Drug assessment at a glance: A25-137[1]

Avapritinib (advanced systemic mastocytosis)

20 July 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 A25-137. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated haematological neoplasm (SM-AHN) or mast cell leukaemia (MCL), after at least one systemic therapy
Intervention	avapritinib
Comparator	Individualized treatment from a choice of ▪ midostaurin ▪ cladribine (only for patients previously treated with midostaurin) and ▪ imatinib (only for patients previously treated with midostaurin and without KIT D816V mutation or with unknown KIT mutation status, as well as for patients previously treated with midostaurin and with presence of eosinophilia with FIP1L1-PDGFRA fusion gene)
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 data presented on the single-arm studies PATHFINDER and EXPLORER were not suitable, as they did not allow a comparison of avapritinib with the comparator therapy.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Avapritinib (fortgeschrittene systemische Mastozytose); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 09.07.2026]. URL: https://doi.org/10.60584/A25-137.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Avapritinib (Neubewertung Orphan > 30 Mio: fortgeschrittene systemische Mastozytose, nach mind. 1 Vortherapie) [online]. 2026 [Accessed: 09.07.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1273/.

English translations for this project are published at https://www.iqwig.de/en/projects/a25-137.html.

Publisher details

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