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
Tislelizumab (new therapeutic indication: recurrent or metastatic nasopharyngeal carcinoma (NPC), first-line, combination with gemcitabine and cisplatin)

From 19 March 2026

At their session on 19 March 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 Tislelizumab in accordance with the resolution of 19 March 2026 (small cell lung cancer, first-line, combination with etoposide and platinum chemotherapy):**

Tislelizumab

Resolution of: 19 March 2026
Entry into force on: 19 March 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 9 July 2025):

Tevimbra, in combination with gemcitabine and cisplatin, is indicated for the first-line treatment of adult patients with recurrent, not amenable to curative surgery or radiotherapy, or metastatic NPC.

Therapeutic indication of the resolution (resolution of 19 March 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 curative surgery or radiotherapy, or metastatic nasopharyngeal carcinoma (NPC); first-line treatment

Appropriate comparator therapy:

- Cisplatin in combination with gemcitabine

Extent and probability of the additional benefit of tislelizumab 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 curative surgery or radiotherapy, or metastatic nasopharyngeal carcinoma (NPC); first-line treatment

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-119), unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	There is no relevant difference for the benefit assessment.
Morbidity	↔	There are no relevant differences for the benefit assessment.
Health-related quality of life	↔	There are no relevant differences for the benefit assessment.
Side effects	↔	There are 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		

RATIONALE 309 study:

- Tislelizumab + gemcitabine + cisplatin **vs** gemcitabine + cisplatin
- Double-blind, randomised controlled phase III study
- Final data cut-off from 8 December 2023

Mortality

Endpoint	Tislelizumab + gemcitabine + cisplatin		Gemcitabine + cisplatin		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Mortality					
	131	45.3 [33.4; n.c.] 55 (42.0)	132	31.8 [25.0; n.c.] 64 (48.5)	0.73 [0.51; 1.05] 0.084

Morbidity

Endpoint	Tislelizumab + gemcitabine + cisplatin		Gemcitabine + cisplatin		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 (%)*	HR [95% CI] p value Absolute difference (AD) [a]
Progression-free survival (PFS)[2]					
	131	9.6 [7.6; 11.6] 95 (72.5)	132	7.4 [5.6; 7.6] 106 (80.3)	0.528 [0.394; 0.708] < 0.0001 AD: + 2.2 months

Endpoint	Tislelizumab + gemcitabine + cisplatin		Gemcitabine + cisplatin		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 (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Symptomatology (EORTC QLQ-C30 – Time to first deterioration)[b]					
Fatigue	131	1.4 [0.8; 2.3] 92 (70.2)	132	2.2 [2.0; 3.8] 84 (63.6)	1.18 [0.87; 1.59] 0.307
Nausea and vomiting	131	2.6 [2.2; 5.2] 78 (59.5)	132	3.5 [2.2; 10.4] 74 (56.1)	1.04 [0.75; 1.43] 0.801
Pain	131	17.2 [7.8; 24.4] 59 (45.0)	132	8.4 [6.2; 19.6] 62 (47.0)	0.82 [0.57; 1.18] 0.280
Dyspnoea	131	22.6 [12.5; n.c.] 52 (39.7)	132	13.7 [11.1; n.c.] 45 (34.1)	1.08 [0.72; 1.63] 0.705
Insomnia	131	27.6 [10.8; n.c.] 49 (37.4)	132	n.r. [10.3; n.c.] 44 (33.3)	0.98 [0.64; 1.48] 0.914
Appetite loss	131	2.4 [2.1; 3.9] 80 (61.1)	132	3.4 [2.2; 4.6] 74 (56.1)	1.15 [0.83; 1.57] 0.405
Constipation	131	_[c] 53 (40.5)	132	_[c] 52 (39.4)	0.94 [0.64; 1.38] 0.727
Diarrhoea	131	n.r. [30.4; n.c.] 34 (26.0)	132	n.r. 27 (20.5)	1.15 [0.68; 1.93] 0.607

[2] Data on tislelizumab from Module 4 of the pharmaceutical company from 08.12.2023 at the final data cut-off

