Drug assessment at a glance: A26-18[1]

Teprotumumab (thyroid eye disease)

24 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 A26-18. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Adults with moderate to severe thyroid eye disease in the acute disease phase receiving first-line treatment
Intervention	teprotumumab
Comparator	Individualized treatment from a choice of: ▪ methylprednisolone ▪ methylprednisolone in combination with mycophenolate mofetil
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 1

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects – research question 1

- No relevant study was identified.

Research question 2 of the benefit assessment

Population	Adults with moderate to severe thyroid eye disease in the acute disease phase who are eligible for second-line treatment
Intervention	teprotumumab
Comparator	Individualized treatment from a choice of: ▪ methylprednisolone ▪ glucocorticoids in combination with orbital radiotherapy, cyclosporine or azathioprine ▪ rituximab (monotherapy)
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 2

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects – research question 2

- No relevant study was identified.

Research question 3 of the benefit assessment

Population	Adults with moderate to severe thyroid eye disease in the chronic disease phase
Intervention	teprotumumab
Comparator	watchful waiting
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 3

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects – research question 3

- No suitable data were available. The data on the total population from the HZNP-TEP-403 study (a 2-arm RCT comparing teprotumumab with placebo in patients with chronic thyroid eye disease) were unsuitable.
- It was assumed that fewer than 80% of the patients included in the study had moderate to severe thyroid eye disease as per the definition from the 2021 European Group on Graves' orbitopathy guidelines, and therefore did not correspond to the research question.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Teprotumumab (endokrine Orbitopathie); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 20.08.2026]. URL: https://doi.org/10.60584/A26-18.

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English translations for this project are published at https://www.iqwig.de/en/projects/a26-18.html and https://www.iqwig.de/en/projects/a26-80.html.

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