Drug assessment at a glance: A25-159[1]

Selpercatinib (RET fusion-positive NSCLC, first line)

26 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 A25-159. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor, with PD-L1 expression ≥ 50% of tumour cells
Intervention	selpercatinib
Comparator	▪ pembrolizumab as monotherapy, or ▪ atezolizumab as monotherapy, or ▪ cemiplimab as monotherapy, or ▪ nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only an option for patients with ECOG PS 0–1), or ▪ pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only an option for patients with ECOG PS 0–1), or ▪ atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only an option for patients with ECOG PS 0–1), or ▪ atezolizumab in combination with nab-paclitaxel and carboplatin (only an option for patients with ECOG PS 0–1), or ▪ cemiplimab in combination with platinum-based chemotherapy (only an option for patients with ECOG PS 0–1), or ▪ durvalumab in combination with tremelimumab and platinum-based chemotherapy (only an option for patients with ECOG PS 0–1)
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	∅	–
	∅ 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 – research question 1

- Evidence base: LIBRETTO-431 study
- The study results were not assessed, as the pharmaceutical company did not provide analyses for all relevant outcomes for the relevant data cut of the LIBRETTO-431 study.

Research question 2 of the benefit assessment

Population	Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor, with PD-L1 expression < 50% of tumour cells
Intervention	selpercatinib
Comparator	Individualized treatment from a choice of ▪ pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy ▪ atezolizumab as monotherapy ▪ atezolizumab in combination with bevacizumab, paclitaxel and carboplatin ▪ atezolizumab in combination with nab-paclitaxel and carboplatin ▪ nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy ▪ cemiplimab in combination with platinum-based chemotherapy ▪ durvalumab in combination with tremelimumab and platinum-based chemotherapy ▪ carboplatin in combination with a third-generation cytostatic agent ▪ carboplatin in combination with nab-paclitaxel
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 ↔ 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 – research question 2

- Evidence base: LIBRETTO-431 study
- The study results were not assessed, as the pharmaceutical company did not provide analyses for all relevant outcomes for the relevant data cut of the LIBRETTO-431 study.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Selpercatinib (RET-Fusions-positives NSCLC, Erstlinie); Nutzenbewertung gemäß § 35a SGB V (Ablauf Befristung); Dossierbewertung [online]. 2026 [Accessed: 24.06.2026]. URL: https://doi.org/10.60584/A25-159.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Selpercatinib (Neubewertung nach Fristablauf: Nicht-kleinzelliges Lungenkarzinom, RET-Fusion+, Erstlinie) [online]. 2026 [Accessed: 07.05.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1301/.

English translations for this project are published at https://www.iqwig.de/en/projects/a25-159.html.

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