Drug assessment at a glance: A25-154[1]

Nivolumab (urothelial carcinoma, adjuvant)

26 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 A25-154. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adults with muscle invasive urothelial carcinoma with tumour cell PD-L1 expression ≥ 1% and a high risk of recurrence after undergoing radical resection, for whom cisplatin-containing therapy is not suitable or who have already received neoadjuvant treatment with cisplatin
Intervention	nivolumab as monotherapy, adjuvant treatment
Comparator	Watchful waiting
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	ø	–
Morbidity	Men: ↑↑ (failure to cure) Women: ↔ (failure to cure) ↑ (health status)	★
Symptoms	↔	–
Health-related quality of life	↔	–
Side effects	↓↓↓	★
	ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall:

- Men: a small advantage with low informative value
- Women: no advantage or disadvantage

Evidence base and noteworthy aspects

- Evidence base: CA209-274 study (an ongoing, double-blind RCT comparing nivolumab with placebo; relevant subpopulation comprising 140 patients in the nivolumab arm and 142 patients in the placebo arm)

- Uncertainties regarding the allocation of patients who refused adjuvant cisplatin-containing chemotherapy to the given research question
- Overall survival not interpretable due to inadequate subsequent therapies

Key study findings

Study Outcome category Outcome	nivolumab N	nivolumab Median time to event in months [95% CI] Patients with event n (%)	placebo N	placebo Median time to event in months [95% CI] Patients with event n (%)	nivolumab vs. placebo HR [95% CI]; p-value
CA209-274 (data cut-off: 06 January 2025)					
Mortality					
Overall survival	No suitable data				
Morbidity					
Failure of curative treatment					
Event rate	140	– 68 (48.6)	142	– 92 (64.8)	RR: 0.75 [0.61; 0.92]; 0.006
DFS	140	55.49 [25.79; 66.50] 68 (48.6)	142	8.41 [5.59; 20.04] 92 (64.8)	0.57 [0.42; 0.79]; < 0.001
Health status (time to first deterioration)					
EQ-5D VAS	127	25.13 [12.02; 63.61] 68 (53.5)	129	9.43 [5.88; 17.25] 80 (62.0)	0.63 [0.45; 0.87]; 0.025

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Health-related quality of life					
EORTC QLQ-C30 (time to first deterioration)					
Global health status	123	9.95 [6.93; NC] 57 (46.3)	127	10.51 [5.59; NC] 64 (50.4)	0.94 [0.66; 1.36]; 0.747
Physical functioning	123	16.43 [8.84; NC] 48 (39.0)	128	NA [9.20; NC] 54 (42.2)	0.84 [0.57; 1.25]; 0.395
Role functioning	123	8.31 [4.63; 12.75] 68 (55.3)	128	5.55 [4.04; 11.73] 70 (54.7)	0.93 [0.66; 1.30]; 0.656
Emotional functioning	123	NA [15.24; NC] 46 (37.4)	127	12.91 [7.16; NC] 55 (43.3)	0.78 [0.53; 1.16]; 0.218
Cognitive functioning	123	7.66 [4.67; 15.77] 64 (52.0)	127	8.61 [4.86; NC] 64 (50.4)	1.01 [0.71; 1.43]; 0.973
Social functioning	122	15.64 [6.47; NC] 55 (45.1)	126	NA [7.56; NC] 52 (41.3)	1.06 [0.72; 1.55]; 0.766

Study Outcome category Outcome	nivolumab N	nivolumab Median time to event in months [95% CI] Patients with event n (%)	placebo N	placebo Median time to event in months [95% CI] Patients with event n (%)	nivolumab vs. placebo HR [95% CI]; p-value
Side effects					
AEs (supplementary information)	139	0.49 [0.33; 0.49] 138 (99.3)	139	0.59 [0.49; 0.85] 133 (95.7)	–
SAEs	139	NA [14.23; NC] 51 (36.7)	139	NA [9.53; NC] 57 (41.0)	0.83 [0.57; 1.21]; 0.327
Severe AEs	139	9.49 [6.11; NC] 74 (53.2)	139	15.01 [8.41; NC] 61 (43.9)	1.23 [0.88; 1.73]; 0.235
Discontinuation due to AEs	139	NA 30 (21.6)	139	NA 15 (10.8)	1.94 [1.05; 3.62]; 0.033
Immune-mediated SAEs	139	NA 16 (11.5)	139	NA 6 (4.3)	2.49 [0.97; 6.37]; 0.049
Immune-mediated severe AEs	139	NA 27 (19.4)	139	NA 9 (6.5)	2.89 [1.36; 6.14]; 0.004

References

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English translations for this project are published at https://www.iqwig.de/en/projects/a25-154.html and https://www.iqwig.de/en/projects/a26-45.html.

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