Drug assessment at a glance: A26-04[1]

Toripalimab (nasopharyngeal carcinoma)

19 August 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-04. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma in first-line treatment
Intervention	toripalimab in combination with cisplatin and gemcitabine
Comparator	cisplatin in combination with gemcitabine
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	recurrent: ↑↑↑ metastatic: ↔	★
Morbidity	↔	–
Symptoms	↔	–
Health-related quality of life	↔	–
Side effects	recurrent: ↓↓↓ (pneumonia [severe AEs]) metastatic: ↔ (pneumonia [severe AEs])	★
	Ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall:

- Patients with metastatic NPC: no advantage or disadvantage
- Patients with recurrent NPC: a moderate advantage with low informative value

Evidence base and noteworthy aspects

- Evidence base: JUPITER-02 study (completed, double-blind RCT; toripalimab + cisplatin + gemcitabine [N = 146] versus placebo + cisplatin + gemcitabine [N = 143])

- The certainty of conclusions of the results was limited: The JUPITER-02 study was conducted exclusively in Asia, which led to uncertainties as to whether the study results are fully transferable to the German health care context. Furthermore, consolidating locoregional radiotherapy was not permitted during the study.
- For the outcome overall survival, a clear effect modification was observed for the characteristic disease stage (recurrent vs. metastatic).

Key study findings

Study Outcome category Outcome Characteristic Subgroup	toripalimab + cisplatin + gemcitabine N	Median time to event in months [95% CI] Patients with event n (%)	placebo + cisplatin + gemcitabine N	Median time to event in months [95% CI] Patients with event n (%)	toripalimab + cisplatin + gemcitabine vs. placebo + cisplatin + gemcitabine HR [95% CI]; p-value
JUPITER-02					
Mortality (18 November 2022)					
Overall survival	146	NA [38.7; NC] 57 (39.0)	143	33.7 [27.0; 44.2] 76 (53.1)	0.63 [0.45; 0.89]; 0.008
Disease stage					
Recurrent	83	NA [41.5; NC] 28 (33.7)	82	27.4 [21.4; 39.0] 51 (62.2)	0.45 [0.28; 0.71]; < 0.001
Metastatic	63	NA [31.9; NC] 29 (46.0)	61	44.3 [30.3; NC] 25 (41.0)	1.09 [0.64; 1.86]; 0.748
Total					Interaction: 0.010

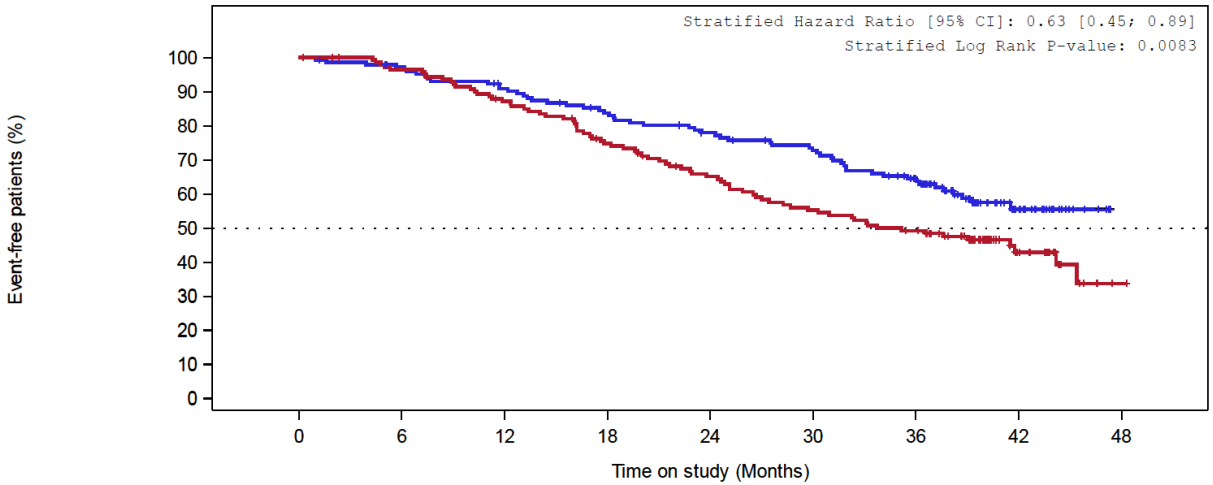
Study Outcome category Outcome Characteristic Subgroup	toripalimab + cisplatin + gemcitabine N	Median time to event in months [95% CI] Patients with event n (%)	placebo + cisplatin + gemcitabine N	Median time to event in months [95% CI] Patients with event n (%)	toripalimab + cisplatin + gemcitabine vs. placebo + cisplatin + gemcitabine HR [95% CI]; p-value
Health-related quality of life (8 June 2021)					
EORTC QLQ-C30 – time to 1st deterioration					
Global health status	145	9.0 [2.9; NC] 67 (46.2)	143	NA [4.0; NC] 63 (44.1)	1.05 [0.75; 1.49]; 0.762
Physical functioning	145	3.0 [2.3; 4.3] 82 (56.6)	143	2.3 [2.1; 3.0] 92 (64.3)	0.85 [0.63; 1.15]; 0.291
Role functioning	145	2.8 [1.4; 4.1] 89 (61.4)	143	2.3 [1.5; 3.3] 91 (63.6)	0.97 [0.72; 1.30]; 0.784
Emotional functioning	145	NA [3.8; NC] 61 (42.1)	143	13.8 [4.3; NC] 60 (42.0)	1.05 [0.73; 1.50]; 0.812
Cognitive functioning	145	3.0 [2.1; 4.4] 91 (62.8)	143	2.9 [2.1; 4.3] 86 (60.1)	1.02 [0.76; 1.37]; 0.926
Social functioning	145	3.9 [2.8; 11.2] 79 (54.5)	143	NA [4.8; NC] 61 (42.7)	1.32 [0.94; 1.85]; 0.108

