Drug assessment at a glance: A26-20[1]

Ivosidenib (cholangiocarcinoma)

4 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 A26-20. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1-R132 mutation who were previously treated by at least one prior line of systemic therapy
Intervention	ivosidenib
Comparator	Individualized treatment from a choice of ▪ folinic acid in combination with 5-fluorouracil and oxaliplatin (FOLFOX; only suitable for patients without an FGFR2 fusion, FGFR2 rearrangement, MSI-H or dMMR), ▪ pemigatinib (only suitable for patients with an FGFR2 fusion or an FGFR2 rearrangement), ▪ futibatinib (only suitable for patients with an FGFR2 fusion or an FGFR2 rearrangement), ▪ pembrolizumab (only suitable for patients with MSI-H or dMMR) and ▪ 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.
- There is a randomized controlled trial, ClarIDHy, comparing ivosidenib versus placebo. In the study, the treatment in the comparator arm did not correspond to the appropriate comparator therapy specified by the G-BA. Consequently, the study was not suitable for drawing conclusions about the added benefit of ivosidenib compared to the G-BA's appropriate comparator therapy.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Ivosidenib (Cholangiokarzinom); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 22.07.2026]. URL: https://doi.org/10.60584/A26-20.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Ivosidenib (Neubewertung Orphan > 30 Mio: Cholangiokarzinom mit IDH1-R132-Mutation, nach mind. 1 Vortherapie) [online]. 2026 [Accessed: 22.07.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1322/.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-20.html.

Publisher details

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