

Glofitamab (DLBCL, monotherapy, third line or later)

Benefit assessment according to §35a SGB V¹



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Part I: Benefit assessment

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² Table numbers start with “2” as numbering follows that of the full dossier assessment.

I List of abbreviations

Abbreviation	Meaning
ACT	appropriate comparator therapy
CAR	chimeric antigen receptor
CD20	cluster of differentiation 20
DLBCL	diffuse large B-cell lymphoma
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
HTA	health technology assessment
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
IRC	Independent Review Committee
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)

I 1 Executive summary of the benefit assessment

Background

In accordance with §35a Social Code Book V, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug glofitamab. The assessment is based on a dossier compiled by the pharmaceutical company (hereinafter referred to as the 'company'). The dossier was sent to IQWiG on 14 May 2025.

Research question

The aim of this report is to assess the added benefit of glofitamab as monotherapy in comparison with the appropriate comparator therapy (ACT) in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after 2 or more lines of systemic therapy.

The research questions presented in Table 2 were defined in accordance with the ACT specified by the G-BA.

Table 2: Research questions for the benefit assessment of glofitamab

Research question	Therapeutic indication	ACT ^a
1	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are eligible for CAR T-cell therapy or stem cell transplantation ^{b, c}	Individualized treatment ^{d, e, f} selecting from <ul style="list-style-type: none"> ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with autologous stem cell transplantation if there is a response to induction therapy and ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with allogeneic stem cell transplantation if there is a response to induction therapy
2	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are ineligible for CAR T-cell therapy and stem cell transplantation ^{g, h}	<ul style="list-style-type: none"> ▪ polatuzumab vedotin in combination with bendamustine and rituximab or <ul style="list-style-type: none"> ▪ tafasitamab in combination with lenalidomide

a. Presented are the respective ACTs specified by the G-BA.
 b. According to the G-BA, treatment with curative intent is assumed to be an option for these patients.
 c. In patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is, according to the G-BA, an option in those patients who have a very high risk of relapse or in whom sufficient stem cell collection for autologous stem cell transplantation was not possible.
 d. The term ‘individualized treatment’ is used instead of previously used terms such as ‘patient-specific therapy’ or ‘treatment of physician’s choice’. This ensures consistency with the terms used in European health technology assessments (EU HTAs).
 e. According to the G-BA, it is assumed that the decision on treatment will be made taking into account, in particular, the previous treatment of patients with CAR T-cell therapy, autologous stem cell transplantation or allogeneic stem cell transplantation.
 f. For the implementation of individualized therapy in a study of direct comparison, the G-BA expects investigators to have a choice of several treatment options at their disposal, enabling them to make individualized treatment decisions (multi-comparator study).
 g. According to the G-BA, treatment with curative intent is not assumed to be an option for these patients.
 h. According to the S3 guideline, radiotherapy can be a suitable method for local disease control in palliative situations and should, if indicated, be offered in both study arms.

ACT: appropriate comparator therapy; CAR: chimeric antigen receptor; DLBCL: diffuse large B-cell lymphoma; G-BA: Federal Joint Committee; HTA: health technology assessment; R-DHAP: rituximab, dexamethasone, cisplatin, cytarabine; R-GDP: rituximab, gemcitabine, dexamethasone, cisplatin or carboplatin; R-ICE: rituximab, ifosfamide, carboplatin, etoposide

On 6 May 2025, shortly before the dossier was submitted by the company, the G-BA modified the ACT to that shown in Table 2. The company deviated from the ACT specified by the G-BA and initially referred to the ACT from the 2021 consultation in its dossier.

For the research question 1 patients (eligible for chimeric antigen receptor [CAR] T-cell therapy or stem cell transplantation), the company named the drugs axicabtagene ciloleucel, lisocabtagene maraleucel, tisagenlecleucel, or allogeneic or autologous stem cell transplantation as options – and not individualized treatment selected from the therapies listed. In addition, the company did not specify the drug combinations that can be used within an induction therapy preceding stem cell transplantation.