Study Outcome category Outcome Characteristic Subgroup	toripalimab + cisplatin + gemcitabine N	Median time to event in months [95% CI] Patients with event n (%)	placebo + cisplatin + gemcitabine N	Median time to event in months [95% CI] Patients with event n (%)	toripalimab + cisplatin + gemcitabine vs. placebo + cisplatin + gemcitabine HR [95% CI]; p-value
EORTC QLQ-H&N – time to 1st deterioration					
Problems with social eating	145	8.8 [3.1; NC] 69 (47.6)	143	3.5 [2.3; NC] 74 (51.7)	0.85 [0.61; 1.18]; 0.298
Problems with social contact	145	3.3 [2.2; 9.4] 78 (53.8)	143	2.2 [2.0; 3.5] 90 (62.9)	0.75 [0.55; 1.01]; 0.053
Reduced sexuality	145	3.0 [2.3; 5.3] 80 (55.2)	143	3.5 [2.1; 6.0] 79 (55.2)	1.02 [0.75; 1.40]; 0.904
Side effects (8 May 2022)					
SAEs	146	NA [6.2; NC] 63 (43.2)	143	NA [5.1; NC] 61 (42.7)	0.98 [0.69; 1.39]; 0.897
Severe AEs	146	0.7 [0.4; 0.9] 131 (89.7)	143	0.7 [0.5; 0.8] 129 (90.2)	1.04 [0.82; 1.33]; 0.739
Discontinuation due to AEs				No suitable data	
Immune-mediated AEs (supplementary information)				No suitable data	
Immune-mediated SAEs				No suitable data	
Immune-mediated severe AEs				No suitable data	

Study Outcome category Outcome Characteristic Subgroup	toripalimab + cisplatin + gemcitabine N	 Median time to event in months [95% CI] Patients with event n (%)	placebo + cisplatin + gemcitabine N	 Median time to event in months [95% CI] Patients with event n (%)	toripalimab + cisplatin + gemcitabine vs. placebo + cisplatin + gemcitabine HR [95% CI]; p-value
Pneumonia (PT, severe AEs)	146	NA 17 (11.6)	143	NA 5 (3.5)	3.29 [1.21; 8.97]; 0.014
Disease stage					
Recurrent	83	NA 13 (15.7)	82	NA 1 (1.2)	13.0 [1.69; 99.46]; 0.001
Metastatic	63	NA 4 (6.3)	61	NA 4 (6.6)	0.85 [0.21; 3.48]; 0.825
Total					Interaction: 0.034

