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
Teplizumab (type 1 diabetes mellitus, ≥ 8 years)

From 6 August 2026

At their session on 6 August 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 teplizumab shall be added in alphabetical order as follows:

Teplizumab

Resolution of: 6 August 2026
Entry into force on: 6 August 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 8 January 2026):

Teizeild is indicated to delay the onset of stage 3 type 1 diabetes (T1D) in adult and paediatric patients 8 years of age and older with stage 2 T1D.

Therapeutic indication of the resolution (resolution of 6 August 2026):

See therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

Adults and children 8 years of age and older with stage 2 type 1 diabetes mellitus (T1D), who do not (yet) have clinically manifest T1D; for delaying the onset of stage 3 T1D

Appropriate comparator therapy:

- Monitoring wait-and-see approach

Extent and probability of the additional benefit of teplizumab over the monitoring wait-and-see approach:

Hint of a non-quantifiable additional benefit.

Study results according to endpoints:[1]

Adults and children 8 years of age and older with stage 2 type 1 diabetes mellitus (T1D), who do not (yet) have clinically manifest T1D; for delaying the onset of stage 3 T1D

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No deaths occurred.
Morbidity	↑	Advantage in the time to onset of type 1 diabetes mellitus.
Health-related quality of life	∅	No data available.
Side effects	↓	Disadvantage in the endpoint of severe AEs (CTCAE grade ≥ 3).
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		

TN-10 study: RCT, treatment with teplizumab versus placebo over a 14-day period; follow-up until the endpoint "onset of type 1 diabetes mellitus" is reached or until the end of the study (the study will end when 40 subjects have reached this endpoint)

Mortality

Endpoint	Teplizumab		Placebo		Teplizumab vs placebo
	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[a]
Overall mortality					
	44	n.r. 0 (0)	32	n.r. 0 (0)	–

[1] Data from the dossier assessment of the IQWiG (A26-11) and from the addendum (A26-73), unless otherwise indicated.

Morbidity

Endpoint	Teplizumab		Placebo		Teplizumab vs Placebo
	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[b] *Absolute difference[d] (AD)*
Time to onset of type 1 diabetes mellitus[c]					
	44	49.5 [32.2; n.c.] 20 (45.5)	32	24.9 [9.5; 48.6] 23 (71.9)	0.41 [0.22; 0.78]; 0.007 *AD: 24.6 months*

Health-related quality of life

The endpoint health-related quality of life was not collected in the TN-10 study.

Side effects

Endpoint	Teplizumab		Placebo		Teplizumab vs Placebo
	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[a] *Absolute difference[d] (AD)*
Total adverse events (AEs) *(presented additionally)*					
	44	n.d. 43 (97.7)	32	n.d. 22 (68.8)	–
Serious adverse events (SAEs)					
	44	61.1 [61.1; n.c.] 7 (15.9)	32	n.r. 1 (3.1)	4.76 [0.57; 39.76]; 0.112
Severe adverse events (CTCAE grade ≥ 3)					
	44	0.7 [0.1; n.c.] 26 (59.1)	32	n.r. [26.0; n.c.] 3 (9.4)	8.24 [2.48; 27.36]; < 0.001 *AD: 49.7%*

Therapy discontinuation due to adverse events					
	44	– 1 (2.3)	32	– 2 (6.3)	RR[e]: 0.36 [0.03; 3.99]; 0.408
Specific adverse events					
Infections and infestations (SOC, AE)					
	44	27.2 [15.8; 42.5] 23 (52.3)	32	25.3 [16.9; n.c.] 8 (25.0)	1.43 [0.63; 3.24]; 0.390
Serious infections and infestations (SOC, SAE)					
	44	61.1 [61.1; n.c.] 4 (9.1)	32	n.r. 0 (0)	RR[f]: 6.66 [0.37; 118.40] 0.092
Skin and subcutaneous tissue disorders (SOC, AE)					
	44	57.8 [0.5; n.c.] 20 (45.5)	32	n.r. [44.8; n.c.] 3 (9.4)	6.52 [1.92; 22.09]; < 0.001 *AD: 36.1%*
Severe lymphopenia (PT, AE) (CTCAE grade ≥ 3)					
	44	n.r. [0.1; n.c.] 21 (47.7)	32	n.r. 0 (0)	RR[f]: 31.53 [1.98; 502.04]; < 0.001 *AD: 47.7%*

a. Effect and CI: Cox proportional hazards model; p value: unstratified log-rank test.
b. Cox proportional hazards model, stratified by age and confirmatory status of the oral glucose tolerance test (oGTT) (age < 18 years with a confirmed abnormal oGTT vs age < 18 years with an unconfirmed abnormal oGTT vs age ≥ 18 years with a confirmed abnormal OGTT).
c. The diagnosis was made on the basis of one of the following criteria: severe hyperglycaemia with acute metabolic decompensation (diabetic ketoacidosis), clinical symptoms of type 1 diabetes mellitus (polyuria, polydipsia and unexplained weight loss) and a random (i.e. regardless of the time since the last meal) plasma glucose concentration ≥ 200 mg/dl (11.1 mmol/l), a fasting plasma glucose level ≥ 126 mg/dl (7.0 mmol/l) or a 2-hour plasma glucose level ≥ 200 mg/dl (11.1 mmol/l); results for the individual criteria are not available.
d. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation.
e. According to the pharmaceutical company, the results are based on a logistic regression model.
f. Results of time-to-event analyses in the case of zero events in a study arm are unsuitable for assessment, as no appropriate method for estimating the HR was used. RR serves as a surrogate endpoint when time-to-event analyses are either unavailable or unsuitable. IQWiG calculation of RR, 95% CI (asymptotic) and p value (unconditional exact test, CSZ method).

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; n.d.: no data available; 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; PT = preferred term; RR = relative risk; SOC = system organ class; SAE = serious adverse event; AE= adverse event; vs = versus

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

Adults and children 8 years of age and older with stage 2 type 1 diabetes mellitus (T1D), who do not (yet) have clinically manifest T1D; for delaying the onset of stage 3 T1D

Approx. 57,000 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 Teizeild (active ingredient: teplizumab) at the following publicly accessible link (last access: 18 June 2026):

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

Treatment with teplizumab should be initiated and monitored by experienced specialists.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient card). The training material contains, in particular, information and warnings about possible serious side effects of teplizumab: Cytokine release syndrome, lymphopenia and serious infections.

4. Treatment costs

Annual treatment costs:

Adults and children 8 years of age and older with stage 2 type 1 diabetes mellitus (T1D), who do not (yet) have clinically manifest T1D; for delaying the onset of stage 3 T1D

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Teplizumab	€ 160,269.06
Appropriate comparator therapy:	
Monitoring wait-and-see approach	Not calculable

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 June 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
Teplizumab	Surcharges for the preparation of parenteral solutions with monoclonal antibodies	€ 100	1	14	€ 1,400

II. The resolution will enter into force on the day of its publication on the G-BA website on 6 August 2026.

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

Berlin, 6 August 2026

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

Dr Optendrenk