For the research question 2 patients (ineligible for CAR T-cell therapy and stem cell transplantation), the company stated treatment of physician's choice as the ACT, taking into account epcoritamab, loncastuximab tesirine, polatuzumab vedotin in combination with bendamustine and rituximab (polatuzumab vedotin + bendamustine + rituximab) or tafasitamab in combination with lenalidomide (tafasitamab + lenalidomide). However, the ACT most recently defined by the G-BA only included the 2 drug combinations polatuzumab vedotin + bendamustine + rituximab or tafasitamab + lenalidomide, which were considered equally appropriate.

This benefit assessment was conducted in comparison with the ACT specified by the G-BA on 6 May 2025. The company's deviation from the G-BA's ACT remained without consequence, as the company did not present any suitable data for the benefit assessment – neither versus the comparator therapy it had specified nor versus the ACT specified by the G-BA. Since no suitable data were available for either of the 2 research questions, both research questions are assessed below in joint sections of the report.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) were used to derive the added benefit. This concurred with the company's inclusion criteria.

Results

Consistent with the findings of the company, a review of the completeness of the study pool did not identify any relevant RCTs for either research question for the direct comparison of glofitamab with the ACT specified by the G-BA in the given therapeutic indication.

The company did not conduct an information retrieval for further studies. Nevertheless, the company did present as supporting information the pivotal study NP30179, as the best available evidence. However, the single-arm study presented did not allow a comparison with the ACT defined by the G-BA and was therefore not suitable for the benefit assessment of glofitamab.

Results on added benefit

Since no suitable data were available for the benefit assessment, there is no hint of an added benefit of glofitamab in comparison with the ACT for either research question of this benefit assessment; an added benefit is therefore not proven.

Probability and extent of added benefit, patient groups with therapeutically important added benefit³

Table 3 presents a summary of the probability and extent of the added benefit of glofitamab.

³ On the basis of the scientific data analysed, IQWiG draws conclusions on the (added) benefit or harm of an intervention for each patient-relevant outcome. Depending on the number of studies analysed, the certainty of their results, and the direction and statistical significance of treatment effects, conclusions on the probability of (added) benefit or harm are graded into 4 categories: (1) "proof", (2) "indication", (3) "hint", or (4) none of the first 3 categories applies (i.e., no data available or conclusions 1 to 3 cannot be drawn from the available data). The extent of added benefit or harm is graded into 3 categories: (1) major, (2) considerable, (3) minor (in addition, 3 further categories may apply: non-quantifiable extent of added benefit, added benefit not proven, or less benefit). For further details see [1,2].

Table 3: Glofitamab – probability and extent of added benefit

Research question	Therapeutic indication	ACT ^a	Probability and extent of added benefit
1	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are eligible for CAR T-cell therapy or stem cell transplantation ^{b, c}	Individualized treatment ^{d, e, f} selecting from <ul style="list-style-type: none"> ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with autologous stem cell transplantation if there is a response to induction therapy and ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with allogeneic stem cell transplantation if there is a response to induction therapy 	Added benefit not proven
2	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are ineligible for CAR T-cell therapy and stem cell transplantation ^{g, h}	<ul style="list-style-type: none"> ▪ polatuzumab vedotin in combination with bendamustine and rituximab or <ul style="list-style-type: none"> ▪ tafasitamab in combination with lenalidomide 	Added benefit not proven

a. Presented are the respective ACTs specified by the G-BA.
 b. According to the G-BA, treatment with curative intent is assumed to be an option for these patients.
 c. In patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is, according to the G-BA, an option in those patients who have a very high risk of relapse or in whom sufficient stem cell collection for autologous stem cell transplantation was not possible.
 d. The term ‘individualized treatment’ is used instead of previously used terms such as ‘patient-specific therapy’ or ‘treatment of physician’s choice’. This ensures consistency with the terms used in European health technology assessments (EU HTAs).
 e. According to the G-BA, it is assumed that the decision on treatment will be made taking into account, in particular, the previous treatment of patients with CAR T-cell therapy, autologous stem cell transplantation or allogeneic stem cell transplantation.
 f. For the implementation of individualized therapy in a study of direct comparison, the G-BA expects investigators to have a choice of several treatment options at their disposal, enabling them to make individualized treatment decisions (multi-comparator study).
 g. According to the G-BA, treatment with curative intent is not assumed to be an option for these patients.
 h. According to the S3 guideline, radiotherapy can be a suitable method for local disease control in palliative situations and should, if indicated, be offered in both study arms.