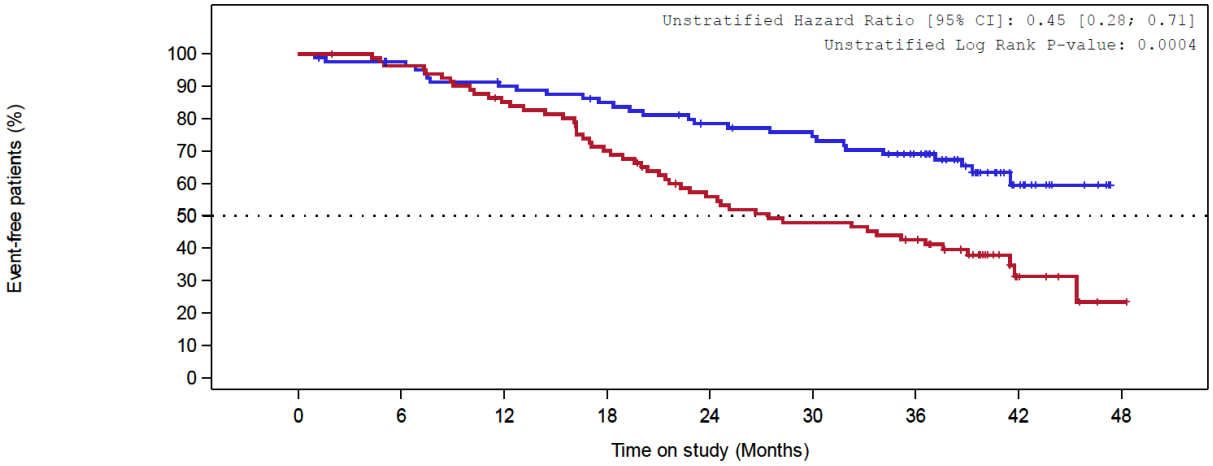
Kaplan-Meier curves on overall survival

Total population



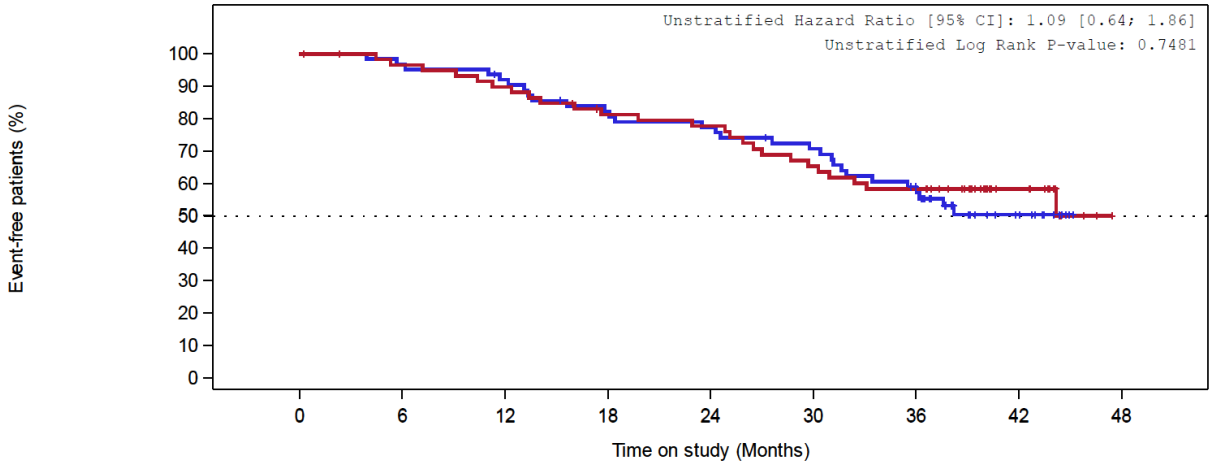
N at risk (% censored)									
Placebo + Chemotherapy	143 (-)	135 (2%)	121 (1%)	102 (2%)	86 (3%)	73 (0%)	64 (1%)	21 (59%)	1 (86%)
Toripalimab + Chemotherapy	146 (-)	139 (2%)	128 (1%)	116 (2%)	106 (2%)	97 (2%)	79 (7%)	25 (58%)	0 (100%)

Subgroup disease stage: recurrent



N at risk (censored)									
Placebo + Chemotherapy	82 (-)	78 (1%)	68 (1%)	56 (0%)	42 (5%)	36 (0%)	31 (3%)	7 (61%)	1 (71%)
Toripalimab + Chemotherapy	83 (-)	78 (4%)	71 (1%)	66 (1%)	59 (3%)	55 (2%)	46 (9%)	13 (63%)	0 (100%)

Subgroup disease stage: metastatic



N at risk (censored)									
Placebo + Chemotherapy	61 (-)	57 (3%)	53 (0%)	46 (4%)	44 (0%)	37 (0%)	33 (0%)	14 (58%)	0 (93%)
Toripalimab + Chemotherapy	63 (-)	61 (0%)	57 (2%)	50 (2%)	47 (0%)	42 (2%)	33 (5%)	12 (52%)	0 (100%)

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Toripalimab (Nasopharynxkarzinom); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 15.07.2026]. URL: https://doi.org/10.60584/A26-04.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Toripalimab (Rezidiviertes oder metastasiertes Nasopharynxkarzinom (NPC), Erstlinie, Kombination mit Cisplatin und Gemcitabin) [online]. 2026 [Accessed: 15.07.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1304/#nutzenbewertung.

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