Drug assessment at a glance: A26-53[1]

Asciminib (CML, T315I mutation, previously treated)

4 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 A26-53. The GBA decides on the added benefit.

Research question for the benefit assessment

Population	Adult patients with Ph+ CML-CP with the T315I mutation who are resistant to, intolerant to or ineligible for ponatinib
Intervention	asciminib
Comparator	best supportive care
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	–	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

- No suitable data were available.
- The non-comparative CABL001X2101 study in adult patients with CML, including a subpopulation covered by the therapeutic indication with Ph+ CML-CP with the T315I mutation, did not allow for a comparison with the appropriate comparator therapy.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Asciminib (CML, T315I-Mutation, vorbehandelt); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 02.11.2026]. URL: https://doi.org/10.60584/A26-53.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Asciminib (Neues Anwendungsgebiet: Chronische myeloische Leukämie, Ph+, CML-CP mit T315I-Mutation, vorbehandelt) [online]. 2026 [Accessed: 02.11.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1344/.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-53.html.

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