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Drug assessment at a glance: A26-11[1]

Teplizumab
(type 1 diabetes mellitus, stage 2, ≥ 8 years)

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 A26-11. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adult and paediatric patients 8 years of age and older with stage 2 type 1 diabetes mellitus, who do not (yet) have clinically manifest type 1 diabetes mellitus, but who do have persistent autoantibodies in conjunction with a fasting plasma glucose level between 100 and 125 mg/dL or an HbA1c value between 5.7% and 6.4%, to delay the onset of stage 3
Intervention	teplizumab
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	↔	–
Morbidity	↔ (manifestation of type 1 diabetes mellitus)	–
Symptoms	ø	–
Health-related quality of life	ø	–
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:

- Patients with a family history: no advantage or disadvantage
- Patients without a family history: no advantage or disadvantage (no data)

Evidence base and noteworthy aspects

- Evidence base: Study TN-10, a double-blind RCT comparing teplizumab (N = 44) with placebo or watchful waiting (N = 32)

- The study population was restricted to individuals with stage 2 type 1 diabetes mellitus and a family history of the condition.
- Teplizumab was administered in a formulation differing from the authorized market product, which, due to a different dosing regimen, resulted in a 20% lower cumulative dose.
- Criteria not recommended by guidelines, amongst others, were used to diagnose stage 2 following an oral glucose tolerance test. It is unclear what proportion of participants were included in the TN-10 study in this way.
- For the outcome manifestation of type 1 diabetes mellitus, teplizumab demonstrated an advantage, with a median delay in onset of 2 years. However, it is unclear to what extent this delay has a positive effect on the long-term course of the disease (particularly the occurrence of micro- and macrovascular late complications). The potential effects of the delay on health-related quality of life and symptoms were not recorded.

- The observed disadvantage in the side effects category was not sufficient to justify an overall lesser benefit of teplizumab, as it was not clear what effects teplizumab has on morbidity and health-related quality of life.

Key study findings

Study Outcome category Outcome	teplizumab N	teplizumab 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 (%)	teplizumab vs. placebo HR [95% CI]; p-value
TN-10					
Mortality					
All-cause mortality	44	NA 0 (0)	32	NA 0 (0)	–
Morbidity					
Manifestation of type 1 diabetes mellitus	44	49.5 [32.2; NC] 20 (45.5)	32	24.9 [9.5; 48.6] 23 (71.9)	0.41 [0.22; 0.78]; 0.007
Health-related quality of life	No suitable data available				
Side effects					
AEs (supplementary information)	44	ND 43 (97.7)	32	ND 22 (68.8)	–
SAEs	44	61.1 [61.1; NC] 7 (15.9)	32	NA 1 (3.1)	4.76 [0.57; 39.76]; 0.112
Severe AEs	44	0.7 [0.1; NC] 26 (59.1)	32	NA [26.0; NC] 3 (9.4)	8.24 [2.48; 27.36]; < 0.001

Study Outcome category Outcome	teplizumab N	teplizumab 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 (%)	teplizumab vs. placebo HR [95% CI]; p-value
Discontinuation due to AEs	44	– 1 (2.3)	32	– 2 (6.3)	RR: 0.36 [0.03; 3.99]; 0.408
Infections (AEs)	44	27.2 [15.8; 42.5] 23 (52.3)	32	25.3 [16.9; NC] 8 (25.0)	1.43 [0.63; 3.24]; 0.390
Infections (SAEs)	44	61.1 [61.1; NC] 4 (9.1)	32	NA 0 (0)	RR: 6.66 [0.37; 118.40]; 0.092
Skin and subcutaneous tissue disorders (SOC, AEs)	44	57.8 [0.5; NC] 20 (45.5)	32	NA [44.8; NC] 3 (9.4)	6.52 [1.92; 22.09]; < 0.001
Lymphopenia (PT, severe AEs)	44	NA [0.1; NC] 21 (47.7)	32	NA 0 (0)	RR: 31.53 [1.98; 502.04]; < 0.001

References

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English translations for this project are published at https://www.iqwig.de/en/projects/a26-11.html and https://www.iqwig.de/en/projects/a26-73.html.

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