Symptomatology (EORTC QLQ-H&N35 – Time to 1st deterioration)[b]					
Pain	131	n.r. [24.9; n.c.] 44 (33.6)	132	–[c] 35 (26.5)	1.18 [0.75; 1.86] 0.469
Dysphagia	131	n.r. [22.5; n.c.] 41 (31.3)	132	n.r. [11.1; n.c.] 37 (28.0)	0.97 [0.61; 1.53] 0.887
Emotional disorders	131	10.8 [4.8; 33.8] 64 (48.9)	132	10.8 [6.2; n.c.] 57 (43.2)	1.11 [0.77; 1.61] 0.570
Speech disorders	131	n.r. 24 (18.3)	132	27.5 [16.1; n.c.] 27 (20.5)	0.77 [0.44; 1.36] 0.365
Dental problems	131	20.0 [12.0; 44.0] 54 (41.2)	132	13.1 [7.9; 38.9] 54 (40.9)	0.83 [0.57; 1.22] 0.346
Mouth opening problems	131	24.6 [13.8; n.c.] 46 (35.1)	132	15.6 [10.4; 21.9] 44 (33.3)	0.80 [0.52; 1.23] 0.305
Mouth dryness	131	–[c] 49 (37.4)	132	n.r. [15.6; n.c.] 36 (27.3)	1.31 [0.85; 2.02] 0.223
Cough	131	33.6 [14.6; n.c.] 44 (33.6)	132	16.4 [11.1; n.c.] 40 (30.3)	0.93 [0.60; 1.45] 0.755
Malaise	131	13.1 [5.2; n.c.] 60 (45.8)	132	18.9 [10.6; n.c.] 41 (31.1)	1.51 [1.01; 2.26] 0.043
Feeding tube	131	n.r. [42.3; n.c.] 4 (3.1)	132	n.r. 7 (5.3)	0.33 [0.09; 1.20] 0.080
Use of analgesics (presented additionally)	131	*n.r.* *22 (16.8)*	*132*	*n.r.* *29 (22.0)*	–
Use of dietary supplements (presented additionally)	131	*n.r.* *42 (32.1)*	*132*	*n.r.* *32 (24.2)*	–
Weight loss (presented additionally)	131	*n.r. [13.1; n.c.]* *46 (35.1)*	*132*	–[c] *39 (29.5)*	–
Weight gain (presented additionally)	131	*6.4 [5.0; 8.0]* *72 (55.0)*	*132*	*5.1 [4.1; 6.5]* *68 (51.5)*	–

Health-related quality of life

Endpoint	**Tislelizumab + gemcitabine + cisplatin**		**Gemcitabine + cisplatin**		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 (%)*	HR [95% CI] p value Absolute difference (AD)[a]
EORTC QLQ-C30 – Time to first deterioration[d]					
General health status	131	10.8 [4.0; n.c.] 61 (46.6)	132	6.6 [3.6; 15.0] 67 (50.8)	0.84 [0.59; 1.20] 0.336
Physical functioning	131	10.8 [4.1; 18.8] 67 (51.1)	132	6.6 [3.8; n.c.] 61 (46.2)	1.03 [0.73; 1.46] 0.862
Role functioning	131	5.2 [2.5; n.c.] 66 (50.4)	132	7.6 [4.9; 33.5] 65 (49.2)	1.03 [0.73; 1.46] 0.859
Emotional functioning	131	n.r. [18.8; n.c.] 46 (35.1)	132	n.r. [19.1; n.c.] 34 (25.8)	1.30 [0.83; 2.04] 0.244
Cognitive functioning	131	6.0 [3.8; 18.9] 68 (51.9)	132	8.4 [5.1; n.c.] 60 (45.5)	1.08 [0.76; 1.53] 0.674
Social functioning	131	5.2 [2.5; 13.2] 72 (55.0)	132	10.4 [4.4; n.c.] 60 (45.5)	1.23 [0.87; 1.73] 0.251
EORTC QLQ-H&N35 – Time to 1st deterioration[b]					
Problems with eating in public	131	28.2 [8.4; n.c.] 53 (40.5)	132	13.6 [10.4; n.c.] 47 (35.6)	1.10 [0.74; 1.64] 0.651
Social interaction problems	131	n.r. 38 (29.0)	132	27.5 [16.4; n.c.] 37 (28.0)	0.90 [0.57; 1.43] 0.658
Decreased sex drive	131	3.7 [2.3; 10.8] 74 (56.5)	132	5.2 [3.4; 8.7] 73 (55.3)	1.09 [0.78; 1.51] 0.675

