Gemeinsamer Bundesausschuss

Glofitamab (new therapeutic indication: diffuse large B-cell lymphoma, relapsed or refractory, combination with gemcitabine and oxaliplatin, ineligible for autologous stem cell transplant)

Resolution of: 6 November 2025/ 13 January 2026 Valid until: unlimited
Entry into force on: 6 November 2025/ 15 January 2026
Federal Gazette, BAnz AT 17 12 2025 B5/ 13 02 2026 B2

New therapeutic indication (according to the marketing authorisation of 10 April 2025):

Columvi in combination with gemcitabine and oxaliplatin is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT).

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

See new 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 not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) after failure of one line of systemic therapy

Appropriate comparator therapy:

– Tafasitamab in combination with lenalidomide

or

– Polatuzumab vedotin in combination with bendamustine and rituximab

Extent and probability of the additional benefit glofitamab of in combination with gemcitabine and oxaliplatin compared to the appropriate comparator therapy:

An additional benefit is not proven.

b1) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) and who are eligible for CAR-T cell therapy or allogeneic haematopoietic stem cell transplant after failure of two or more lines of systemic therapy

Appropriate comparator therapy:

An individualised therapy with selection of

- tisagenlecleucel,

- axicabtagene ciloleucel,
- lisocabtagene maraleucel 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 glofitamab of in combination with gemcitabine and oxaliplatin compared to the appropriate comparator therapy:

An additional benefit is not proven.

b2) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for CAR-T cell therapy and haematopoietic stem cell transplant after failure of two or more lines of systemic therapy

Appropriate comparator therapy:

– Tafasitamab in combination with lenalidomide

or

– Polatuzumab vedotin in combination with bendamustine and rituximab

Extent and probability of the additional benefit glofitamab of in combination with gemcitabine and oxaliplatin 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 not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) after failure of one line 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.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-64) unless otherwise indicated.

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		

b1) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) and who are eligible for CAR-T cell therapy or allogeneic haematopoietic stem cell transplant after failure of 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		

b2) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for CAR-T cell therapy and haematopoietic stem cell transplant after failure of 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

a) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) after failure of one line of systemic therapy

Approx. 1270 to 1420 patients

b1) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) and who are eligible for CAR-T cell therapy or allogeneic haematopoietic stem cell transplant after failure of two or more lines of systemic therapy

Approx. 600 to 1240 patients

b2) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for CAR-T cell therapy and haematopoietic stem cell transplant after failure of two or more lines of systemic therapy

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

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

Annual treatment costs:

a) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) after failure of one line of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Glofitamab in combination with gemcitabine and oxaliplatin	
glofitamab	€ 155,157.62
Gemcitabine	€ 1,439.36
Oxaliplatin	€ 3,005.36
Total	€ 159,602.34
Additionally required SHI services	€ 137.87 – € 140.74
Appropriate comparator therapy:	
Tafasitamab in combination with lenalidomide	
Tafasitamab	€ 101,821.50
Lenalidomide	€ 428.68
Total	€ 102,250.18
Additionally required SHI services	€ 10.49
Polatuzumab vedotin in combination with bendamustine and rituximab	
Polatuzumab vedotin	€ 44,950.80
Bendamustine	€ 6,148.05
Rituximab	€ 16,151.40
Total	€ 67,250.25
Additionally required SHI services	€ 65.82 – € 66.15

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					
Appropriate comparator therapy					
Glofitamab in combination with gemcitabine and oxaliplatin					
glofitamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 2 cycle 2 – 12: 1	13	€ 1,300
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8	€ 800
Oxaliplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8	€ 800
Appropriate comparator therapy					
Tafasitamab in combination with 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
Polatuzumab vedotin in combination with bendamustine and rituximab					
Polatuzumab vedotin	Surcharge for the preparation of parenteral solutions containing polatuzumab vedotin	€ 100	1	6	€ 600
Bendamustine	Surcharge for the preparation of a parenteral solution	€ 100	2	12	€ 1,200

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6	€ 600

b1) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) and who are eligible for CAR-T cell therapy or allogeneic haematopoietic stem cell transplant after failure of two or more lines of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Glofitamab in combination with gemcitabine and oxaliplatin	
Glofitamab	€ 155,157.62
Gemcitabine	€ 1,439.36
Oxaliplatin	€ 3,005.36
Total	€ 159,602.34
Additionally required SHI services	€ 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 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

Designation of the therapy	Annual treatment costs/ patient
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) – € 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	
Stem cell collection/ procurement	not calculable
High-dose chemotherapy with allogeneic stem cell transplant	€ 54,438.60 - € 62,018.26
Total	
R-GDP induction chemotherapy + Stem cell collection/ procurement + High-dose chemotherapy with allogeneic stem cell transplant	€ 6,379.63 – € 9,920.78 not calculable € 54,438.60 - € 62,018.26
Total	not calculable
Additionally required SHI costs	€ 145.49 – € 203.38
R-ICE induction chemotherapy + Stem cell collection/ procurement + High-dose chemotherapy	€ 10,181.26 – € 10,372.18 (2 cycles) € 13,418.67 – € 13,705.05 (3 cycles) not calculable

Designation of the therapy	Annual treatment costs/ patient
with allogeneic stem cell transplant	€ 54,438.60 - € 62,018.26
Total	not calculable
Additionally required SHI costs	€ 120.72 – € 400.72
R-DHAP induction chemotherapy + Stem cell collection/ procurement + High-dose chemotherapy with allogeneic stem cell transplant	€ 6,292.33 – € 12,143.55 not calculable € 54,438.60 - € 62,018.26
Total	not calculable
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					
Appropriate comparator therapy					
Glofitamab in combination with gemcitabine and oxaliplatin					
glofitamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 2 cycle 2 – 12: 1	13	€ 1,300
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8	€ 800
Oxaliplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8	€ 800
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 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
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	1s	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 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

b2) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for CAR-T cell therapy and allogeneic haematopoietic stem cell transplant after failure of two or more lines of systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Glofitamab in combination with gemcitabine and oxaliplatin	
glofitamab	€ 155,157.62
Gemcitabine	€ 1,439.36
Oxaliplatin	€ 3,005.36
Total	€ 159,602.34
Additionally required SHI services	€ 137.87 – € 140.74
Appropriate comparator therapy:	
Tafasitamab in combination with lenalidomide	
Tafasitamab	€ 101,821.50
Lenalidomide	€ 428.68
Total	€ 102,250.18
Additionally required SHI services	€ 10.49
Polatuzumab vedotin in combination with bendamustine and rituximab	
Polatuzumab vedotin	€ 44,950.80
Bendamustine	€ 6,148.05
Rituximab	€ 16,151.40
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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					
Appropriate comparator therapy					
Glofitamab in combination with gemcitabine and oxaliplatin					
glofitamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	Cycle 1: 2 cycle 2 – 12: 1	13	€ 1,300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Gemcitabine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8	€ 800
Oxaliplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	8	€ 800
Appropriate comparator therapy					
Tafasitamab in combination with 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
Polatuzumab vedotin in combination with bendamustine and rituximab					
Polatuzumab vedotin	Surcharge for the preparation of parenteral solutions containing polatuzumab vedotin	€ 100	1	6	€ 600
Bendamustine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	12	€ 1,200
Rituximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6	€ 600

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 not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) after failure of one line 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.

b1) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT) and who are eligible for CAR-T cell therapy or allogeneic haematopoietic stem cell transplant after failure of 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.

b2) Adults with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for CAR-T cell therapy and allogeneic haematopoietic stem cell transplant after failure of 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.