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
Glofitamab (repeal of regulatory orphan status: diffuse large B-cell lymphoma (DLBCL), after ≥ 2 previous therapies)

of 6 November 2025

At their session on 6 November 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 information on the active ingredient Glofitamab in the version of the resolution of 1 February 2024 (Federal Gazette, BAnz AT 19.03.2024 B2) shall be replaced by the following information:**

Glofitamab

Resolution of: 6 November 2025
Entry into force on: 6 November 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 7 July 2023):

Columvi as monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy.

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

See therapeutic indication according to marketing authorisation.

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

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplant

Appropriate comparator therapy:

Individualised therapy with selection of

- tisagenlecleucel,
- axicabtagene ciloleucel,
- lisocabtagene maraleucel,
- an induction therapy with
    - R-GDP (rituximab, gemcitabine, dexamethasone, cisplatin) *or*
    - R-DHAP (rituximab, dexamethasone, cisplatin, cytarabine) *or*
    - R-ICE (rituximab, ifosfamide, carboplatin, etoposide)

  followed by high-dose therapy with autologous stem cell transplantation if there is a response to induction therapy and
- an induction therapy with
    - R-GDP (rituximab, gemcitabine, dexamethasone, cisplatin) *or*
    - R-DHAP (rituximab, dexamethasone, cisplatin, cytarabine) *or*
    - R-ICE (rituximab, ifosfamide, carboplatin, etoposide)

  followed by high-dose therapy with allogeneic stem cell transplantation if there is a response to induction therapy

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

An additional benefit is not proven.

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplant

Appropriate comparator therapy:

– Polatuzumab vedotin in combination with bendamustine and rituximab

or

– tafasitamab in combination with lenalidomide

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplant

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		

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplant

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-65) 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

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplant

Approx. 600 to 1,240 patients

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplant

Approx. 360 to 890 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 Columvi (active ingredient: glofitamab) at the following publicly accessible link (last access: 28 October 2025):

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

Treatment with glofitamab should only be initiated and monitored by specialists in internal medicine, haematology and oncology, experienced in the treatment of patients with diffuse large B-cell lymphoma (DLBCL).

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card).

The training material contains, in particular, information and warnings about the cytokine release syndrome.

Obinutuzumab is not approved for pretreatment prior to starting therapy with glofitamab. The application for marketing authorisation was withdrawn. Obinutuzumab is not reimbursable for this indication.

4. Treatment costs

Annual treatment costs:

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

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplant

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Glofitamab	€ 156,320.74
Additionally required SHI costs	*€ 137.87 - € 140.74*
Appropriate comparator therapy:	
CAR-T cell therapies	
Axicabtagene ciloleucel	€ 230,621.00
Additionally required SHI costs	*€ 768.44*
Lisocabtagene maraleucel	€ 227,500.00
Additionally required SHI costs	*€ 767.10*
Tisagenlecleucel	€ 239,000.00
Additionally required SHI costs	*€ 768.44*
Induction chemotherapy followed by high-dose chemotherapy with autologous stem cell transplant if there is a response to induction chemotherapy	
Induction chemotherapies	
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2 - 3 cycles	
Rituximab	€ 5,383.80 - € 8,413.88
Gemcitabine	€ 719.68 - € 1,079.52
Dexamethasone	€ 44.29 - € 79.59
Cisplatin	€ 231.86 - € 347.79
R-GDP	€ 6,379.63 - € 9,920.78
Additionally required SHI costs	*€ 145.49 - € 203.38*
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2 - 3 cycles including a single dose of rituximab before the start of treatment	
Rituximab	€ 8,413.88 - € 10,767.60
Ifosfamide	€ 672.40 - € 1,008.60
Carboplatin	€ 634.30 - € 825.22 (2 cycles) –

Designation of the therapy	Annual treatment costs/ patient
	€ 951.45 - € 1,237.83 (3 cycles)
Etoposide	€ 460.68 - € 691.02
R-ICE	€ 10,181.26 - € 10,372.18 (2 cycles) – € 13,418.67 - € 13,705.05 (3 cycles)
Additionally required SHI costs	*€ 120.72 - € 400.72*
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2 - 3 cycles including optional single dose of rituximab before the start of treatment	
Rituximab	€ 5,383.80 - € 10,767.60
Dexamethasone	€ 44.29 - € 79.59
Cytarabine	€ 577.36 - € 866.04
Cisplatin	€ 286.88 - € 430.32
R-DHAP	€ 6,292.33 - € 12,143.55
Additionally required SHI costs	*€ 145.49 - € 203.38*
High-dose chemotherapy with autologous stem cell transplant	
High-dose chemotherapy with autologous stem cell transplant	€ 40,334.50
Total	
R-GDP induction chemotherapy + High-dose chemotherapy with autologous stem cell transplant	€ 46,714.13 - € 50,255.28
Additionally required SHI costs	*€ 145.49 - € 203.38*
R-ICE induction chemotherapy + High-dose chemotherapy with autologous stem cell transplant	€ 50,515.76 - € 50,706.68 (2 cycles R-ICE) – € 53,753.17 - € 54,039.55 (3 cycles R-ICE)
Additionally required SHI costs	*€ 120.72 - € 400.72*
R-DHAP induction chemotherapy + High-dose chemotherapy with autologous stem cell transplant	€ 46,626.83 - € -52,478.05
Additionally required SHI costs	*€ 145.49 - € 203.38*
Induction chemotherapy followed by *high-dose chemotherapy with allogeneic stem cell transplant if there is a response to induction chemotherapy*	
Induction chemotherapies	
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2 - 3 cycles	
Rituximab	€ 5,383.80 - € 8,413.88
Gemcitabine	€ 719.68 - € 1,079.52
Dexamethasone	€ 44.29 - € 79.59
Cisplatin	€ 231.86 - € 347.79