ACT: appropriate comparator therapy; CAR: chimeric antigen receptor; DLBCL: diffuse large B-cell lymphoma; G-BA: Federal Joint Committee; HTA: health technology assessment; R-DHAP: rituximab, dexamethasone, cisplatin, cytarabine; R-GDP: rituximab, gemcitabine, dexamethasone, cisplatin or carboplatin; R-ICE: rituximab, ifosfamide, carboplatin, etoposide

The G-BA decides on the added benefit.

Supplementary note

The result of the assessment deviates from the result of the G-BA's assessment conducted in the context of the market launch in 2023. At that time the G-BA had determined a non-quantifiable added benefit of glofitamab for the entire therapeutic indication of this benefit assessment. However, in the G-BA's assessment the added benefit was considered proven by the marketing authorization, regardless of the underlying data, due to the special situation for orphan drugs.

I 2 Research question

The aim of this report is to assess the added benefit of glofitamab as monotherapy in comparison with the ACT in adult patients with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy.

The research questions presented in Table 4 were defined in accordance with the ACT specified by the G-BA.

Table 4: Research questions for the benefit assessment of glofitamab

Research question	Therapeutic indication	ACT ^a
1	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are eligible for CAR T-cell therapy or stem cell transplantation ^{b, c}	Individualized treatment ^{d, e, f} selecting from <ul style="list-style-type: none"> ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with autologous stem cell transplantation if there is a response to induction therapy and ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with allogeneic stem cell transplantation if there is a response to induction therapy
2	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are ineligible for CAR T-cell therapy and stem cell transplantation ^{g, h}	<ul style="list-style-type: none"> ▪ polatuzumab vedotin in combination with bendamustine and rituximab or <ul style="list-style-type: none"> ▪ tafasitamab in combination with lenalidomide
<p>a. Presented are the respective ACTs specified by the G-BA. b. According to the G-BA, treatment with curative intent is assumed to be an option for these patients. c. In patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is, according to the G-BA, an option in those patients who have a very high risk of relapse or in whom sufficient stem cell collection for autologous stem cell transplantation was not possible. d. The term ‘individualized treatment’ is used instead of previously used terms such as ‘patient-specific therapy’ or ‘treatment of physician’s choice’. This ensures consistency with the terms used in European health technology assessments (EU HTAs). e. According to the G-BA, it is assumed that the decision on treatment will be made taking into account, in particular, the previous treatment of patients with CAR T-cell therapy, autologous stem cell transplantation or allogeneic stem cell transplantation. f. For the implementation of individualized therapy in a study of direct comparison, the G-BA expects investigators to have a choice of several treatment options at their disposal, enabling them to make individualized treatment decisions (multi-comparator study). g. According to the G-BA, treatment with curative intent is not assumed to be an option for these patients. h. According to the S3 guideline, radiotherapy can be a suitable method for local disease control in palliative situations and should, if indicated, be offered in both study arms.</p> <p>ACT: appropriate comparator therapy; CAR: chimeric antigen receptor; DLBCL: diffuse large B-cell lymphoma; G-BA: Federal Joint Committee; HTA: health technology assessment; R-DHAP: rituximab, dexamethasone, cisplatin, cytarabine; R-GDP: rituximab, gemcitabine, dexamethasone, cisplatin or carboplatin; R-ICE: rituximab, ifosfamide, carboplatin, etoposide</p>		

On 6 May 2025, shortly before the dossier was submitted by the company, the G-BA modified the ACT to that shown in Table 4. The company deviated from the ACT specified by the G-BA and initially referred to the ACT from the 2021 consultation in its dossier.

