Gemeinsamer Bundesausschuss

Justification

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V

Odronextamab (diffuse large B-cell lymphoma (DLBCL), after ≥ 2 previous therapies)

of 22 January 2026

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1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application,
7. number of study participants who participated in the clinical studies at study sites within the scope of SGB V, and total number of study participants.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA pass a resolution on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient odronextamab on 1 August 2025 in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure (VerfO) of the G-BA. Pursuant to Section 4, paragraph 3, No. 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, No. 1 Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the G-BA on 31 July 2025.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 3 November 2025 on the G-BA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of odronextamab compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of odronextamab.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have made the following assessment:

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

2.1.1 Approved therapeutic indication of Odronextamab (Ordspono) in accordance with the product information

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

Therapeutic indication of the resolution (resolution of 22.01.2026):

See the approved therapeutic indication.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

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 transplantation

Appropriate comparator therapy for odronextamab:

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)

[1] General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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

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 transplantation

Appropriate comparator therapy for odronextamab as monotherapy:

- polatuzumab vedotin in combination with bendamustine and rituximab
  or
- tafasitamab in combination with lenalidomide

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication in accordance with the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5 Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment

according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved in the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved in the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

On 1. In addition to odronextamab, the following active ingredients are approved for the present therapeutic indication:

Bleomycin, cyclophosphamide, cytarabine, dexamethasone, doxorubicin, epcoritamab, etoposide, glofitamab, ifosfamide, melphalan, methotrexate, methylprednisolone, mitoxantrone, polatuzumab vedotin, prednisolone, prednisone, tafasitamab, trofosfamide, vinblastine, vincristine, vindesine, rituximab, loncastuximab tesirine, axicabtagene ciloleucel, lisocabtagene maraleucel and tisagenlecleucel.

On 2. In principle, an autologous or allogeneic stem cell transplantation can be considered as a non-medicinal treatment for relapsed or refractory DLBCL. In addition, radiotherapy can be a suitable method for local disease control in palliative situations.

On 3. Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:

- Glofitamab (resolution of 6 November 2025)
- Epcoritamab (resolution of 17 April 2025)
- Tisagenlecleucel (resolution of 15 February 2024)
- Glofitamab (resolution of 1 February 2024)
- Axicabtagene ciloleucel (resolution of 21 December 2023)
- Loncastuximab tesirine (resolution of 2 November 2023)
- Lisocabtagene maraleucel (resolution of 6 April 2023)
- Tafasitamab (resolution of 3 March 2022)
- Polatuzumab vedotin (resolution of 20 June 2024)
- Pixantrone (resolution of 16 May 2013)

Directive on Inpatient Treatment Methods (last revised 7 December 2022: allogeneic stem cell transplantation for aggressive B-non-Hodgkin lymphomas):

- Section 4 Excluded methods: Allogeneic stem cell transplantation in adult patients with aggressive B-non-Hodgkin lymphoma who have not yet been treated with an

autologous stem cell transplantation (exceptions: a) patients who have a very high risk of recurrence and who achieve a response at least in the sense of stable disease after salvage therapy; b) patients in whom sufficient stem cell harvesting for an autologous stem cell transplantation was not possible and who achieve a response at least in the sense of stable disease after salvage therapy).

- Annex I - Methods required for hospital care: Allogeneic stem cell transplantation in adult patients with aggressive B-cell non-Hodgkin lymphomas who relapse after receiving an autologous stem cell transplantation and achieve a response at least in the sense of stable disease after salvage therapy.

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V. No written opinions were received.

Among the approved active ingredients listed under 1., only certain active ingredients named below will be included in the appropriate comparator therapy, taking into account the evidence on therapeutic benefit, the guideline recommendations and the reality of care.

Overall, the evidence on treatment options for the present advanced treatment setting of relapsed or refractory DLBCL after at least two lines of therapy is limited.

The approved therapeutic indication generally refers to patients with relapsed or refractory (r/r) DLBCL, after two or more lines of systemic therapy, and is not limited in terms of patient eligibility or ineligibility for an intensive therapeutic approach. According to the S3 guideline, there are distinct treatment recommendations for therapy with a primarily curative intent, such as CAR-T cell therapy and stem cell transplantation on the one hand, and for therapy with a primarily palliative intent on the other. The G-BA consider it appropriate to differentiate between two patient groups depending on their suitability for CAR-T cell therapy or stem cell transplantation when determining the appropriate comparator therapy.

<u>Patient group a)</u>

For patient group a), it is assumed that the patients are eligible for a therapy with curative intent.

According to the S3 guideline, CAR-T cell therapy should be carried out from the second relapse onwards if it has not already been carried out in second-line therapy. The CAR-T cell therapies axicabtagene ciloleucel, tisagenlecleucel and lisocabtagene maraleucel are available in this therapeutic indication. In the respective benefit assessments, it was determined that an additional benefit of axicabtagene ciloleucel (G-BA's resolution of 21 December 2023) and lisocabtagene maraleucel (G-BA's resolution of 6 April 2023) is not proven, as there was no suitable data in each case to enable an assessment of the additional benefit. A hint for a non-quantifiable additional benefit of tisagenlecleucel was identified by resolution of 15 February 2024 within the scope of an orphan drug assessment since the scientific data did not allow quantification.

According to the available guidelines, salvage chemoimmunotherapy including an (autologous or allogeneic) stem cell transplantation is a treatment option, especially after CAR-T cell therapy or for patients who are ineligible for such therapy. This is particularly the case for patients who have not received a stem cell transplantation in the second line of therapy. A salvage chemoimmunotherapy followed by an autologous or allogeneic stem cell transplantation is therefore considered by the G-BA to be a further suitable comparator in the context of individualised therapy.

According to the guidelines[2,3], platinum-based chemoimmunotherapy is used as standard for induction therapy, with the platinum-containing combinations GDP (gemcitabine, dexamethasone, cisplatin) and ICE (ifosfamide, carboplatin, etoposide), each in combination with rituximab, being recommended as specific treatment regimens. In accordance with the S3 guidelines, these treatment regimens were compared with each other in prospective randomised studies, whereby differences in toxicity were found with the same efficacy.[4,5]

The protocols R-GDP, R-DHAP and R-ICE have already been used as standard protocols for induction therapy in this therapeutic indication as part of the G-BA's assessment of the "allogeneic stem cell transplantation for B-cell non-Hodgkin lymphomas" method.[6] Rituximab is only approved in the present indication in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone), and individual components of the combination therapies mentioned (cisplatin, carboplatin, gemcitabine) are also not approved in the present indication.

