preparation	€ 100	1	4	€ 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8	€ 800
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8	€ 800
Monitoring wait-and-see approach					
Not calculable					
Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab as monotherapy (adjuvant treatment)					
Neoadjuvant treatment:					
Pembrolizumab + platinum-based chemotherapy					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing	€ 100	1	2 – 4	€ 200 – € 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	monoclonal antibodies				
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8	€ 800
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8	€ 800
Adjuvant treatment:					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pembrolizumab (monotherapy)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	7 - 13	€ 700 - € 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 resectable NSCLC at high risk of recurrence and no EGFR mutations or ALK rearrangements; neoadjuvant and adjuvant therapy

- No medicinal product with new active ingredients 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 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