Odronextamab (DLBCL)

Benefit assessment according to §35a SGB V[1]

EXTRACT

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Medical and scientific advice

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IQWiG thanks the medical and scientific advisor for his contribution to the dossier assessment. However, the advisor was not involved in the actual preparation of the dossier assessment. The responsibility for the contents of the dossier assessment lies solely with IQWiG.

Patient and family involvement

The questionnaire on the disease and its treatment was answered by Bernhard Jochheim.

IQWiG thanks the respondent and the patient organization ‘Leukämie und Lymphom SHG Ruhr-Lippe e. V.‘ for participating in the written exchange and for their support. The respondent and the ‘Leukämie und Lymphom SHG Ruhr-Lippe e. V.‘ were not involved in the actual preparation of the dossier assessment.

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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
DLBCL	diffuse large B-cell lymphoma
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
SGB	Sozialgesetzbuch (Social Code Book)
SmPC	summary of product characteristics

I 1 Executive summary of the benefit assessment

Background

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug odronextamab in accordance with §35a Social Code Book V. 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 31 July 2025.

Research question

The aim of this report is to assess the added benefit of odronextamab 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 odronextamab

Research question	Therapeutic indication	ACT[a]
1	Adults with relapsed or refractory DLBCL, after at least 2 prior systemic therapies, who are eligible for CAR T-cell therapy or stem cell transplantation[b, c]	Individualized treatment[d, e, f] selecting from ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with ▫ 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 ▫ 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 at least 2 prior systemic therapies, who are ineligible for CAR T-cell therapy and stem cell transplantation[g, h]	▪ polatuzumab vedotin in combination with bendamustine and rituximab or ▪ tafasitamab in combination with lenalidomide

a. Presented is the respective ACT 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. According to the G-BA, in patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is 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. 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 treatment in a study of direct comparison, it is expected that investigators 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 12 August 2025, after the dossier was submitted by the company, the G-BA modified the ACT to that shown in Table 2. In its dossier, the company referred to the ACT from its consultation with the G-BA on 10 April 2024. The company deviated both from the ACT specified in this consultation and from the current ACT as defined by the G-BA. The deviations related in particular to the treatment options of autologous and allogeneic stem cell transplantation, which the company did not consider for research question 1. The company also did not consider the suitability for stem cell transplantation to be decisive when categorizing the patient groups for research questions 1 and 2, but instead only the suitability for chimeric antigen receptor (CAR) T-cell therapy. In deviation from the G-BA's ACT, the company named treatment of physician's choice, taking into account epcoritamab, glofitamab and loncastuximab tesirine, for patients in research question 2. The deviations described were of no consequence for this benefit assessment, as the company did not present any suitable data for the comparison of odronextamab versus the current ACT of the G-BA or versus the ACT modified by the company.

This benefit assessment was conducted in comparison with the ACT specified by the G-BA on 12 August 2025 and by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier.

Results

The review of the completeness of the study pool did not identify any studies that would allow a direct comparison of odronextamab versus the ACT.

As the company did not identify any studies for a direct comparison either, it conducted an information retrieval for further studies on odronextamab. In doing so, it identified the single-arm studies ELM-1 and ELM-2 on treatment with odronextamab and used these studies for its assessment of the added benefit. In Module 4 A of the dossier, the company stated that it would not conduct any indirect comparisons of the treatment arms from ELM-1 and ELM-2 with individual arms from studies with drugs of the ACT. Accordingly, the company did not conduct an information retrieval for further investigations with the ACT and only used data from the studies ELM-1 and ELM-2 on treatment with odronextamab for its assessment.

The use of data from the single-arm studies ELM-1 and ELM-2 on treatment with odronextamab was not suitable for the benefit assessment, as it did not allow a comparison of odronextamab versus the ACT. There were therefore no suitable data available for either research question.