Of the active ingredients approved for the treatment of non-Hodgkin lymphoma, only the platinum-free induction therapy MINE (mesna, ifosfamide, mitoxantrone, etoposide), which is mentioned in the American guideline of the National Comprehensive Cancer Network (NCCN) as another possible treatment regimen of lower priority, is available.[7] The statements of the clinical experts in the benefit assessment procedures on axicabtagene ciloleucel for the treatment of relapsed/ refractory DLBCL in the second line of therapy or relapsed/ refractory DLBCL and relapsed/ refractory primary mediastinal large B-cell lymphoma (PMBCL) in the third line of therapy indicate that MINE has no relevant significance in this therapeutic indication and, if used separately in the past, was consolidated with a platinum-containing therapy. In agreement with the estimate of the clinical experts, all the

[2] Guideline programme in oncology (German Cancer Society, German Cancer Aid, Association of the Scientific-Medical Societies (AWMF)): Diagnostics, therapy and after-care for adult patients with diffuse large B-cell lymphoma and related entities, long version 1.0, 2022, AWMF registry number: 018/038OL https://www.leitlinienprogramm-onkologie.de/leitlinien/diffuses-grosszelligen-b-zell-lymphom-dlbcl

[3] National Institute for Health and Care Excellence (NICE). Non-Hodgkin's lymphoma: diagnosis and management [online]. 10.2021. London (GBR): NICE; 2016. (NICE Guideline; Band NG52). URL: https://www.nice.org.uk/guidance/ng52/resources/nonhodgkins-lymphoma-diagnosis-and-management-pdf-1837509936325.

[4] Gisselbrecht C, Glass B, Mounier N, Linch D, Gill D, Trneny M. R-ICE versus R-DHAP in relapsed patients with CD20 diffuse large B-cell lymphoma (DLBCL) followed by autologous stem cell transplantation: CORAL study. 2009;27:15s

[5] Crump M, Kuruvilla J, Couban S, MacDonald D, Kukreti V, Kouroukis C, et al. Randomized comparison of gemcitabine, dexamethasone, and cisplatin versus dexamethasone, cytarabine, and cisplatin chemotherapy before autologous stem-cell transplantation for relapsed and refractory aggressive lymphomas: NCIC-CTG LY12. J Clin Oncol. 2014; 32:3490-6. URL: https://pubmed.ncbi.nlm.nih.gov/25267740/

[6] Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Directive on Inpatient Treatment Methods: Allogeneic stem cell transplantation for aggressive B-cell non-Hodgkin lymphomas; 9 April 2020

[7] National Comprehensive Cancer Network (NCCN). B-Cell lymphomas; Vers. 18.01.2024 [online]. Fort Washington (USA): NCCN; 2024. (NCCN Clinical Practice Guidelines in Oncology)

available guidelines unanimously recommend platinum-containing induction therapy with R-GDP, R-ICE or R-DHAP with priority, although it should be noted that the platinum-free induction therapy MINE is not mentioned at all in the S3 guideline relevant to the German healthcare context.

In summary, if CAR-T cell therapy has already been carried out or is not an option for medical reasons, salvage chemoimmunotherapy consisting of R-GDP, R-ICE or R-DHAP should be accordingly carried out with the inclusion of stem cell transplantation. In these cases, the use of induction therapy with R-GDP, R-ICE or R-DHAP is generally preferable to induction therapy with MINE for this relevant patient group in accordance with Section 6, paragraph 2, number 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV). Therefore, it is appropriate to determine the off-label use of these combinations of medicinal products as the appropriate comparator therapy for this patient population.

The active ingredients loncastuximab tesirine, epcoritamab and glofitamab as monotherapy are also available as treatment options for this patient group. These therapy options are recommended in the NCCN guideline and the statements of the scientific-medical societies. It was determined by the G-BA's resolution of 2 November 2023 that an additional benefit of loncastuximab tesirine is not proven, as no suitable data were available to enable an assessment of the additional benefit. As part of the benefit assessment following repeal of the regulatory orphan status, an additional benefit of epcoritamab by resolution of 17 April 2025 and that of glofitamab by resolution of 6 November 2025 is not proven, as no suitable data were available. In addition, these therapy options are not listed in the current version of the S3 guideline.

Loncastuximab tesirine, epcoritamab and glofitamab as monotherapy are not included in the appropriate comparator therapy for the present resolution.

Overall, an individualised therapy with selection of tisagenlecleucel, axicabtagene ciloleucel and lisocabtagene maraleucel, an induction therapy with R-GDP, R-ICE or R-DHAP followed by a high-dose therapy with an autologous or allogeneic stem cell transplantation in response to the induction therapy is therefore determined as the appropriate comparator therapy.

When selecting therapy options as part of an individualised therapy, the patients' previous therapy with CAR-T cell therapy, autologous stem cell transplantation or allogeneic stem cell transplantation must accordingly be taken into account.

For patients who have not yet been treated with an autologous stem cell transplantation, an allogeneic stem cell transplantation is an option for patients who have a very high risk of recurrence or for whom stem cell harvesting was not possible for an autologous stem cell transplantation.

Patient group b)

For patient group b), it is assumed that the patients are not eligible for a therapy with curative intent. For these patients, who are ineligible for CAR-T cell therapy and stem cell transplantation due to the course of their disease or their general condition, various chemotherapies or chemoimmunotherapies as well as newer substances represent therapy options according to guidelines and the joint statement of the German Society for Haematology and Medical Oncology (DGHO) and German Lymphoma Alliance (GLA).

The antibody-drug conjugate polatuzumab vedotin is approved in combination with bendamustine and rituximab (Pola-BR) for the treatment of adults with relapsed or

refractory DLBCL if they are ineligible for a haematopoietic stem cell transplantation. In the benefit assessment for polatuzumab vedotin, it was determined that an additional benefit thereof is not proven (benefit reassessment due to exceeding the EUR 30 million turnover limit for orphan drugs; resolution of 20 June 2024).

The CD19-specific antibody tafasitamab is approved in combination with lenalidomide for the treatment of patients with relapsed or refractory DLBCL who are ineligible for an autologous stem cell transplantation. By resolution of 3 March 2022, a hint for a non-quantifiable additional benefit of tafasitamab was identified within the scope of an orphan drug assessment since the scientific data did not allow quantification.

The combination chemotherapies CEOP (cyclophosphamide, etoposide, vincristine, prednisone) and EPOCH (etoposide, vincristine, doxorubicin, cyclophosphamide, prednisone) are also approved for this indication. From the statements of the clinical experts in the benefit assessment procedure on loncastuximab tesirine,[8] it emerged that the combination chemotherapies mentioned have no relevant significance in the present treatment setting - especially as the combination therapies mentioned or the active ingredients contained in these combination therapies have already been used within the therapeutic sequence. The combination therapies mentioned are not determined as an appropriate comparator therapy.

