

Drug assessment at a glance: A25-139¹

Momelotinib (myelofibrosis)

10 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 A25-139. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and who are JAK inhibitor naive
Intervention	momelotinib
Comparator	<ul style="list-style-type: none">▪ ruxolitinibor▪ fedratinib
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	↓↓,↑↑	★
	<div> <div>∅</div> <div>↔</div> <div>↑ / ↓</div> <div>↑↑ / ↓↓</div> <div>↑↑↑ / ↓↓↓</div> </div> <div> <div>No (suitable) data</div> <div>No advantage or disadvantage</div> <div>Small advantage/disadvantage</div> <div>Moderate advantage/disadvantage</div> <div>Large advantage/disadvantage</div> </div>	<div>–</div> <div>★</div> <div>★★</div> <div>★★★</div> <div>Not applicable</div> <div>Low</div> <div>Moderate</div> <div>High</div>

Overall: No advantage or disadvantage

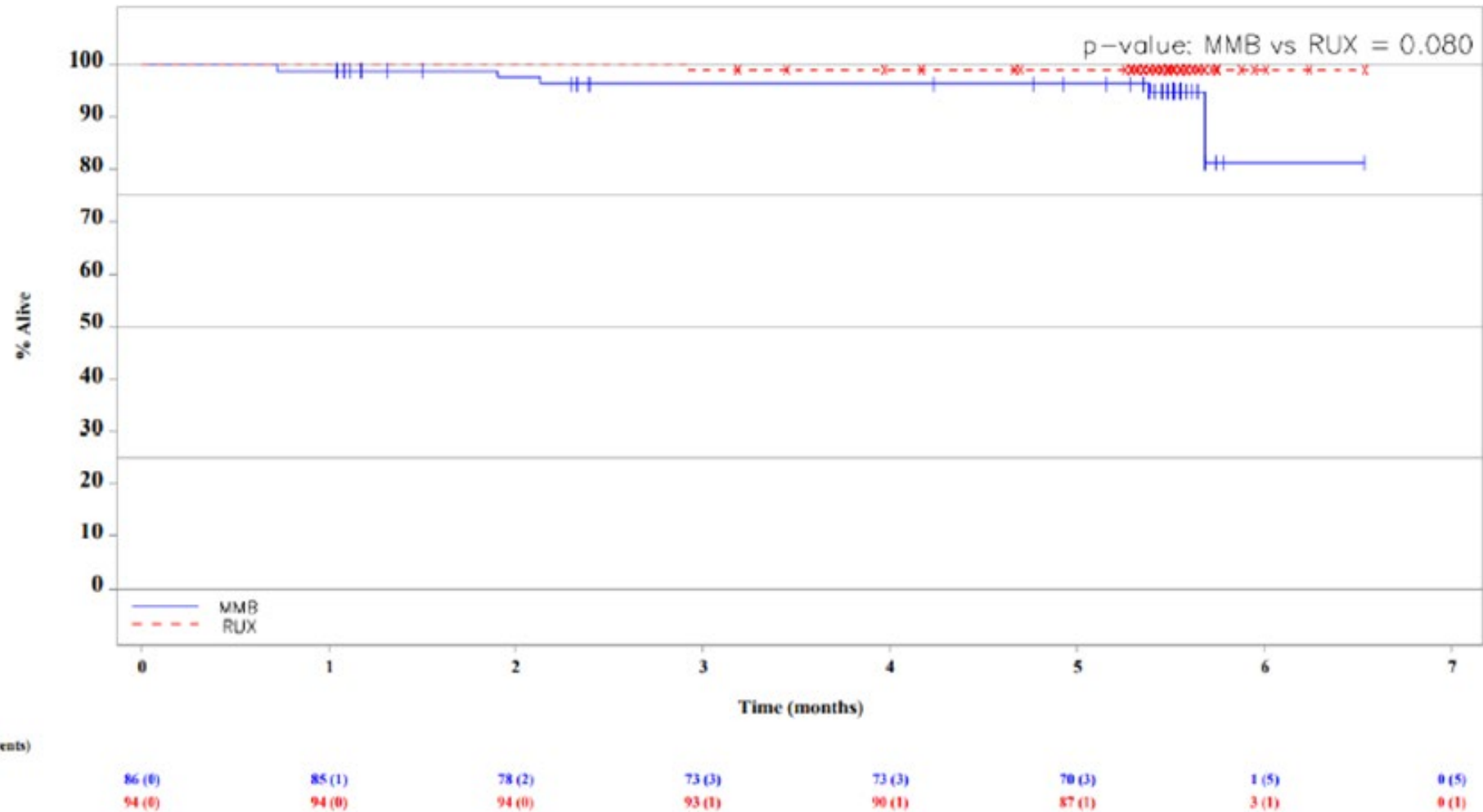
Evidence base and noteworthy aspects – research question 1