Results on added benefit

Since no suitable data were available for the benefit assessment, there is no hint of an added benefit of odronextamab 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 benefit[3]

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

Table 3: Odronextamab – probability and extent of added benefit (multipage table)

Research question	Therapeutic indication	ACT[a]	Probability and extent of added benefit
1	Adults with relapsed or refractory DLBCL, after at least 2 prior systemic therapies, who are eligible for CAR T-cell therapy or stem cell transplantation[b, c]	Individualized treatment[d, e, f] selecting from ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with ▫ 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 ▫ 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 at least 2 prior systemic therapies, who are ineligible for CAR T-cell therapy and stem cell transplantation[g, h]	▪ polatuzumab vedotin in combination with bendamustine and rituximab or ▪ tafasitamab in combination with lenalidomide	Added benefit not proven

[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: Odronextamab – probability and extent of added benefit (multipage table)

Research question	Therapeutic indication	ACT[a]	Probability and extent of added benefit
a. Presented is the respective ACT 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. According to the G-BA, in patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is 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. 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 treatment in a study of direct comparison, it is expected that investigators 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.

I 2 Research question

The aim of this report is to assess the added benefit of odronextamab 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 4 were defined in accordance with the ACT specified by the G-BA.

Table 4: Research questions for the benefit assessment of odronextamab

Research question	Therapeutic indication	ACT[a]
1	Adults with relapsed or refractory DLBCL, after at least 2 prior systemic therapies, who are eligible for CAR T-cell therapy or stem cell transplantation[b, c]	Individualized treatment[d, e, f] selecting from ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with ▫ 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 ▫ 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 at least 2 prior systemic therapies, who are ineligible for CAR T-cell therapy and stem cell transplantation[g, h]	▪ polatuzumab vedotin in combination with bendamustine and rituximab or ▪ tafasitamab in combination with lenalidomide

a. Presented is the respective ACT 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. According to the G-BA, in patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is 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. 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 treatment in a study of direct comparison, it is expected that investigators 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 12 August 2025, after the dossier was submitted by the company, the G-BA modified the ACT to that shown in Table 4. In its dossier, the company referred to the ACT from its consultation with the G-BA on 10 April 2024. The company deviated both from the ACT specified in this consultation and from the current ACT as defined by the G-BA. The deviations related in particular to the treatment options of autologous and allogeneic stem cell transplantation, which the company did not consider for research question 1. The company also did not consider the suitability for stem cell transplantation to be decisive when categorizing the patient groups for research questions 1 and 2, but instead only the suitability for chimeric antigen receptor (CAR) T-cell therapy. In deviation from the G-BA's ACT, the company named treatment of physician's choice, taking into account epcoritamab, glofitamab and loncastuximab tesirine, for patients in research question 2. The deviations described were of no consequence for this benefit assessment, as the company did not present any suitable data for the comparison of odronextamab versus the current ACT of the G-BA or versus the ACT modified by the company (see Chapter I 3 for details).

This benefit assessment was conducted in comparison with the ACT specified by the G-BA on 12 August 2025 and by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Since no suitable data were available for either of the research questions listed in Table 4, both research questions are assessed below in joint sections of the report.

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 odronextamab (status: 10 June 2025)
- Bibliographical literature search on odronextamab (last search on 10 June 2025)
- Search of trial registries / trial results databases for studies on odronextamab (last search on 16 June 2025)
- Search on the G-BA website for odronextamab (last search on 12 June 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on odronextamab (last search on 12 August 2025); for search strategies, see I Appendix A of the full dossier assessment

Concurring with the company, the review of the completeness of the study pool did not identify any studies that would allow a direct comparison of odronextamab versus the ACT.

As the company did not identify any studies for a direct comparison, it conducted an information retrieval for further studies on odronextamab. In doing so, it identified the single-arm studies ELM-1 [3] and ELM-2 [4] on treatment with odronextamab and used these studies for its assessment of the added benefit. In Module 4 A of the dossier, the company stated that it would not conduct any indirect comparisons of the treatment arms from ELM-1 and ELM-2 with individual arms from studies with drugs of the ACT. It justified this, among other things, with the challenges of a comprehensive confounder adjustment and the high heterogeneity of study populations that have undergone extensive prior treatment. Correspondingly, the company did not conduct an information retrieval for the ACT. The completeness of the study pool presented by the company for further investigations was not checked.

The data presented by the company were unsuitable for drawing conclusions on the added benefit of odronextamab in comparison with the ACT. The following section describes the studies ELM-1 and ELM-2 and explains why they are unsuitable.

Evidence provided by the company

Studies ELM-1 and ELM-2

ELM-1 and ELM-2 are ongoing, single-arm studies of treatment with odronextamab in adult patients with relapsed or refractory B-cell non-Hodgkin lymphoma, which were pivotal for the marketing authorization of odronextamab.

Depending on the tumour entity and the dosage regimen administered, the patients in the studies were treated in different cohorts. The dosage of odronextamab was gradually increased; however, the escalation scheme was modified during the ongoing studies and therefore only met the specifications of the summary of product characteristics (SmPC) [5] for some of the patients included. The target dosage in the studies also deviated in part from the specifications in the SmPC.

The primary outcome of both ELM-1 and ELM-2 was the tumour response according to the Lugano Classification for malignant lymphoma and as assessed by independent central review.

Analyses presented by the company

In Module 4 A of the dossier, the company used results from ELM-1 and ELM-2 for a subpopulation of patients with DLBCL who were escalated to the target dose of 160 mg of odronextamab per treatment cycle in the induction therapy. The company considered patients with this target dose regardless of whether they received the escalation regimen in compliance with the SmPC or not. For the ELM-1 study, the company only considered results from a cohort for dose expansion in which patients were included after failure of a previous CAR-T cell therapy. In addition, the company considered 2 different data cuts for ELM-1 (data cut-offs of 20 December 2022 and 22 January 2024) and for ELM-2 (data cut-offs of 31 January 2023 and 20 October 2023) for its assessment, depending on the outcome; according to the company, the later data cuts were provided to the European Medicines Agency as part of the marketing authorization procedure.

Evidence presented by the company unsuitable for the benefit assessment

The use of data from the single-arm studies ELM-1 and ELM-2 on treatment with odronextamab was not suitable for the benefit assessment, as it did not allow a comparison of odronextamab versus the ACT. There were therefore no suitable data available for either research question.

I 4 Results on added benefit

No suitable data were available to assess the added benefit of odronextamab as monotherapy in comparison with the ACT in adult patients with relapsed or refractory DLBCL, after 2 or more lines of systemic therapy. This applies to both research questions. In each case, there is no hint of an added benefit of odronextamab 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 odronextamab in comparison with the ACT is summarized in Table 5.

Table 5: Odronextamab – probability and extent of added benefit (multipage table)

Research question	Therapeutic indication	ACT[a]	Probability and extent of added benefit
1	Adults with relapsed or refractory DLBCL, after at least 2 prior systemic therapies, who are eligible for CAR T-cell therapy or stem cell transplantation[b, c]	Individualized treatment[d, e, f] selecting from ▪ tisagenlecleucel, ▪ axicabtagene ciloleucel, ▪ lisocabtagene maraleucel, ▪ induction therapy with ▫ 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 ▫ 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 at least 2 prior systemic therapies, who are ineligible for CAR T-cell therapy and stem cell transplantation[g, h]	▪ polatuzumab vedotin in combination with bendamustine and rituximab or ▪ tafasitamab in combination with lenalidomide	Added benefit not proven

Table 5: Odronextamab – probability and extent of added benefit (multipage table)

Research question	Therapeutic indication	ACT[a]	Probability and extent of added benefit
a. Presented is the respective ACT 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. According to the G-BA, in patients who have not yet been treated with autologous stem cell transplantation, allogeneic stem cell transplantation is 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. 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 treatment in a study of direct comparison, it is expected that investigators 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 departs from that by the company, which derived a hint of non-quantifiable added benefit for the total population of the present therapeutic indication.

The G-BA decides on the added benefit.

I 6 References for English extract

Please see full dossier assessment for full reference list.

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