The active ingredients loncastuximab tesirine, epcoritamab and glofitamab as monotherapy as well as glofitamab in combination with gemcitabine and oxaliplatin are also available as treatment options for this patient group. These therapy options are recommended in the statements of the scientific-medical societies. The NCCN guideline recommends the therapy options of loncastuximab tesirine, epcoritamab and glofitamab as monotherapy; the combination of glofitamab with gemcitabine and oxaliplatin is not listed in the current version of the NCCN guideline. In the benefit assessment, an additional benefit of loncastuximab tesirine by resolution of 2 November 2023 and glofitamab in combination with gemcitabine and oxaliplatin by resolution of 6 November 2025 could not be proven, as no suitable data were available. As part of the benefit assessment following repeal of the regulatory orphan status, an additional benefit of epcoritamab by resolution of 17 April 2025 and that of glofitamab by resolution of 6 November 2025 is not proven, as no suitable data were available. In addition, these therapy options are not listed in the current version of the S3 guideline.

Loncastuximab tesirine, epcoritamab, glofitamab as monotherapy and glofitamab in combination with gemcitabine and oxaliplatin are not included in the appropriate comparator therapy for the present resolution.

Against this background, polatuzumab vedotin in combination with bendamustine and rituximab as well as tafasitamab in combination with lenalidomide are determined to be equally appropriate therapy options for patient group b).

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5 Section 6, paragraph 3 Rules of Procedure.

[8] Summary documentation of the benefit assessment procedure for D-936 loncastuximab tesirine, resolution of 2 November 2023

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of odronextamab is assessed as follows:

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 transplantation

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 transplantation

An additional benefit is not proven.

Justification:

In the absence of direct comparator studies of odronextamab versus the appropriate comparator therapy, the pharmaceutical company demonstrated the additional benefit using the phase I ELM-1 study and the phase II ELM-2 study. The pharmaceutical company states that an indirect comparison of the treatment arms of the ELM-1 and ELM-2 studies with individual arms from studies with active ingredients of the appropriate comparator therapy was not conducted due to the challenges of full confounder adjustment and the high heterogeneity of intensely pretreated study populations.

ELM-1 and ELM-2 studies

Patients with different tumour entities (follicular lymphoma, diffuse large B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma) were enrolled In the ongoing, single-arm studies, and treated in cohorts with different dosage regimens. The primary endpoint of the studies is tumour response according to the Lugano classification of malignant lymphomas according to the assessment by an independent review committee.

The ELM-1 study has been conducted at 17 study sites in North America, Europe and Israel since January 2015. In the dossier, the pharmaceutical company submitted the data cut-offs from 20 December 2022 and 22 January 2024. At the last data cut-off, 60 patients who received a dosage in line with the product information were enrolled.

The ELM-2 study has been ongoing since November 2019 in 92 study sites in Asia, Australia, North America and Europe. In the dossier, the pharmaceutical company submitted the data cut-offs from 31 January 2023 and 20 October 2023. At the last data cut-off, 141 patients who received a dosage in line with the product information were enrolled.

Conclusion:

Due to the single-arm study design, the ELM-1 and ELM-2 studies do not allow a comparison with the appropriate comparator therapy for both research questions and are therefore unsuitable for the assessment of an additional benefit of odronextamab. An additional benefit of odronextamab for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy is therefore not proven for either patient group.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Ordspono with the active ingredient odronextamab.

Ordspono as monotherapy received a conditional marketing authorisation for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

In the therapeutic indication to be considered, 2 patient groups were distinguished:

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 transplantation

and

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 transplantation

Patient group a)

An individualised therapy with selection of tisagenlecleucel, axicabtagene ciloleucel and lisocabtagene maraleucel, an induction therapy with R-GDP, R-ICE or R-DHAP followed by a high-dose therapy with an autologous or allogeneic stem cell transplantation in response to the induction therapy was determined as the appropriate comparator therapy.

Patient group b)

As appropriate comparator therapy, polatuzumab vedotin in combination with bendamustine and rituximab as well as tafasitamab in combination with lenalidomide were determined to be equally appropriate therapy options.

For the benefit assessment, the pharmaceutical company submitted the results of the ELM-1 and ELM-2 studies. Due to the single-arm study design, the ELM-1 and ELM-2 studies do not allow a comparison with the appropriate comparator therapy for both research questions and are therefore unsuitable for the assessment of an additional benefit of odronextamab. The pharmaceutical company states that an indirect comparison of the treatment arms of the ELM-1 and ELM-2 studies with individual arms from studies with active ingredients of the appropriate comparator therapy did not appear expedient on the basis of the available data basis and was therefore not conducted. An additional benefit of odronextamab for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy is therefore not proven for either patient group.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The resolution is based on the information from the resolution on the benefit assessment of glofitamab in the same therapeutic indication (resolution of 6 November 2025).

The patient number determined by the pharmaceutical company is subject to uncertainties, but is comparable to the patient numbers treated with the previous procedure of glofitamab in the therapeutic indication.

In order to ensure a consistent determination of the patient numbers in the present therapeutic indication, the G-BA refers to the derivation of the target population used as a basis in the resolution on the benefit assessment of glofitamab (resolution of 5 November 2025). A valid estimate of the number of patients in the SHI target population is available here; this can be used despite continuing uncertainties.

2.3 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 Ordspono (active ingredient: odronextamab) at the following publicly accessible link (last access: 19 September 2025):

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

Treatment with odronextamab 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.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

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

In particular, the training material contains information and warnings on cytokine release syndrome (CRS) and neurological toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS).

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 November 2025). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or co-morbidities) are not taken into account when calculating the annual treatment costs.

According to the product information, maintenance treatment with the active ingredient odronextamab is carried out in a 14-day cycle after completion of the first 4 cycles and a one-week break. According to the product information, maintenance treatment is switched to a 28-day cycle if a complete response (CR) has been achieved for 9 months. This results in a range in the cost representation, as the time at which a complete response is achieved is different from patient to patient. As an example, the calculation is based on the assumption that a CR was achieved after completion of the 4th cycle.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements of the official representative statistics "Microcensus 2021 – body measurements of the population" were applied (average body height: 1.72 m; average body weight: 77.7 kg). This results in a body surface area of 1.91 m² (calculated according to Du Bois 1916).[9]

The dosage according to the target AUC of carboplatin is calculated using the Calvert formula and the estimation of renal function with the Cockcroft-Gault equation using the average height (women: 166 cm, men: 179 cm), the average weight (women 69.2 kg, men 85.8 kg) and the average age of women and men in Germany in 2021 (women: 46 years, men: 43.4 years)[10] and the mean standard serum creatinine concentration (women: 0.75 mg/dl, men: 0.9 mg/dl).[11]

The mean value (AUC 5 = 700.8 mg) formed from these doses for women (AUC 5 = 637 mg) and men (AUC 5 = 764.5 mg) was used as the basis for calculating the costs of carboplatin.

