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

(recurrent or metastatic nasopharyngeal carcinoma (NPC), first-line, combination with cisplatin and gemcitabine)

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, information on the active ingredient toripalimab shall be added in alphabetical order as follows:**

**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 gemcitabine, is indicated for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal 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

Adults with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma; first-line treatment

**Appropriate comparator therapy:**

- Tislelizumab in combination with cisplatin and gemcitabine

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

An additional benefit is not proven.

**Study results according to endpoints:**[1]

Adults with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma; first-line treatment

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-04), unless otherwise indicated.

**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:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

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

Adults with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma; first-line treatment

Approx. 70 to 120 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 nasopharyngeal carcinoma as well as ear, nose and throat (otorhinolaryngology) specialists 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 a patient identification card which contains, in particular, information on potential immune-mediated side effects.

## 4. Treatment costs

**Annual treatment costs:**

The annual treatment costs shown refer to the first year of treatment.

Adults with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma; first-line treatment

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Toripalimab in combination with cisplatin and gemcitabine | |
| Toripalimab | € 98,823.65 |
| Cisplatin | € 2,310.20 |
| Gemcitabine | € 6,261.22 |
| Total | € 107,395.07 |
| Appropriate comparator therapy: | |
| Tislelizumab in combination with cisplatin and gemcitabine | |
| Tislelizumab | € 59,975.02 |
| Cisplatin | € 2,310.20 |
| Gemcitabine | € 6,261.22 |
| Total | € 68,546.44 |

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

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: | | | | | |
| Toripalimab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| Cisplatin | Surcharge for production of a | € 100 | 1 | 17.4 | € 1,740 |

| | | | | | |
|---|---|---|---|---|---|
| | parenteral preparation containing cytostatic agents | | | | |
| Gemcitabine | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 2 | 34.8 | € 3,480 |
| Appropriate comparator therapy: | | | | | |
| Tislelizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4<br>or<br>8.7 | € 1,740<br>or<br>€ 870 |
| Cisplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Gemcitabine | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 2 | 34.8 | € 3,480 |

**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 recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma; first-line treatment

– 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. Entry into force**

1. **The resolution will enter into force on the day of its publication on the G-BA website on 2 July 2026.**
2. **The period of validity of the resolution is limited to 15 January 2027.**

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