Gemeinsamer Bundesausschuss

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
Ivosidenib (reassessment of an orphan drug after exceeding the EUR 30 million limit: cholangiocarcinoma with an IDH1 R132 mutation, after at least 1 prior therapy)

From 20 August 2026

At their session on 20 August 2026, 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. In Annex XII, the information on the active ingredient ivosidenib in the version of the resolution of 18 January 2024 (Federal Gazette, BAnz AT 11.03.2024 B5) shall be replaced by the following information:

Ivosidenib

Resolution of: 20 August 2026
Entry into force on: 20 August 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

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

Tibsovo monotherapy is indicated for the treatment of 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.

Therapeutic indication of the resolution (resolution of 20 August 2026):

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 an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy

Appropriate comparator therapy:

Individualised therapy with selection of

- folinic acid in combination with 5-fluorouracil and oxaliplatin (FOLFOX; only suitable for patients without FGFR2 fusion, FGFR2 rearrangement, MSI-H and 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

Extent and probability of the additional benefit of ivosidenib 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 an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy

There are no assessable data.

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 an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy

Approximately 80 to 160 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 Tibsovo (active ingredient: ivosidenib) at the following publicly accessible link (last access: 18 June 2026):

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

Treatment with ivosidenib should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-20), unless otherwise indicated.

cholangiocarcinoma, as well as specialists in internal medicine and gastroenterology, and other doctors from other specialist groups participating in the Oncology Agreement.

An electrocardiogram (ECG) must be performed before start of treatment and at least once a week during the first 3 weeks of therapy.

4. Treatment costs

The costs for the first year of treatment are shown for the cost representation in the resolution.

Annual treatment costs:

Adults with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Ivosidenib	
Ivosidenib	€ 158,588.36
Appropriate comparator therapy:	
Folinic acid in combination with 5-fluorouracil and oxaliplatin (FOLFOX; only suitable for patients without FGFR2 fusion, FGFR2 rearrangement, MSI-H and dMMR)	
Folinic acid	€ 5,688.44
5-fluorouracil	€ 1,466.82
Oxaliplatin	€ 9,804.99
Total	€ 16,960.25
Pemigatinib (only suitable for patients with an FGFR2 fusion or an FGFR2 rearrangement)	
Pemigatinib	€ 122,537.41
Futibatinib (only suitable for patients with an FGFR2 fusion or an FGFR2 rearrangement)	
Futibatinib	€ 109,661.12
Pembrolizumab (only suitable for patients with MSI-H or dMMR)	
Pembrolizumab	€ 79,650.41
Best supportive care	
Best supportive care[2]	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 June 2026)

[2] When comparing ivosidenib versus best supportive care, the costs of best supportive care must also be additionally considered for the medicinal product to be assessed.

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number / cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Folinic acid in combination with 5-fluorouracil and oxaliplatin (FOLFOX; only suitable for patients without FGFR2 fusion, FGFR2 rearrangement, MSI-H and dMMR)					
Folinic acid	Surcharge for the production of a parenteral calcium folinate solution	€ 100	1	26.1	€ 2,610
5-fluorouracil *Bolus*	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
5-fluorouracil *46-hour infusion*	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	26.1	€ 5,220
Oxaliplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	26.1	€ 2,610
Pembrolizumab (only suitable for patients with MSI-H or dMMR)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.7 or 17.4	€ 870 or € 1,740

II. The resolution will enter into force on the day of its publication on the G-BA website on 20 August 2026.

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

Berlin, 20 August 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk