Drug assessment at a glance: A26-56[1]

Marstacimab (haemophilia B, with factor IX inhibitors)

2 November 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 A26-56. The GBA decides on the added benefit.

Research question for the benefit assessment

Population	Routine prophylaxis of bleeding episodes in patients 12 years of age and older, weighing at least 35 kg, with haemophilia B (congenital factor IX deficiency) with factor IX inhibitors
Intervention	marstacimab
Comparator	Individualised treatment, selecting from ▪ On-demand treatment with a product with bypassing activity (human plasma fraction enriched with factor VIII inhibitor bypassing activity) ▪ On-demand treatment with eptacog alfa ▪ Routine prophylaxis with recombinant or human plasma-derived factor IX products ▪ concizumab
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	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

- No suitable data were available.
- The intra-individual before-and-after comparison in the BASIS study did not allow for a comparison with the comparator therapy.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Marstacimab (Hämophilie B, mit Faktor-IX-Inhibitoren); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 01.09.2026]. URL: https://doi.org/10.60584/A26-56.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Marstacimab (Nutzenbewertungsverfahren zum Wirkstoff Marstacimab (Neues Anwendungsgebiet: Hämophilie B, ≥ 12 Jahre, mit Faktor IX-Inhibitoren) [online]. 2026 [Accessed: 01.09.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1357/.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-56.html.

Publisher details

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