CAR-T cell therapies

Axicabtagene ciloleucel, lisocabtagene maraleucel and tisagenlecleucel are genetically modified, patient's own (autologous) T cells, which are usually obtained by leukapheresis. Since leukapheresis is part of the manufacture of the medicinal product according to Section 4 paragraph 14 Medicinal Products Act, no further costs are incurred in this respect for these active ingredients as treatment options of the medicinal product to be assessed.

Axicabtagene ciloleucel, lisocabtagene maraleucel and tisagenlecleucel are listed on LAUER-TAXE®, but are only dispensed to appropriately qualified inpatient treatment facilities. Accordingly, the active ingredients are not subject to the Pharmaceutical Price Ordinance (Arzneimittelpreisverordnung) and no rebates according to Section 130 or Section 130a SGB V apply. The calculation is based on the purchase price of the respective clinic pack, in deviation from the LAUER-TAXE® data usually taken into account.

Axicabtagene ciloleucel, lisocabtagene maraleucel and tisagenlecleucel are administered as a single intravenous infusion according to the requirements in the underlying product information.

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[9] Federal health reporting. Average body measurements of the population (2021, both sexes, 15 years and older), www.gbe-bund.de

[10] Federal Institute for Population Research, average age of the population in Germany (1871-2021) https://www.bib.bund.de/DE/Fakten/Fakt/B19-Durchschnittsalter-Bevoelkerung-ab-1871.html

[11] DocCheck Flexikon – Serum creatinine, URL: https://flexikon.doccheck.com/de/Serumkreatinin [last access: 15.11.2025]

Induction chemotherapy before stem cell transplantation

The induction chemotherapies R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin), R-ICE (rituximab + ifosfamide + carboplatin + etoposide) and R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin) do not have a marketing authorisation in the present therapeutic indication. In accordance with the recommendation of the S3 guideline, the G-BA uses 2 - 3 cycles as the basis for calculating costs in the context of off-label use of these combination therapies[12]. Furthermore, for the treatment regimens and dosages in relation to the combination therapy R-GDP, the study by Crump et al. (2014) [13] referenced in the S3 guideline and, in relation to the combination therapies R-ICE and R-DHAP, the study by Gisselbrecht et al. referenced in the S3 guideline (2010)[14] are taken into account.

Inpatient treatments

Some treatment options of the appropriate comparator therapy are carried out on an inpatient basis. The inpatient costs are calculated on the basis of the case flat fee revenues, which result from the valuation ratios of the respective DRG (Diagnosis Related Group) multiplied by the federal base rate value of 2025 (€ 4,394.22). Furthermore, the nursing revenue, which is calculated from the average length of stay of the concerned Diagnosis Related Group (DRG) multiplied by the nursing fee according to Section 15 paragraph 2a German Hospital Fee Act (KHEntgG) and the treatment-specific nursing revenue valuation ratio, is taken into account in the inpatient costs. The calculation of the costs of the inpatient treatments is standardised in the following on the basis of the DRG case flat fee catalogue 2025 and the nursing revenue catalogue 2025, the Federal base rate value of 2025 as well as the nursing fee pursuant to Section 15, paragraph 2a German Hospital Fee Act (KHEntgG), since the federal base rate value for 2026 was not yet available at the time of the cost calculation (15 November 2025).

Treatment period:

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 transplantation

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Odronextamab	Cycle 1: Day 1, 2, 8, 9, 15 and 16	4	Cycle 1: 6	15

[12] Association of the Scientific-Medical Societies (AWMF). Diagnostics, therapy and after-care for adult patients with diffuse large B-cell lymphoma and related entities; S3-guideline [online]. AWMF registry number 018-038OL. Berlin (GER): Oncology guideline programme; 2022.

[13] Crump M, Kuruvilla J, Couban S, MacDonald D, Kukreti V, Kouroukis C, et al. Randomized comparison of gemcitabine, dexamethasone, and cisplatin versus dexamethasone, cytarabine, and cisplatin chemotherapy before autologous stem-cell transplantation for relapsed and refractory aggressive lymphomas: NCIC-CTG LY12. J Clin Oncol. 2014;32:3490-6.

[14] Gisselbrecht C, Glass B, Mounier N, Singh Gill D, Linch DC, Trneny M, et al. Salvage regimens with autologous transplantation for relapsed large B-cell lymphoma in the rituximab era. J Clin Oncol 2010;28 (27):4184-90

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	of a 21-day cycle <u>Cycle 2 – 4:</u> Day 1, 8 and 15 of a 21-day cycle		<u>Cycle 2 – 4</u>: 3	
	<u>Maintenance treatment:</u> 1 x every 14 days or 1 x every 14 days (CR until the 9th month), then 1 x every 28 days	19.3 – 19.6	1	19.3 – 19.6
Appropriate comparator therapy				
Individualised therapy with selection of				
Tisagenlecleucel, axicabtagene ciloleucel, lisocabtagene maraleucel				
Axicabtagene ciloleucel	Single dose	1	1	1
Lisocabtagene maraleucel	Single dose	1	1	1
Tisagenlecleucel	Single dose	1	1	1
Induction therapy with R-GDP, R-DHAP or R-ICE followed by high-dose therapy with autologous or allogeneic stem cell transplantation if there is a response to induction therapy				
Induction chemotherapies				
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin) [13]				
Rituximab	1 x per 21-day cycle (day 1)	2 – 3	1	2 – 3
Gemcitabine	2 x per 21-day cycle (day 1 + 8)	2 – 3	2	4 – 6
Dexamethasone PO	4 x per 21-day cycle (day 1 - 4)	2 – 3	4	8 – 12
Cisplatin	1 x per 21-day cycle (day 1)	2 – 3	1	2 – 3
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin) [13,14]				
Rituximab	1 x per 21-day cycle (day 1; additionally once **optionally** on the day before the first cycle)	2 – 3	1	2 – 4
Dexamethasone	4 x per 21-day cycle (day 1 - 4)	2 – 3	4	8 – 12

