Drug assessment at a glance: A25-157[1]

Iptacopan (complement 3 glomerulopathy)

25 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 A25-157. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adults with complement 3 glomerulopathy
Intervention	iptacopan
Comparator	mycophenolate mofetil in combination with corticosteroids
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

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

Overall: No advantage or disadvantage

Evidence base and noteworthy aspects

- Evidence base: the completed double-blind RCT APPEAR-C3G comparing iptacopan with placebo (relevant subpopulation: patients who received mycophenolate mofetil and glucocorticoids as prior and concomitant therapy [N = 9 per study arm])

- It was only possible to assess iptacopan as an add-on therapy to ongoing treatment with mycophenolate mofetil and glucocorticoids on the basis of the pretreated subpopulation.
- An uncertainty remained as to whether, given a study duration of 6 months, results relating to patient-relevant outcomes can be meaningfully interpreted.

Key study findings

Study Outcome category Outcome	iptacopan + mycophenolate mofetil + glucocorticoids		placebo + mycophenolate mofetil + glucocorticoids		iptacopan vs. placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p-value
APPEAR-C3G					
Mortality					
All-cause mortality	9	0 (0)	9	0 (0)	–
Side effects					
SAEs	9	1 (11.1)	9	1 (11.1)	1.00 [0.07; 13.64]; > 0.999
Discontinuation due to AEs	9	0 (0)	9	0 (0)	–

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Iptacopan (Komplement-3-Glomerulopathie); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 10.06.2026]. URL: https://doi.org/10.60584/A25-157.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Iptacopan (Neubewertung Orphan > 30 Mio: Komplement-3-Glomerulopathie) [online]. 2026 [Accessed: 10.06.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1289/.

English translations for this project are published at https://www.iqwig.de/en/projects/a25-157.html.

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