

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

of 6 November 2025

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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,

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 decide 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 medicinal product Columvi with the active ingredient glofitamab was first approved as a medicinal product for the treatment of rare diseases (orphan drug) under Regulation (EC) Number 141/2000 of the European Parliament and of the Council of 16 December 1999. This marketing authorisation as an orphan drug was granted for the therapeutic indication "Columvi as monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy."

On 1 February 2024, the G-BA decided on the benefit assessment of glofitamab for this therapeutic indication on the basis of the statutory provisions on the benefit assessment of medicinal products for the treatment of a rare disease (Section 35a, paragraph 1, sentence 11 SGB V).

On 21 March 2025, the orphan designation for the medicinal product Columvi was withdrawn from the Community Register of Orphan Drugs. This cancelled the orphan drug status. As a result, the pharmaceutical company was requested by the G-BA in a letter dated 17 April 2025

to submit evidence in accordance with Chapter 5 Section 5, paragraphs 1 to 6 of the VerfO and to demonstrate the additional benefit compared with the appropriate comparator therapy.

On 9 May 2025, i.e. within three months of receiving the G-BA's request, the pharmaceutical company submitted a dossier for the active ingredient glofitamab in accordance with Section 35a, paragraph 1, sentence 10 SGB V in conjunction with Chapter 5 Section 8, paragraph 1, number 6 and Section 12, number 2 of the Rules of Procedure of the G-BA (VerfO).

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 August 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 glofitamab 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 glofitamab.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA has come to 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 Glofitamab (Columvi) in accordance with the product information

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

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

See 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 transplant

Appropriate comparator therapy:

Individualised therapy with selection of

- tisagenlecleucel,

1 General Methods, version 7.0 of 19.09.2023. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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

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

Appropriate comparator therapy:

- Polatuzumab vedotin in combination with bendamustine and rituximab
- or*
- tafasitamab in combination with lenalidomide

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 it determines 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 glofitamab as monotherapy, the following active ingredients are approved for the present therapeutic indication:

Bleomycin, cyclophosphamide, cytarabine, dexamethasone, doxorubicin, epcoritamab, etoposide, glofitamab in combination with gemcitabine and oxaliplatin, ifosfamide, melphalan, methotrexate, methylprednisolone, mitoxantrone, odronextamab, 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 transplant 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:

- 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 transplant for aggressive B-non-Hodgkin lymphomas):

- Section 4 Excluded methods: Allogeneic stem cell transplant in adult patients with aggressive B-non-Hodgkin lymphoma who have not yet been treated with an autologous stem cell transplant (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 transplant 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 transplant in adult patients with aggressive B-cell non-Hodgkin lymphomas who relapse after receiving an autologous stem cell transplant 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 transplant 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 transplant when determining the appropriate comparator therapy.

Patient group a)

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. It was determined by the G-BA's resolution of 21 December 2023 that an additional benefit of axicabtagene ciloleucel is not proven, as no suitable data were available 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. It was determined by resolution of 6 April 2023 that an additional benefit of lisocabtagene maraleucel is not proven, as no data were available to enable an assessment of the additional benefit.

According to the available guidelines, salvage chemoimmunotherapy including an (autologous or allogeneic) stem cell transplant 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 transplant in the second line of therapy. A salvage chemoimmunotherapy followed by an autologous or allogeneic stem cell transplant 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 transplant 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/

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/dlbcl/>; accessed [04.03.2025]

³ National Institute for Health and Care Excellence (NICE). Non-Hodgkin's lymphoma: diagnosis and management [online]. 10.2021. London (GBR): NICE; 2016. [Accessed: 11.07.2024]. (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 transplant for aggressive B-cell non-Hodgkin lymphomas; 9 April 2020

⁷ National Comprehensive Cancer Network (NCCN). B-Cell lymphomas; Vers. 05.2022 [online]. Fort Washington (USA): NCCN; 2022. (NCCN Clinical Practice Guidelines in Oncology)

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 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 transplant. 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 other approved active ingredients listed under 1. do not correspond to the therapy recommendations for the present indication and to the therapy standard in the reality of care as set out in the guidelines and in the written statement of the scientific-medical societies.

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 transplant 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 transplant or allogeneic stem cell transplant must accordingly be taken into account.

For patients who have not yet been treated with an autologous stem cell transplant, an allogeneic stem cell transplant 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 transplant.