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Cytarabine	2 x on day 2 of a 21-day cycle	2 – 3	1	2 – 3
Cisplatin	1 x per 21-day cycle (day 1)	2 – 3	1	2 – 3
R-ICE (rituximab + ifosfamide + carboplatin + etoposide)[14]				
Rituximab	1 x per 21-day cycle (day 1, additionally once on the day before the first cycle)	2 – 3	1	3 – 4
Ifosfamide	1 x per 21-day cycle (day 2)	2 – 3	1	2 – 3
Carboplatin	1 x per 21-day cycle (day 2)	2 – 3	1	2 – 3
Etoposide	3 x per 21-day cycle (day 1 – 3)	2 – 3	3	6 – 9
High-dose chemotherapy with **autologous** stem cell transplantation				
Stem cell collection	once		4.2 – 5.0 (average length of stay)	4.2 – 5.0
High-dose chemotherapy + autologous stem cell transplantation	once		22.3 (average length of stay)	22.3
High-dose chemotherapy with **allogeneic** stem cell transplantation				
Stem cell collection/ acquisition	once		Not calculable	
High-dose chemotherapy + allogeneic stem cell transplantation	once		33.6 – 38.2 (average length of stay)	33.6 – 38.2

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 transplantation

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Odronextamab	Cycle 1: Day 1, 2, 8, 9, 15 and 16 of a 21-day cycle Cycle 2 – 4: Day 1, 8 and 15 of a 21-day cycle	4	Cycle 1: 6 Cycle 2 – 4: 3	15
	Maintenance treatment: 1 x every 14 days or 1 x every 14 days (CR until the 9th month), then 1 x every 28 days	19.3 – 19.6	1	19.3 – 19.6
Appropriate comparator therapy				
tafasitamab in combination with lenalidomide				
Tafasitamab	Combination therapy 28-day cycle; Cycle 1: Day 1, 4, 8, 15 and 22 Cycle 2 + 3: Day 1, 8, 15 and 22 Cycle 4 – 12: Day 1 and 15	12.0	Cycle 1: 5 Cycle 2 + 3: 4 Cycle 4 – 12: 2	31.0
	Monotherapy 28-day cycle; Day 1 and 15	1.0	2	2.0
Lenalidomide	Day 1 – 21 of a 28-day cycle	12.0	21	252
Polatuzumab vedotin in combination with bendamustine and rituximab				
Polatuzumab vedotin	1 x per 21-day cycle	6.0	1	6
Bendamustine	2 x per 21-day cycle	6.0	2	12
Rituximab	1 x per 21-day cycle	6.0	1	6

Consumption:

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 transplantation

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Odronextamab	Cycle 1 Day 1 0.2 mg	0.2 mg	1 x 2 mg	1	14 x 2 mg
	Cycle 1 Day 2 0.5 mg	0.5 mg	1 x 2 mg	1	
	Cycle 1 Day 8 and 9 2 mg	2 mg	1 x 2 mg	2	
	Cycle 1 Day 15 and 16 10 mg	10 mg	5 x 2 mg	2	
	Cycle 2 – 4 Day 1, 8 and 15 160 mg	160 mg	2 x 80 mg	9	18 x 80 mg
	Maintenance treatment 320 mg	Maintenance treatment 320 mg	1 x 320 mg	19.3 – 19.6	19.3 x 320 mg – 19.6 x 320 mg
Appropriate comparator therapy					
Individualised therapy with selection of					
Tisagenlecleucel, axicabtagene ciloleucel, lisocabtagene maraleucel					
Axicabtagene ciloleucel	< 100 kg: 1 - 2 x 10^6 viable CAR+ T cells/kg	1 - 2 x 10^6/kg CAR+ T cells	1 single infusion bag	1	1 single infusion bag
	≥ 100 kg: 2 x 10^8 Viable CAR+ T cells (from 100 kg regardless of body weight)	2 x 10^8 CAR+ T cells			

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Lisocabtagene maraleucel	100×10^6 viable CAR+ T cells	100×10^6 viable CAR+ T cells	1 single infusion bag	1	1 single infusion bag
Tisagenlecleucel	$0.6 - 6 \times 10^8$ CAR+ viable T cells (regardless of the body weight)	$0.6 - 6 \times 10^8$ CAR+ T cells	1 single infusion bag	1	1 single infusion bag
Induction therapy with R-GDP, R-DHAP or R-ICE followed by high-dose therapy with autologous or allogeneic stem cell transplantation if there is a response to induction therapy					
Induction chemotherapies					
R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin)[13]					
Rituximab	375 mg/m² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	2 – 3	2 x 500 mg + 6 x 100 mg – 3 x 500 mg + 9 x 100 mg
Gemcitabine	1,000 mg/m² = 1,910 mg	1,910 mg	2 x 1,000 mg	4 – 6	8 x 1,000 mg – 12 x 1,000 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	8 – 12	8 x 40 mg – 12 x 40 mg
Cisplatin	75 mg/m² = 143.3 mg	143.3 mg	1 x 100 mg + 1 x 50 mg	2 – 3	2 x 100 mg + 2 x 50 mg – 3 x 100 mg + 3 x 50 mg
R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin) [13,14]					
Rituximab	375 mg/m² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	2 – 4	2 x 500 mg + 6 x 100 mg – 4 x 500 mg + 12 x 100 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	8 – 12	8 x 40 mg – 12 x 40 mg
Cytarabine	2 x daily 2,000 mg/m² = 2 x 3,820 mg	7,640 mg	4 x 2,000 mg	2 – 3	8 x 2,000 mg – 12 x 2,000 mg

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Cisplatin	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	2 – 3	4 x 100 mg – 6 x 100 mg
R-ICE *(rituximab + ifosfamide + carboplatin + etoposide)*[14]					
Rituximab	375 mg/m^2 = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	3 – 4	3 x 500 mg + 9 x 100 mg – 4 x 500 mg + 12 x 100 mg
Ifosfamide	5,000 mg/m^2 = 9,550 mg	9,550 mg	2 x 5,000 mg	2 – 3	4 x 5,000 mg – 6 x 5,000 mg
Carboplatin	AUC 5 (= 700.8 mg); max. 800 mg	700.8 mg – 800 mg	1 x 600 mg + 1 x 150 mg – 1 x 600 mg + 1 x 150 mg + 1 x 50 mg	2 – 3	2 x 600 mg + 2 x 150 mg – 3 x 600 mg + 3 x 150 mg + 3 x 50 mg
Etoposide	100 mg/m^2 = 191 mg	191 mg	1 x 200 mg	6 – 9	6 x 200 mg – 9 x 200 mg