Side effects

Endpoint	Tislelizumab + gemcitabine + cisplatin		Gemcitabine + cisplatin		Intervention vs control
	N	Median in months [95% CI] *Patients with event n (%)*	N	Median in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Adverse events in total					
	133	0.1 [0.1; 0.1] 133 (100)	130	0.1 [0.1; 0.1] 129 (99.2)	
Serious adverse events (SAEs)					
	133	44.6 [22.7; n.c.] 47 (35.3)	130	n.r. [11.9; n.c.] 46 (35.4)	0.81 [0.54; 1.23] 0.328
Severe adverse events (CTCAE grade 3 or 4)					
	133	0.7 [0.5; 1.0] 113 (85.0)	130	0.7 [0.5; 0.9] 111 (85.4)	1.00 [0.77; 1.30] 0.988
Therapy discontinuation due to adverse events					
	133	n.r. 22 (16.5)	130	n.r. 14 (10.8)	1.29 [0.65; 2.56] 0.469
Specific adverse events					
Immune-mediated AEs (presented additionally)	133	6.2 [4.6; 14.8] 75 (56.4)	130	13.0 [6.7; n.c.] 56 (43.1)	–
Immune-mediated SAEs	133	n.r. 5 (3.8)	130	n.r. 1 (0.8)	4.44 [0.52; 38.04] 0.137
Immune-mediated severe AEs	133	n.r. 7 (5.3)	130	n.r. 1 (0.8)	6.98 [0.86; 56.74] 0.034
Fever (PT, AE)	133	n.r. [34.5; n.c.] 35 (26.3)	130	n.r. 13 (10.0)	2.56 [1.34; 4.88] 0.003

[a] Indication of absolute difference (AD) only in case of statistically significant difference; own calculation

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

[c] Median time [95% CI] to event not meaningfully interpretable. The long median durations of observation shown in the Kaplan-Meier curves occur after a plateau phase, when the number of patients at risk is very low, and are therefore not significant.

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

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; QLQ-C30 = Quality of Life Questionnaire - Core 30; QLQ H&N35 = Quality of Life Questionnaire-Head and Neck-35 Module; vs = versus

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

Adults with recurrent, not amenable to curative surgery or radiotherapy, or metastatic nasopharyngeal carcinoma (NPC); 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 Tevimbra (active ingredient: tislelizumab) at the following publicly accessible link (last access: 10 March 2026):

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

Therapy with tislelizumab 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 training material that contains information for medical professionals and patients (including patient identification card). The training material contains, in particular, instructions on the management of immune-mediated side effects potentially occurring with tislelizumab.

4. Treatment costs

Annual treatment costs:

The costs for the first year of treatment are shown for the cost representation in the resolution.

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tislelizumab in combination with cisplatin and gemcitabine	
Tislelizumab	€ 59,975.02
Cisplatin	€ 788.34
Gemcitabine	€ 2,159.04
Total	€ 62,922.40
Appropriate comparator therapy:	
Cisplatin in combination with gemcitabine	
Cisplatin	€ 788.34
Gemcitabine	€ 2,159.04
Total	€ 2,947.38

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 January 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:					
Tislelizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4 or 8.7	€ 1,740 or € 870
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	6.0	€ 600
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	6.0	€ 1,200
Appropriate comparator therapy:					

Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	6.0	€ 600
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	6.0	€ 1,200

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 curative surgery or radiotherapy, or metastatic nasopharyngeal carcinoma (NPC); first-line treatment

- 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 approved in monotherapy.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between statutory 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 G-BA website on 19 March 2026.

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

Berlin, 19 March 2026

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

Prof. Hecken