For the research question 1 patients (eligible for CAR T-cell therapy or stem cell transplantation), the company named the drugs axicabtagene ciloleucel, lisocabtagene maraleucel, tisagenlecleucel, or allogeneic or autologous stem cell transplantation as options – and not individualized treatment selected from the therapies listed. In addition, the company did not specify the drug combinations that can be used within an induction therapy preceding stem cell transplantation.

For the research question 2 patients (ineligible for CAR T-cell therapy and stem cell transplantation), the company stated treatment of physician's choice as the ACT, taking into account epcoritamab, loncastuximab tesirine, polatuzumab vedotin in combination with bendamustine and rituximab (polatuzumab vedotin + bendamustine + rituximab) or tafasitamab in combination with lenalidomide (tafasitamab + lenalidomide). However, the ACT most recently defined by the G-BA only included the 2 drug combinations polatuzumab vedotin + bendamustine + rituximab or tafasitamab + lenalidomide, which were considered equally appropriate.

This benefit assessment was conducted in comparison with the ACT specified by the G-BA on 6 May 2025. The company's deviation from the G-BA's ACT remained without consequence, as the company did not present any suitable data for the benefit assessment – neither versus the comparator therapy it had specified nor versus the ACT specified by the G-BA (see Chapter I 3). Since no suitable data were available for either of the 2 research questions, both research questions are assessed below in joint sections of the report.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. RCTs were used to derive the added benefit. This concurred with the company's inclusion criteria.

I 3 Information retrieval and study pool

The study pool for the assessment was compiled on the basis of the following information:

Sources used by the company in the dossier:

- Study list on glofitamab (status: 11 March 2025)
- Bibliographical literature search on glofitamab (last search on 11 March 2025)
- Search of trial registries/trial results databases for studies on glofitamab (last search on 11 March 2025)
- Search on the G-BA website for glofitamab (last search on 11 March 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on glofitamab (last search on 27 May 2025); for search strategies, see I Appendix A of the full dossier assessment

Consistent with the findings of the company, a review of the completeness of the study pool did not identify any relevant RCTs for either research question for the direct comparison of glofitamab with the ACT specified by the G-BA in the given therapeutic indication.

The company did not conduct an information retrieval on any further studies, neither on glofitamab nor on the ACT. Nevertheless, the company did present as supporting information the pivotal study NP30179 [3], as the best available evidence. However, the single-arm study presented did not allow a comparison with the ACT defined by the G-BA and was therefore not suitable for the benefit assessment of glofitamab. The company's study is described below.

Study NP30179

NP30179 is an ongoing, single-arm phase I/II dose escalation study with glofitamab monotherapy or in combination with obinutuzumab for the treatment of adult patients with relapsed/refractory B-cell non-Hodgkin lymphoma. The study consists of 3 parts: the dose-escalation phase (part 1: glofitamab monotherapy; part 2: glofitamab monotherapy or combination therapy with glofitamab + obinutuzumab) and the dose-expansion phase (part 3: glofitamab monotherapy or combination therapy with glofitamab + obinutuzumab). Patients were included with histologically confirmed haematological malignancy that is expected to express cluster of differentiation (CD)20, with relapse after at least one prior therapy or failure to respond to at least one prior therapy. A further prerequisite for inclusion in the study was that no treatment options were currently available to the patients that would prolong survival (e.g. standard chemotherapy or autologous stem cell transplantation). Excluded from participation in the study were patients with chronic lymphocytic leukaemia, Burkitt

lymphoma or lymphoplasmacytic lymphoma as well as patients with lymphoma of the central nervous system, either currently or in the past. The primary outcome of NP30179 was complete remission as assessed by the Independent Review Committee (IRC).

In Module 4 A of the dossier, the company presented a data cut from 17 May 2024 of a subpopulation of patients (N = 155) who had received at least 2 previous lines of systemic therapy and, according to the company, were treated with glofitamab as monotherapy at the approved dosage [4]. The tumour histology of these patients was DLBCL, transformed follicular lymphoma, high-grade B-cell lymphoma or primary mediastinal large B-cell lymphoma. The company presented the data for the entire subpopulation of patients and not separately for the 2 research questions.

The data presented by the company in Module 4 A on study NP30179 were not suitable for the benefit assessment, as they did not allow a comparison of glofitamab with the ACT for either of the 2 research questions. There were therefore no suitable data available for either research question.

I 4 Results on added benefit

For the assessment of glofitamab for the treatment of adult patients with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, no suitable data were available for comparison with the ACT specified by the G-BA. This applies to both research questions. In each case, there is no hint of an added benefit of glofitamab in comparison with the ACT; an added benefit is therefore not proven.

I 5 Probability and extent of added benefit

The result of the assessment of the added benefit of glofitamab in comparison with the ACT is summarized in Table 5.

Table 5: Glofitamab – probability and extent of added benefit

Research question	Therapeutic indication	ACT ^a	Probability and extent of added benefit
1	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are eligible for CAR T-cell therapy or stem cell transplantation ^{b, c}	<p>Individualized treatment^{d, e, f} selecting from</p> <ul style="list-style-type: none"> ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with autologous stem cell transplantation if there is a response to induction therapy and ▪ induction therapy with <ul style="list-style-type: none"> ▫ R-GDP or ▫ R-DHAP or ▫ R-ICE followed by high-dose therapy with allogeneic stem cell transplantation if there is a response to induction therapy 	Added benefit not proven
2	Adults with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy, who are ineligible for CAR T-cell therapy and stem cell transplantation ^{g, h}	<ul style="list-style-type: none"> ▪ polatuzumab vedotin in combination with bendamustine and rituximab or <ul style="list-style-type: none"> ▪ tafasitamab in combination with lenalidomide 	Added benefit not proven

a. Presented are the respective ACTs specified by the G-BA.
 b. According to the G-BA, treatment with curative intent is assumed to be an option for these patients.
 c. In patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is, according to the G-BA, an option in those patients who have a very high risk of relapse or in whom sufficient stem cell collection for autologous stem cell transplantation was not possible.
 d. The term ‘individualized treatment’ is used instead of previously used terms such as ‘patient-specific therapy’ or ‘treatment of physician’s choice’. This ensures consistency with the terms used in European health technology assessments (EU HTAs).
 e. According to the G-BA, it is assumed that the decision on treatment will be made taking into account, in particular, the previous treatment of patients with CAR T-cell therapy, autologous stem cell transplantation or allogeneic stem cell transplantation.
 f. For the implementation of individualized therapy in a study of direct comparison, the G-BA expects investigators to have a choice of several treatment options at their disposal, enabling them to make individualized treatment decisions (multi-comparator study).
 g. According to the G-BA, treatment with curative intent is not assumed to be an option for these patients.
 h. According to the S3 guideline, radiotherapy can be a suitable method for local disease control in palliative situations and should, if indicated, be offered in both study arms.

ACT: appropriate comparator therapy; CAR: chimeric antigen receptor; DLBCL: diffuse large B-cell lymphoma; G-BA: Federal Joint Committee; HTA: health technology assessment; R-DHAP: rituximab, dexamethasone, cisplatin, cytarabine; R-GDP: rituximab, gemcitabine, dexamethasone, cisplatin or carboplatin; R-ICE: rituximab, ifosfamide, carboplatin, etoposide

The assessment described above concurs with that by the company.

The G-BA decides on the added benefit.

Supplementary note

The result of the assessment deviates from the result of the G-BA's assessment conducted in the context of the market launch in 2023. At that time the G-BA had determined a non-quantifiable added benefit of glofitamab for the entire therapeutic indication of this benefit assessment. However, in the G-BA's assessment the added benefit was considered proven by the marketing authorization, regardless of the underlying data, due to the special situation for orphan drugs.

I 6 References for English extract

Please see full dossier assessment for full reference list.

The reference list contains citations provided by the company in which bibliographical information may be missing.

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Allgemeine Methoden; Version 7.0 [online]. 2023 [Accessed: 02.09.2024]. URL: https://www.iqwig.de/methoden/allgemeine-methoden_version-7-0.pdf.
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