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 transplantation

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Odronextamab	Cycle 1 Day 1 0.2 mg	0.2 mg	1 x 2 mg	1	14 x 2 mg
	Cycle 1 Day 2 0.5 mg	0.5 mg	1 x 2 mg	1	
	Cycle 1 Day 8 and 9 2 mg	2 mg	1 x 2 mg	2	
	Cycle 1 Day 15 and 16 10 mg	10 mg	5 x 2 mg	2	
	Cycle 2 – 4 Day 1, 8 and 15 160 mg	160 mg	2 x 80 mg	9	18 x 80 mg
	Maintenance treatment 320 mg	Maintenance treatment 320 mg	1 x 320 mg	19.3 – 19.6	19.3 x 320 mg – 19.6 x 320 mg
Appropriate comparator therapy					
tafasitamab in combination with lenalidomide					
Tafasitamab	12 mg/kg = 932.4 mg	932.4 mg	5 x 200 mg	33.0	165 x 200 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	252	252 x 25 mg
Polatuzumab vedotin in combination with bendamustine and rituximab					
Polatuzumab vedotin	1.8 mg/kg = 139.9 mg	139.9 mg	1 x 140 mg	6	6 x 140 mg
Bendamustine	90 mg/m^2 = 171.9 mg	171.9 mg	1 x 100 mg + 3 x 25 mg	12	12 x 100 mg + 36 x 25 mg
Rituximab	375 mg/m^2 = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	6	6 x 500 mg + 18 x 100 mg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Inpatient treatments:

For DRGs Z42Z and Z43Z or ZE2025-35, hospital-specific fees must be agreed in accordance with the catalogue of case flat fees pursuant to Section 6, paragraph 1, sentence 1 of the German Hospital Remuneration Act. The costs can therefore not be definitively quantified.

Calculation year	DRG	Average length of stay [d]	DRG valuation ratio (main department)	Federal base case value	Nursing revenue valuation ratio	Nursing fee	Case flat fee revenue	Nursing revenue	Total case flat fee revenue and nursing revenue
Appropriate comparator therapy									
High-dose chemotherapy with **allogeneic** stem cell transplantation									
Stem cell collection/ acquisition									
2025	Z42Z	Not calculable							
or									
2025	Z43Z	Not calculable							
or									
2025	ZE2025-35	Not calculable							
Stem cell transplantation									
2025	A04E	33.6	9.004	€ 4,394.22	1.7706	€ 250	€ 39,565.56	€ 14,873.04	€ 54,438.60
2025	A04D	38.2	10.161	€ 4,394.22	1.8187	€ 250	€ 44,649.67	€ 17,368.59	€ 62,018.26
High-dose chemotherapy with **autologous** stem cell transplantation									
Stem cell collection									
2025	A42C	4.2	0.809	€ 4,394.22	0.843	€ 250	€ 3,554.92	€ 885.15	€ 4,440.07
or									
2025	R61H	5.0	0.609	€ 4,394.22	0.8204	€ 250	€ 2,676.08	€ 1,025.50	€ 3,701.58
Stem cell transplantation									
2025	A15C	22.3	4.918	€ 4,394.22	1.2007	€ 250	€ 21,610.77	€ 6,693.90	€ 28,304.67

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Odronextamab					
Odronextamab 2 mg	1 CIS	€ 113.41	€ 1.77	€ 5.65	€ 105.99
Odronextamab 80 mg	1 CIS	€ 4,016.67	€ 1.77	€ 226.10	€ 3,788.80
Odronextamab 320 mg	1 CIS	€ 15,893.70	€ 1.77	€ 904.40	€ 14,987.53
Appropriate comparator therapy					
Designation of the therapy	Packaging size	Costs (purchase price clinic pack plus value added tax)		Value-added tax (19%)	Costs of the medicinal product
CAR-T cell therapies					
Axicabtagene ciloleucel	1 single infusion bag	€ 230,621.00		€ 0[15]	€ 230,621.00
Lisocabtagene maraleucel	1 single infusion bag	€ 227,500.00		€ 0[15]	€ 227,500.00
Tisagenlecleucel	1 single infusion bag	€ 239,000.00		€ 0[15]	€ 239,000.00
Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
tafasitamab in combination with lenalidomide					
Tafasitamab 200 mg	1 PCI	€ 654.48	€ 1.77	€ 35.61	€ 617.10
Lenalidomide 25[16]	63 HC	€ 117.32	€ 1.77	€ 8.38	€ 107.17
Polatuzumab vedotin in combination with bendamustine and rituximab					
Polatuzumab vedotin 140 mg	1 PIC	€ 7,493.57	€ 1.77	€ 0.00	€ 7,491.80
Bendamustine 100 mg	5 PIC	€ 1,653.78	€ 1.77	€ 208.35	€ 1,443.66
Bendamustine 100 mg	1 PIC	€ 337.73	€ 1.77	€ 41.31	€ 294.65
Bendamustine 25 mg	5 PIC	€ 422.90	€ 1.77	€ 52.08	€ 369.05
Bendamustine 25 mg	1 PIC	€ 101.23	€ 1.77	€ 11.38	€ 88.08
Rituximab 100 mg	2 CIS	€ 717.21	€ 1.77	€ 39.08	€ 676.36

[15] The medicinal product is exempt from value added tax at the applied LAUER-TAXE® last revised.

[16] Fixed reimbursement rate

Rituximab 500 mg	1 CIS	€ 1,777.34	€ 1.77	€ 98.21	€ 1,677.36
Induction chemotherapies (R-GDP, R-DHAP, R-ICE) prior to an autologous or allogeneic stem cell transplantation					
Rituximab 100 mg	2 CIS	€ 717.21	€ 1.77	€ 39.08	€ 676.36
Rituximab 500 mg	1 CIS	€ 1,777.34	€ 1.77	€ 98.21	€ 1,677.36
Carboplatin 150 mg	1 CIS	€ 83.04	€ 1.77	€ 3.40	€ 77.87
Carboplatin 600 mg	1 CIS	€ 300.84	€ 1.77	€ 13.74	€ 285.33
Carboplatin 50 mg	1 CIS	€ 34.66	€ 1.77	€ 1.11	€ 31.78
Carboplatin 150 mg	1 CIS	€ 83.06	€ 1.77	€ 3.40	€ 77.89
Carboplatin 600 mg	1 CIS	€ 300.84	€ 1.77	€ 13.74	€ 285.33
Cisplatin 100 mg	1 CIS	€ 76.59	€ 1.77	€ 3.10	€ 71.72
Cisplatin 50 mg	1 CIS	€ 47.71	€ 1.77	€ 1.73	€ 44.21
Cytarabine 2,000 mg	1 SII	€ 77.06	€ 1.77	€ 3.12	€ 72.17
Dexamethasone 40 mg[16]	10 TAB	€ 46.29	€ 1.77	€ 0.00	€ 44.52
Dexamethasone 40 mg[16]	20 TAB	€ 81.59	€ 1.77	€ 0.00	€ 79.82
Etoposide 200 mg	1 CIS	€ 81.90	€ 1.77	€ 3.35	€ 76.78
Gemcitabine 1,000 mg	1 PIF	€ 102.35	€ 1.77	€ 10.62	€ 89.96
Ifosfamide 5 g	1 CIS	€ 177.77	€ 1.77	€ 7.90	€ 168.10
Abbreviations: HC = hard capsules; CIS = concentrate for the preparation of an infusion solution; SII = solution for injection/infusion; PIF = powder for the preparation of an infusion solution; PIC = powder for the preparation of an infusion solution concentrate; PCI = powder for a concentrate for the preparation of an infusion solution; TAB = tablets					

LAUER-TAXE® last revised: 15 November 2025

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Since the off-label use of medicinal products in the therapy options R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin), R-ICE (rituximab + ifosfamide + carboplatin + etoposide) and R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin) was exceptionally determined as the appropriate comparator therapy in the present case, no relevant statement can be made on whether there were regular differences in the need for availing medical treatment or in the prescription of other services when using the medicinal product to be assessed compared to the appropriate comparator therapy according to the product information. Therefore, no costs for additionally required SHI services are taken into account here for the therapy options mentioned above.

