

Resolution

of the Federal Joint Committee on an Amendment of the
Pharmaceuticals Directive:

Annex XII – Benefit Assessment of Medicinal Products with
New Active Ingredients according to Section 35a (SGB V)
Futibatinib (cholangiocarcinoma, with FGFR2 fusion or FGFR2
rearrangement, after at least 1 prior therapy)

of 22 November 2024

At its session on 22 November 2024, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

- I. **Annex XII shall be amended in alphabetical order to include the active ingredient Futibatinib as follows:**

Futibatinib

Resolution of: 22 November 2024
Entry into force on: 22 November 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 4 July 2023):

Lytgobi monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Therapeutic indication of the resolution (resolution of 22 November 2024):

See therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

Adults with locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or FGFR2 rearrangement; after at least one prior line of systemic therapy

Appropriate comparator therapy for futibatinib as monotherapy:

- Pemigatinib

Extent and probability of the additional benefit of futibatinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:¹

Adults with locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or FGFR2 rearrangement; after at least one prior line of systemic therapy

There are no assessable data.

¹ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-66) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

Adults with locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or FGFR2 rearrangement; after at least one prior line of systemic therapy

Approx. 27 – 229 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Lytgobi (active ingredient: futibatinib) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 30 October 2024):

https://www.ema.europa.eu/en/documents/product-information/lytgobi-epar-product-information_en.pdf

Treatment with futibatinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, internal medicine and gastroenterology, and specialists participating in the Oncology Agreement experienced in the treatment of adults with cholangiocarcinoma.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

4. Treatment costs

Annual treatment costs:

Adults with locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or FGFR2 rearrangement; after at least one prior line of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Futibatinib	€ 146,031.29
Appropriate comparator therapy:	
Pemigatinib	€ 122,533.41

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2024)

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adults with locally advanced or metastatic cholangiocarcinoma with FGFR2 fusion or FGFR2 rearrangement; after at least one prior line of systemic therapy

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 22 November 2024.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 22 November 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken