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
Toripalimab (oesophageal squamous cell carcinoma, first-line, combination with cisplatin and paclitaxel)

From 2 July 2026

At their session on 2 July 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 number 6 to the information on the benefit assessment of toripalimab in accordance with the resolution of 2 July 2026 (recurrent or metastatic nasopharyngeal carcinoma (NPC), first-line, combination with cisplatin and gemcitabine):

Toripalimab

Resolution of: 2 July 2026
Entry into force on: 2 July 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

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

Loqtorzi, in combination with cisplatin and paclitaxel, is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma.

Therapeutic indication of the resolution (resolution of 2 July 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 unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

Appropriate comparator therapy:

- nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (for patients with tumour cell PD-L1 expression ≥ 1%)

  or

- nivolumab in combination with ipilimumab (for patients with tumour cell PD-L1 expression ≥ 1%)

  or

- pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (for patients with a combined positive score (CPS) ≥ 10)

Extent and probability of the additional benefit of toripalimab in combination with cisplatin and paclitaxel compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

Appropriate comparator therapy:

- cisplatin in combination with 5-fluorouracil

Extent and probability of the additional benefit of toripalimab in combination with cisplatin and paclitaxel compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

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		

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

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		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-05), unless otherwise indicated.

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

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

Approx. 1,640 patients

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

Approx. 960 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 Loqtorzi (active ingredient: toripalimab) at the following publicly accessible link (last access: 17 April 2026):

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

Therapy with toripalimab should only be initiated and monitored by specialists in internal medicine, haematology and oncology, experienced in the treatment of patients with oesophageal carcinoma, as well as specialists in internal medicine and gastroenterology and other specialists 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 a patient identification card which contains, in particular, information on potential immune-mediated side effects.

4. Treatment costs

Annual treatment costs:

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Toripalimab in combination with cisplatin and paclitaxel	
Toripalimab	€ 98,823.65
Cisplatin	€ 2,017.18
Paclitaxel	€ 17,094.80
Total	€ 117,935.63

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI services	€ 542.77 - € 612.55
Appropriate comparator therapy:	
Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (for patients with tumour cell PD-L1 expression ≥ 1%)	
Nivolumab	€ 74,117.94 - € 74,403.01
Cisplatin	€ 1,726.01
5-FU	€ 1,355.90
Total	€ 77,199.85 - € 77,484.92
Additionally required SHI services	€ 203.00 - € 255.13
nivolumab in combination with ipilimumab (for patients with tumour cell PD-L1 expression ≥ 1%)	
Nivolumab	€ 75,862.26
Ipilimumab	€ 57,271.75
Total	€ 133,134.01
pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (for patients with a combined positive score (CPS) ≥ 10)	
Pembrolizumab	€ 80,030.78
Cisplatin	€ 2,310.20
5-FU	€ 1,814.82
Total	€ 84,155.80
Additionally required SHI services	€ 271.70 - € 341.48

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 May 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:					
Toripalimab in combination with cisplatin and paclitaxel					
Toripalimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					

Designation of the therapy	Type of service	Costs/ unit	Number / cycle	Number/ patient/ year	Costs/ patient/ year
Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (for patients with tumour cell PD-L1 expression ≥ 1%)					
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	65.0	€ 6,500
nivolumab in combination with ipilimumab (for patients with tumour cell PD-L1 expression ≥ 1%)					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0 - 26.1	€ 1,300 - € 2,610
Ipilimumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7	€ 870
pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (for patients with a combined positive score (CPS) ≥ 10)					
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	1	17.4	€ 1,740
5-FU	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Toripalimab in combination with cisplatin and paclitaxel	
Toripalimab	€ 98,823.65
Cisplatin	€ 2,017.18
Paclitaxel	€ 17,094.80
Total	€ 117,935.63
Additionally required SHI services	€ 542.77 - € 612.55
Appropriate comparator therapy:	
Cisplatin in combination with 5-FU	
Cisplatin	€ 2,495.86
5-FU	€ 1,814.82
Total	€ 4,310.68
Additionally required SHI services	€ 271.70 - € 341.48

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 May 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:					
Toripalimab in combination with cisplatin and paclitaxel					
Toripalimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740

Designation of the therapy	Type of service	Costs/ unit	Number / cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Cisplatin in combination with 5-FU					
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	5	87.0	€ 8,700

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:

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

- No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

- No medicinal product with new active ingredients for use in combination therapy in compliance with 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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Loqtorzi is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5 per cent of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant percentage within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the G-BA website on 2 July 2026.

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

Berlin, 2 July 2026

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

Dr Optendrenk