

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:
mantle cell lymphoma, after ≥ 2 prior therapies)

From 4 June 2026

At their session on 4 June 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 following information shall be added after No. 5 to the information on the benefit assessment of Lisocabtagene maraleucel in accordance with the resolution of 2 October 2025:**

Lisocabtagene maraleucel

Resolution of: 4 June 2026

Entry into force on: 4 June 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 21 November 2025):

Breyanzi is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor.

Therapeutic indication of the resolution (resolution of 4 June 2026):

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 mantle cell lymphoma (MCL) after at least two lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor

Appropriate comparator therapy:

Individualised therapy with selection of

- bendamustine + rituximab,
- lenalidomide ± rituximab,
- R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone),
- VRCAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone),
- R-BAC (rituximab + bendamustine + cytarabine),
- R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab),
- ibrutinib,
- brexucabtagene autoleucel,
- venetoclax and
- High-dose therapy with allogeneic stem cell transplant

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 mantle cell lymphoma (MCL) after at least two lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor

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 relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor

Approx. 105 to 150 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: 18 February 2026):

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

¹ Data from the dossier assessment by the IQWiG (A25-153), unless otherwise indicated.

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 two 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 mantle cell 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:

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

Adults with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Lisocabtagene maraleucel	€ 224,500.00
Additionally required SHI costs	€ 759.45
Appropriate comparator therapy:	
Bendamustine + rituximab	
Bendamustine	€ 12,801.77
Rituximab	€ 35,285.90
Total	€ 48,087.67
Additionally required SHI costs	€ 10.49
Lenalidomide	
Lenalidomide	€ 464.40
Additionally required SHI costs	€ 10.49
Lenalidomide + rituximab	

Designation of the therapy	Annual treatment costs/ patient
Lenalidomide	€ 464.40
Rituximab	€ 139,978.80
Total	€ 140,443.20
R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	
Rituximab	€ 21,714.40 - € 31,214.46
Cyclophosphamide	€ 299.04
Doxorubicin	€ 2,048.44
Vincristine	€ 280.32
Prednisone	€ 52.20
Total	€ 24,394.40 - € 33,894.46
Additionally required SHI costs	€ 10.49
VRCAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)	
Bortezomib	€ 4,208.16 – € 5,610.88
Rituximab	€ 16,151.40 – € 21,535.20
Cyclophosphamide	€ 224.28 – € 299.04
Doxorubicin	€ 1,494.76 – € 2,048.44
Prednisone	€ 149.70 – € 190.66
Total	€ 22,228.30 – € 29,684.22
R-BAC (rituximab + bendamustine + cytarabine)	
Rituximab	€ 34,994.70
Bendamustine	€ 10,951.67
Cytarabine	€ 1,594.32 – € 2,814.63
Total	€ 47,540.69 – € 48,761.00
R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab)	
Fludarabine	€ 1,270.32
Cyclophosphamide	€ 149.52
Mitoxantrone	€ 892.64
Rituximab	€ 10,857.20
Total	€ 13,169.68
Additionally required SHI costs	€ 10.49
Ibrutinib	
Ibrutinib	€ 99,964.64
Additionally required SHI costs	€ 10.49
Brexucabtagene autoleucel	
Brexucabtagene autoleucel	€ 271,000.00
Additionally required SHI costs	€ 768.44

Designation of the therapy	Annual treatment costs/ patient
Venetoclax	
Venetoclax	€ 142,525.80 – € 210,869.60
High-dose therapy with allogeneic stem cell transplant	
Stem cell collection/ acquisition	Not calculable
High-dose chemotherapy with allogeneic stem cell transplant	€ 51,357.81 – € 57,788.73
Total	Not calculable

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 April 2026)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Bendamustine + rituximab					
Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	26.0	€ 2,600
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0	€ 1,300
Lenalidomide + rituximab					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	4	52.0	€ 5,200
R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.0 – 11.5	€ 800 – € 1,150

Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800
Doxorubicin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800
Vincristine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8.0	€ 800
VRCAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)					
Bortezomib	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	4	24.0 – 32.0	€ 2,400 – € 3,200
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.0 – 8.0	€ 600 – € 800
Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	6.0 – 8.0	€ 600 – € 800
Doxorubicin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	6.0 – 8.0	€ 600 – € 800
R-BAC (rituximab + bendamustine + cytarabine)					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0	€ 1,300

Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	26.0	€ 2,600
Cytarabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	39.0	€ 3,900
R-FCM (fludarabine + cyclophosphamide + mitoxantrone + rituximab)					
Fludarabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	12.0	€ 1,200
Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	12.0	€ 1,200
Mitoxantrone	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4.0	€ 400
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4.0	€ 400

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 mantle cell lymphoma (MCL) after at least two lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor

- No medicinal product with new active ingredients for use in combination therapy in compliance with 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 G-BA website on 4 June 2026.

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

Berlin, 4 June 2026

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

Prof. Hecken