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
Epcoritamab (New therapeutic indication: follicular lymphoma, after ≥ 2 prior therapies)

From 6 March 2025

At its session on 6 March 2025 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 following information shall be added after No. 5 to the information on the benefit assessment of Epcoritamab in accordance with the resolution of 4 April 2024:

Epcoritamab

Resolution of: 6 March 2025
Entry into force on: 6 March 2025
BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 16 August 2024):

Tepkinly as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Therapeutic indication of the resolution (resolution of 6 March 2025):

See new therapeutic indication according to marketing authorisation.

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

Adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

Appropriate comparator therapy for epcoritamab:
Individualised therapy with selection of

- bendamustine + obinutuzumab followed by obinutuzumab maintenance treatment in accordance with the marketing authorisation,
- lenalidomide + rituximab,
- rituximab monotherapy,
- mosunetuzumab and
- tisagenlecleucel

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

No adequate data are available to allow an assessment of the additional benefit.

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 relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

Approx. 370 to 840 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 Tepkinly (active ingredient: epcoritamab) at the following publicly accessible link (last access: 25 November 2024):

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

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-95) unless otherwise indicated.

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

The annual treatment costs shown refer to the first year of treatment.

Annual treatment costs:

Adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Epcoritamab	€ 198,696.17
Additionally required SHI costs	€ 56.61 - € 56.94
Appropriate comparator therapy:	
Individualised therapy with selection of	
bendamustine + obinutuzumab followed by obinutuzumab maintenance treatment in accordance with the marketing authorisation	
Bendamustine	€ 6,025.86
Obinutuzumab	€ 27,994.06
Total	€ 34,019.92
Additionally required SHI costs	€ 10.49
Lenalidomide + rituximab	
Lenalidomide	€ 428.68
Rituximab	€ 21,535.20
Total	€ 21,963.88
Additionally required SHI costs	€ 82.97 - € 83.30
Rituximab monotherapy	
Rituximab	€ 10,767.60
Additionally required SHI costs	€ 48.07 - € 48.40
CAR-T cell therapy	
tisagenlecleucel	€ 239,000.00
Additionally required SHI costs	€ 419.21
Mosunetuzumab monotherapy	
Mosunetuzumab	€ 73,882.75 - € 139,676.71
Additionally required SHI costs	€ 67.00 - € 67.33

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 February 2025)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed					
Epcoritamab					
Epcoritamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1 - 3: 4 Cycle 4 - 9: 2 From 10th cycle: 1	28.0	€ 2,800
Appropriate comparator therapy					
Bendamustine + obinutuzumab					
Bendamustine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	12.0	€ 1,200
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 From 2nd cycle: 1	11.2	€ 1,120
Lenalidomide + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 4 Cycle 2–5: 1	8.0	€ 800
Rituximab monotherapy					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400
Tisagenlecleucel - Lymphocyte depletion					
Cyclophosphamide	Surcharge for production of a parenteral solution	€ 100	3	3.0	€ 300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Fludarabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Mosunetuzumab monotherapy					
Mosunetuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 From cycle 2 onwards: 1	10.0 – 19.0	€ 1,000 - € 1,900

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 relapsed or refractory follicular lymphoma (FL) after two or more lines 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 6 March 2025.

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

Berlin, 6 March 2025

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

Prof. Hecken