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
Lisocabtagene maraleucel (new therapeutic indication: follicular lymphoma, after ≥ 2 prior therapies)

of 2 October 2025

At their session on 2 October 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 Lisocabtagene maraleucel in accordance with the resolution of 16 November 2023:

Lisocabtagene maraleucel

Resolution of: 2 October 2025
Entry into force on: 2 October 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 12 March 2025):

Breyanzi 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 2 October 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 after two or more lines of systemic therapy

Appropriate comparator therapy:

Individualised therapy with selection of

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

Extent and probability of the additional benefit of lisocabtagene maraleucel 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 after two or more lines 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) (A25-47) 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 relapsed or refractory follicular lymphoma 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 Breyanzi (active ingredient: lisocabtagene maraleucel) at the following publicly accessible link (last access: 22 July 2025):

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

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material and a patient emergency card. Training material for all healthcare professionals who will prescribe, dispense, and administer lisocabtagene maraleucel includes instructions for identifying, preventing, treating, and monitoring cytokine release syndrome and neurological side effects as well as on the risk of secondary malignancy with T cell origin. It also includes instructions on storage and transport as well as the cell thawing process, availability of one dose of tocilizumab at the point of treatment, provision of relevant information to patients, and full and appropriate reporting of side effects.

The patient training programme should explain the risks of cytokine release syndrome and serious neurologic side effects, the need to report symptoms immediately to the treating

physician, to remain close to the treatment facility for at least four weeks after infusion of lisocabtagene maraleucel and to carry the patient emergency card at all times.

Lisocabtagene maraleucel must be used in a qualified treatment facility.

The quality assurance measures according to the ATMP Quality Assurance Guideline apply to the use of the medicinal product for novel therapies (Advanced Therapy Medicinal Product, ATMP) lisocabtagene maraleucel in the therapeutic indication of follicular lymphoma. Annex 1 "Use of CAR-T cells in B-cell neoplasms" of the ATMP Quality Assurance Guideline provides further details.

A Direct Healthcare Professional Communication ("Rote-Hand-Brief") which reports on the occurrence of secondary malignancies of T-cell origin, including chimeric antigen receptor (CAR)-positive malignancies, is available for the currently approved CD19- or BCMA-targeted CAR T-cell therapies. Patients who have been treated with CAR-T cell products should therefore be monitored throughout their lives for the occurrence of secondary malignancies.

4. Treatment costs

Annual treatment costs:

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Lisocabtagene maraleucel	
Lisocabtagene maraleucel	€ 227,500.00
Additionally required SHI costs	*€ 759.45*
Appropriate comparator therapy:	
Individualised therapy with selection of	
Zanubrutinib + obinutuzumab	
Zanubrutinib	€ 66,643.53
Obinutuzumab	€ 27,994.06
Total	€ 94,637.59
Additionally required SHI costs	*€ 10.49*
Bendamustine + obinutuzumab	
Bendamustine	€ 6,148.05
Obinutuzumab	€ 27,994.06
Total	€ 34,142.11
Additionally required SHI costs	*€ 10.49*
Lenalidomide + rituximab	
Lenalidomide	€ 428.68
Rituximab	€ 21,535.20

Designation of the therapy	Annual treatment costs/ patient
Total	€ 21,963.88
Additionally required SHI costs	*€ 83.37 - € 83.70*
Rituximab monotherapy	
Rituximab	€ 10,767.60
Additionally required SHI costs	*€ 48.27 - € 48.60*
Tisagenlecleucel	
Tisagenlecleucel	€ 239,000.00
Additionally required SHI costs	*€ 419.90*
Mosunetuzumab monotherapy	
Mosunetuzumab	€ 73,882.75 - € 139,676.71
Additionally required SHI costs	*€ 67.20 - € 67.53*

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 August 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					
Lisocabtagene maraleucel					
Cyclophosphamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Fludarabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Appropriate comparator therapy					
Zanubrutinib + obinutuzumab					
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	11.2	€ 1,120
Bendamustine + obinutuzumab					
Bendamustine	Surcharge for production of a	€ 100	2	6	€ 1,200

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing cytostatic agents				
Obinutuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 3 Cycle 2 - 9: 1	11.2	€ 1,120
Lenalidomide + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Induction therapy: 4 Maintenance treatment: 1	Induction therapy: 1 Maintenance treatment: 4	€ 800
Rituximab monotherapy					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4	€ 400
Tisagenlecleucel - Lymphocyte depletion					
Cyclophosphamide	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
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 - 19	€ 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 after two or more lines of systemic therapy

– No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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 2 October 2025.

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

Berlin, 2 October 2025

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

Prof. Hecken