Designation of the therapy	Annual treatment costs/ patient
R-GDP	€ 6,379.63 - € 9,920.78
Additionally required SHI costs	*€ 145.49 - € 203.38*
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2 - 3 cycles including a single dose of rituximab before the start of treatment	
Rituximab	€ 8,413.88 - € 10,767.60
Ifosfamide	€ 672.40 - € 1,008.60
Carboplatin	€ 634.30 - € 825.22 (2 cycles) – € 951.45 - € 1,237.83 (3 cycles)
Etoposide	€ 460.68 - € 691.02
R-ICE	€ 10,181.26 - € 10,372.18 (2 cycles) – € 13,418.67 - € 13,705.05 (3 cycles)
Additionally required SHI costs	*€ 120.72 - € 400.72*
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2 - 3 cycles including optional single dose of rituximab before the start of treatment	
Rituximab	€ 5,383.80 - € 10,767.60
Dexamethasone	€ 44.29 - € 79.59
Cytarabine	€ 577.36 - € 866.04
Cisplatin	€ 286.88 - € 430.32
R-DHAP	€ 6,292.33 - € 12,143.55
Additionally required SHI costs	*€ 145.49 - € 203.38*
High-dose chemotherapy with allogeneic stem cell transplant	
High-dose chemotherapy with allogeneic stem cell transplant	€ 60,654.01
Total	
R-GDP induction chemotherapy + High-dose chemotherapy with allogeneic stem cell transplant	€ 67,033.64 - € 70,574.79
Additionally required SHI costs	*€ 145.49 - € 203.38*
R-ICE induction chemotherapy + High-dose chemotherapy with allogeneic stem cell transplant	€ 70,835.27 - € 71,026.19 (2 cycles R-ICE) – € 74,072.68 - € 74,359.06 (3 cycles R-ICE)
Additionally required SHI costs	*€ 120.72 - € 400.72*
R-DHAP induction chemotherapy + High-dose chemotherapy with allogeneic stem cell transplant	€ 66,946.34 - € 72,797.56
Additionally required SHI costs	*€ 145.49 - € 203.38*

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 September 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					
Glofitamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	35.0	€ 3,500
Appropriate comparator therapy					
CAR-T cell therapies: Lymphocyte depletion					
Axicabtagene ciloleucel, tisagenlecleucel, lisocabtagene maraleucel					
Cyclophosphamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Fludarabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	3.0	€ 300
Induction chemotherapy followed by high-dose chemotherapy with autologous stem cell transplant if there is a response to induction chemotherapy					
Induction chemotherapies					
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2-3 cycles					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2.0 – 3.0	€ 200 – € 300
Gemcitabine	Surcharge for the preparation of a parenteral	€ 100	2	4.0 – 6.0	€ 400 – € 600

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	solution containing cytostatic agents				
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2-3 cycles including a single dose of rituximab before the start of treatment					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	3.0 – 4.0	€ 300 – € 400
Ifosfamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Etoposide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	6.0 – 9.0	€ 600 – € 900
Mesna	Surcharge for production of other parenteral solutions	€ 54	2	4.0 – 6.0	€ 216 - € 324
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2-3 cycles including optional single dose of rituximab before the start of treatment					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2.0 – 4.0	€ 200 – € 400
Cytarabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Induction chemotherapy followed by high-dose chemotherapy with allogeneic stem cell transplant if there is a response to induction chemotherapy					
Induction chemotherapies					
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin); 2-3 cycles					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2.0 – 3.0	€ 200 – € 300
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	4.0 – 6.0	€ 400 – € 600
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
R-ICE (rituximab + ifosfamide + carboplatin + etoposide); 2-3 cycles including a single dose of rituximab before the start of treatment					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	3.0 – 4.0	€ 300 – € 400
Ifosfamide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300
Etoposide	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	3	6.0 – 9.0	€ 600 – € 900
Mesna	Surcharge for production of other parenteral solutions	€ 54	2	4.0 – 6.0	€ 216 - € 324
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin); 2-3 cycles including optional single dose of rituximab before the start of treatment					
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2.0 – 4.0	€ 200 – € 400
Cytarabine	Surcharge for the preparation of a parenteral	€ 100	2	4.0 – 6.0	€ 400 – € 600

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	solution containing cytostatic agents				
Cisplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	2.0 – 3.0	€ 200 – € 300

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplant

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Glofitamab	€ 156,320.74
Appropriate comparator therapy:	
Polatuzumab vedotin + bendamustine + rituximab	
Polatuzumab vedotin	€ 44,950.80
Bendamustine	€ 6,148.05
Rituximab	€ 16,151.40
Total	€ € 67,250.25
Additionally required SHI costs	*€ 65.82 - € 66.15*
Tafasitamab + lenalidomide	
Tafasitamab	€ 101,821.50
Lenalidomide	€ 428.68
Total	€ 102,250.18
Additionally required SHI costs	*€ 10.49*

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 September 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					
Glofitamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	35.0	€ 3,500
Appropriate comparator therapy					
Polatuzumab vedotin + bendamustine + rituximab					
Polatuzumab vedotin	Surcharge for the preparation of a parenteral solution containing polatuzumab vedotin	€ 100	1	6.0	€ 600
Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	12.0	€ 1,200
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.0	€ 600
Tafasitamab + lenalidomide					
Tafasitamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 5 Cycle 2 and 3: 4 From cycle 4 onwards: 2	33.0	€ 3,300

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:

a) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are eligible for CAR-T cell therapy or stem cell transplant

– 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.

b) Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy who are not eligible for CAR-T cell therapy and stem cell transplant

– 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 November 2025.

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

Berlin, 6 November 2025

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

Prof. Hecken