- Evidence base: the SIMPLIFY-1 double-blind RCT (relevant subpopulation: momelotinib [N = 86] vs. ruxolitinib [N = 94]) with a standard treatment and observation period of 24 weeks
- Primary outcome: *spleen response at Week 24* (rated as not patient-relevant in the given operationalization)
- Primary objective in this therapeutic indication: long-term avoidance of transfusions
 - Transfusion avoidance for 24 weeks is considered sufficient to assume long-term avoidance; however, the observed effects are non-quantifiable:
 - An initial increase in the transfusion burden followed by a decrease in the ruxolitinib arm → it is unclear whether the observed effects in favour of momelotinib versus ruxolitinib persist in the long term
 - It is unclear whether late complications arising from transfusions can actually be avoided, as it can be assumed that patients will routinely require transfusions as their condition progresses
- Use of ESAs as a supportive treatment for anaemia was prohibited + lack of an option of reduced starting dose of ruxolitinib in the control arm → reduced informative value of the effects

Key study findings – research question 1

Study	momelotinib		ruxolitinib		momelotinib vs. ruxolitinib
	N	Patients with event n (%)	N	Patients with event n (%)	
Outcome category					RR [95% CI]; p-value ^b
Outcome					
Timepoint					
SIMPLIFY-1					
Morbidity					
Transfusion avoidance	86	33 (38.4)	94	19 (20.2)	2.13 [1.33; 3.33]; 0.001
Health-related quality of life					
SF-36v2 – improvement at Week 24					
Physical Component Summary (PCS)	86	13 (15.1)	94	9 (9.6)	1.49 [0.68; 3.33]; 0.32
Mental Component Summary (MCS)	86	6 (7.0)	94	10 (10.6)	0.66 [0.25; 1.73]; 0.531
Side effects					
AEs (supplementary information)	86	81 (94.2)	94	91 (96.8)	–
SAEs	86	26 (30.2)	94	23 (24.5)	1.24 [0.77; 1.99]; 0.53
Severe AEs	86	42 (48.8)	94	52 (55.3)	0.88 [0.67; 1.17]; 0.53
Discontinuation due to AEs	86	17 (19.8)	94	5 (5.3)	3.72 [1.43; 9.64]; 0.003
Peripheral neuropathy				No suitable data	
Anaemia (PT, severe AEs)	86	10 (11.6)	94	26 (27.7)	0.42 [0.22; 0.82]; 0.007

Kaplan-Meier curves on overall survival – research question 1



Research question 2 of the benefit assessment

Population	Adults with moderate to severe anaemia who have primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis and have been treated with ruxolitinib
Intervention	momelotinib
Comparator	fedratinib
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	–	Not applicable
	↔	No advantage or disadvantage	★	Low
	↑ / ↓	Small advantage/disadvantage	★★	Moderate
	↑↑ / ↓↓	Moderate advantage/disadvantage	★★★	High
	↑↑↑ / ↓↓↓	Large advantage/disadvantage		

Overall: No advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects – research question 2

- No suitable studies to answer the research question

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Wirkstoff (Anwendungsgebiet); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2025 [Accessed: 13.05.2026]. URL: <https://doi.org/10.60584/A25-139>.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Momelotinib (Myelofibrose) [online]. 2026 [Accessed: 13.05.2026]. URL: <https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1277/>.

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