The calculation of the additionally required SHI services is based on packs in distribution with the LAUER-TAXE® last revised on 15 September 2025 and fee structure items (FSI) - last revised in the 3rd quarter of 2025 - of the uniform value scale (UVS 2025/Q3).

Non-prescription medicinal products that are reimbursable at the expense of the statutory health insurance according to Annex I of the Pharmaceuticals Directive (so-called OTC exception list) are not subject to the current medicinal products price regulation. Instead, in accordance with Section 129, paragraph 5a SGB V, when a non-prescription medicinal product is dispensed invoiced according Section 300, a medicinal product sale price applies to the insured person in the amount of the sale price of the pharmaceutical company plus the surcharges according to Sections 2 and 3 of the Pharmaceutical Price Ordinance in the valid version of 31 December 2003.

Prophylactic premedication

Antipyretic and antihistamine premedication is only recommended in the product information for axicabtagene ciloleucel, tisagenlecleucel and lisocabtagene maraleucel and is therefore not calculable.

According to the product information for tafasitamab, patients should be pretreated with premedication, which may include antipyretics, antihistamines or corticosteroids, prior to administration of tafasitamab. This premedication is recommended during the first 3 infusions and is optional for subsequent infusions. The product information does not provide any specific information why the necessary costs cannot be quantified for the premedication.

Conditioning chemotherapy for lymphocyte depletion under CAR-T cell therapy

Axicabtagene ciloleucel, lisocabtagene maraleucel and tisagenlecleucel are autologous cell products produced from the patient's own T cells. Therefore, a leukapheresis is usually necessary to obtain the cell material. Since leukapheresis is part of the manufacture of the medicinal product pursuant to Section 4, paragraph 14 of the Medicinal Products Act (AMG), no further costs are incurred in this respect for axicabtagene ciloleucel, lisocabtagene maraleucel and tisagenlecleucel.

For axicabtagene ciloleucel, a treatment regimen for lymphocyte depletion, consisting of intravenous administration of cyclophosphamide (500 mg/m^2 = 955 mg) and fludarabine (30 mg/m^2 = 57.3 mg), is given daily for 3 days, with infusion administered 3 to 5 days after the start of lymphocyte depletion.

For lisocabtagene maraleucel, a treatment regimen for lymphocyte depletion, consisting of intravenous administration of cyclophosphamide (300 mg/m^2 = 573 mg) and fludarabine (30 mg/m^2 = 57.3 mg), is given daily for 3 days, with infusion administered 2 to 7 days after the start of lymphocyte depletion.

For tisagenlecleucel, provided the white blood cell count is not below ≤ 1,000 cells/µl one week prior to infusion, a treatment regimen for lymphocyte depletion, consisting of intravenous administration of fludarabine (25 mg/m^2 = 47.8 mg) and cyclophosphamide (250 mg/m^2= 477.5 mg) daily over 3 days starting with the first fludarabine dose, with tisagenlecleucel infusion administered 2 to 14 days after the start of lymphocyte depletion.

Screening for hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) under CAR-T cell therapy

Patients should be tested for hepatitis B, hepatitis C and HIV infection prior to starting treatment with axicabtagene ciloleucel, lisocabtagene maraleucel, or tisagenlecleucel. This test is not required for all therapy options of the appropriate comparator therapy. Since there is a regular difference between the medicinal product to be assessed and the appropriate comparator therapy with regard to the tests for hepatitis B, hepatitis C and HIV, the costs of additionally required SHI services are presented in the resolution.

Patients should be tested for hepatitis B infection prior to starting treatment with rituximab and lenalidomide.

Diagnostics to rule out chronic hepatitis B requires sensibly coordinated steps. A step-by-step serological diagnosis initially consists of the examination of HBs antigen and anti-HBc antibodies. If both are negative, a past HBV infection can be excluded. In certain case constellations, further steps may be necessary in accordance with current guideline recommendations.[17]

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Medicinal product to be assessed							
Odronextamab							
Pre and post-medication							
Dexamethasone 10 mg; PO.	100 TAB each 2 mg	€ 32.94	€ 1.77	€ 0.00	€ 31.17	8	€ 31.17
Dexamethasone[16] 20 mg, IV	10 SFI 4 mg each	€ 16.92	€ 1.77	€ 0.44	€ 14.71	7	€ 58.84
Dexamethasone[16] 10 mg, IV	10 SFI 4 mg each	€ 16.92	€ 1.77	€ 0.44	€ 14.71	1	€ 14.71
Dimetindene IV (1 mg/10 kg BW = 7.8 mg, IV)	5 SFI 4 mg each	€ 26.24	€ 1.77	€ 6.92	€ 17.55	8	€ 70.20
Paracetamol[16,18] 500 – 1,000 mg	10 TAB 500 mg each	€ 2.96	€ 0.15	€ 0.13	€ 2.68	8	€ 2.68 – € 3.01

[17] S3 guideline on prevention, diagnosis and therapy of hepatitis B virus infection; AWMF registry no.: 021/011 https://register.awmf.org/assets/guidelines/021-011l_S3_Prophylaxe-Diagnostik-Therapie-der-Hepatitis-B-Virusinfektion_2021-07.pdf

[18] The dosage of 650 mg paracetamol in premedication stated in the product information cannot be achieved by tablets. Because of this, a dosage of 500 - 1,000 mg is used.

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
	10 TAB each 1,000 mg	€ 3.32	€ 0.17	€ 0.14	€ 3.01		
Appropriate comparator therapy:							
CAR T-cell therapies (axicabtagene ciloleucel, tisagenlecleucel and lisocabtagene maraleucel)							
Screening for HBV, HCV and HIV							
HBV test Hepatitis B surface antigen status (FSI 32781)	-	-	-	-	€ 5.06	1	€ 5.06
Anti-HBc antibody (FSI 32614)	-	-	-	-	€ 5.43	1	€ 5.43
Hepatitis C HCV antibody status (FSI 32618)	-	-	-	-	€ 9.02	1	€ 9.02
HIV HIV-1 and HIV-2 antibody status (FSI: 32575)	-	-	-	-	€ 4.09	1	€ 4.09
Axicabtagene ciloleucel							
Conditioning chemotherapy for lymphocyte depletion							
Cyclophosphamide 500 mg/m^2 = 955 mg	6 PSI each 500 mg	€ 85.98	€ 1.77	€ 9.45	€ 74.76	3	€ 74.76
Fludarabine 30 mg/m^2 = 57.3 mg	1 CII each 50 mg	€ 118.54	€ 1.77	€ 5.09	€ 111.68	3	€ 670.08
Tisagenlecleucel							
Conditioning chemotherapy for lymphocyte depletion							
Cyclophosphamide 250 mg/m^2 = 477.5 mg	1 PIJ each 500 mg	€ 23.76	€ 1.77	€ 1.57	€ 20.42	3	€ 61.26
Fludarabine 25 mg/m^2 = 47.8 mg	1 CII each 50 mg	€ 118.54	€ 1.77	€ 5.09	€ 111.68	3	€ 335.04
Lisocabtagene maraleucel							
Conditioning chemotherapy for lymphocyte depletion							

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Cyclophosphamide 300 mg/m^2 = 573 mg	10 PSI each 200 mg	€ 70.83	€ 1.77	€ 3.29	€ 65.77	3	€ 65.77
Fludarabine 30 mg/m^2 = 57.3 mg	1 CII each 50 mg	€ 118.54	€ 1.77	€ 5.09	€ 111.68	3	€ 670.08
Polatuzumab vedotin in combination with bendamustine and rituximab							
Rituximab							
Dimetindene IV (1 mg/10 kg BW = 7.8 mg, IV)	5 SFI 4 mg each	€ 26.24	€ 1.77	€ 6.92	€ 17.55	6	€ 52.65
Paracetamol[16] 500 – 1,000 mg	10 TAB 500 mg each 10 TAB each 1,000 mg	€ 2.96 € 3.32	€ 0.15 € 0.17	€ 0.13 € 0.14	€ 2.68 € 3.01	6	€ 2.68 – € -3.01
HBV diagnostics							
Hepatitis B Surface antigen status (FSI: 32781)	-	-	-	-	€ 5.06	1	€ 5.06
Hepatitis B HBV antibody status (FSI: 32614)	-	-	-	-	€ 5.43	1	€ 5.43
tafasitamab in combination with lenalidomide							
Lenalidomide							
HBV diagnostics							
Hepatitis B Surface antigen status (FSI: 32781)	-	-	-	-	€ 5.06	1	€ 5.06
Hepatitis B HBV antibody status (FSI: 32614)	-	-	-	-	€ 5.43	1	€ 5.43
Abbreviations: AMP = ampoules; SFI = solution for injection, INF = infusion solution; CII = concentrate for injection or infusion solution, PSI = powder for solution for injection, TAB = tablets							

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 1 October 2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131 paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic agents a maximum amount of € 100 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 100 per ready-to-use unit are to be payable. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

2.5 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

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the

pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a paragraph 1 or 6 SGB V and Section 35a paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or
- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2 paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as

part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of

medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

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.

Justification for the findings on designation in the present 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 transplantation

   – 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 transplantation

   – 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.

2.6 Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product odronextamab is a medicinal product placed on the market from 1 January 2025. In accordance with Section 35a, paragraph 3, sentence 5 SGB V, the G-BA must determine whether a relevant percentage of the clinical studies on the medicinal product were conducted within the scope of SGB V. This is the case if the percentage of study participants who have participated in the clinical studies on the medicinal product to be assessed in the therapeutic indication to be assessed at study sites within the scope of SGB V is at least five per cent of the total number of study participants.

The calculation is based on all studies that were submitted as part of the benefit assessment dossier in the therapeutic indication to be assessed in accordance with Section 35a, paragraph 1, sentence 3 SGB V in conjunction with Section 4, paragraph 6 AM-NutzenV.

Approval studies include all studies submitted to the regulatory authority in section 2.7.3 (Summary of Clinical Efficacy) and 2.7.4 (Summary of Clinical Safety) of the authorisation dossier in the therapeutic indication for which marketing authorisation has been applied for. In addition, studies, which were conducted in whole or in part within the therapeutic indication described in this document, and in which the company was a sponsor or is otherwise financially involved, must also be indicated.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is ≥ 5

per cent (5.6% or 6.7%) of the total number of study participants according to the information provided by the pharmaceutical company.

The pharmaceutical company uses the ELM-1 and ELM-2 studies to determine two different percentages for study participants at study sites within the scope of SGB V. Of these, one percentage relates to patients with B-cell non-Hodgkin lymphoma (NHL) (5.57%), while the other relates to a part of this study population – patients with follicular lymphoma (FL) or DLBCL (6.68%).

It should be noted that the information on the B-cell NHL cohort must be used for the ELM-1 study, as data from this cohort – instead of only the FL or DLBCL cohort – were submitted for the assessment of the clinical efficacy and safety of the medicinal product, and recruitment for the B-cell NHL cohort has been completed. According to the information provided by the pharmaceutical company, recruitment of the B-cell NHL cohort for the ELM-2 study has not yet been completed, meaning that the FL and DLBCL cohorts, for which recruitment has been completed, should be used instead. Taking this cohort and the B-cell NHL cohort of the ELM-1 study into account, the percentage of study participants at study sites within the scope of SGB V remains above 5%.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore conducted to a relevant extent within the scope of SGB V.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 12 March 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy took place. The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 12 August 2025.

On 31 July 2025, the pharmaceutical company submitted a dossier for the benefit assessment of odronextamab to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 31 July 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient odronextamab.

The dossier assessment by the IQWiG was submitted to the G-BA on 28 October 2025, and the written statement procedure was initiated with publication on the G-BA website on 3 November 2025. The deadline for submitting statements was 24 November 2025.

The oral hearing was held on 8 December 2025.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI

umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing was discussed at the session of the Subcommittee on 13 January 2026, and the proposed draft resolution was approved.

At their session on 22 January 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	12 March 2024	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	12 August 2025	New determination of the appropriate comparator therapy
Working group Section 35a	3 December 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	8 December 2025	Conduct of the oral hearing
Working group Section 35a	17.12.2025; 07.01.2026	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	13 January 2026	Concluding discussion of the draft resolution
Plenum	22 January 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 22 January 2026

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

Prof. Hecken