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 transplant 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), German Working Group for Haematopoietic Stem Cell Transplantation and Cellular Therapy (DAG-HSCT) 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 transplant. By resolution of 20 August 2020, a hint for a non-quantifiable additional benefit of polatuzumab vedotin over bendamustine in combination with rituximab was identified within the scope of a first orphan drug assessment since the scientific data did not allow

quantification. As part of a new benefit assessment because of exceeding the EUR 30 million turnover limit, the additional benefit of polatuzumab vedotin was determined as not proven by 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 transplant. 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, 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 and epcoritamab are also available as treatment options in this therapeutic indication. 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. No additional benefit of epcoritamab could be determined by resolution of 17 April 2025 in the benefit assessment following the repeal of the regulatory orphan status, as no suitable data were available. In addition, these two therapy options are not recommended in the S3 guideline.

Based on the generally recognised state of medical knowledge, loncastuximab tesirine and epcoritamab are therefore not determined to be appropriate comparator therapies.

The active ingredients odronextamab and glofitamab in combination with gemcitabine and oxaliplatin are new treatment options in this therapeutic indication. Odronextamab was approved on 22 August 2024 and has only recently become available in Germany (1 August 2025). Glofitamab in combination with gemcitabine and oxaliplatin was only recently approved (marketing authorisation on 10 April 2025). Based on the generally accepted state of medical knowledge, odronextamab and glofitamab in combination with gemcitabine and oxaliplatin are not determined to be appropriate comparator therapies.

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.

Change in the appropriate comparator therapy

In the induction therapy, it is not the combination therapy consisting of rituximab, gemcitabine and dexamethasone (R-GD) with carboplatin, but the corresponding combination

(R-GD) with cisplatin which corresponds to the standard in this therapeutic indication. For this reason, the G-BA consider it appropriate to change the appropriate comparator therapy for the present resolution, thus adapting it to the current state of medical knowledge.

The present assessment of the additional benefit of glofitamab remains unaffected by this change in the appropriate comparator therapy.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of glofitamab 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 transplant

An additional benefit is not proven.

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

An additional benefit is not proven.

Justification:

For the demonstration of an additional benefit of glofitamab as monotherapy in patients with relapsed or refractory DLBCL after two or more lines of systemic therapy, the pharmaceutical company did not identify any relevant studies compared to the appropriate comparator therapy. In the dossier, the pharmaceutical company presented the results of the uncontrolled approval study NP30179 as the best available supporting evidence.

NP30179 study

The NP30179 study is a single-arm, ongoing phase I/II dose escalation and dose expansion study in subjects with relapsed or refractory (r/r) B-cell non-Hodgkin lymphoma. The study is designed in three parts and consists of a dose escalation phase (part 1 and part 2) and a dose expansion phase (part 3) to investigate the safety, efficacy, tolerability and pharmacokinetics of glofitamab.

Patients with histologically confirmed haematological malignancy, in which an expression of cluster of differentiation 20 (CD20) was assumed, with relapse after at least one previous therapy or no response to at least one previous therapy were enrolled. Another prerequisite for enrolment in the study was the unavailability of treatment options that would prolong the patients' survival (e.g. standard chemotherapy or autologous stem cell transplant).

The pharmaceutical company submitted data on a sub-population of 155 patients. They had received at least two prior systemic therapies and, according to information provided by the pharmaceutical company, were treated with glofitamab as monotherapy at the dosage in line with the marketing authorisation. The tumour histology DLBCL, transformed follicular lymphoma, high-grade B-cell lymphoma or primary mediastinal large B-cell lymphoma was observed in these patients. The data presented were not categorised according to the patient groups defined in this therapeutic indication.

Due to its single-arm study design, the study presented by the pharmaceutical company did not allow a comparison with the appropriate comparator therapy.

Conclusion:

Due to its single-arm study design, the NP30179 study did not allow a comparison with the appropriate comparator therapy for both research questions and is therefore unsuitable for the assessment of an additional benefit of glofitamab as monotherapy. An additional benefit of glofitamab as monotherapy 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 is the new benefit assessment of the active ingredient glofitamab due to the repeal of the regulatory orphan status.

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

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 transplant
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 transplant

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 transplant in response to the induction therapy was determined as the appropriate comparator therapy.

Patient group b)

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 NP30179 study. Due to its single-arm study design, the NP30179 study did not allow a comparison with the appropriate comparator therapy for both research questions and is therefore unsuitable for the assessment of an additional benefit of glofitamab as monotherapy. An additional benefit 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 G-BA take into account the patient numbers stated in the pharmaceutical company's dossier.

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

The major uncertainties result from the unclear transferability of these percentage values with regard to suitability or unsuitability for CAR-T cell therapy or stem cell transplant, as the underlying publications relate to second-line therapy. Furthermore, the data basis of the publication from which the pharmaceutical company derived the upper percentage values for patients suitable for CAR-T cell therapy is unclear.

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 Columvi (active ingredient: glofitamab) at the following publicly accessible link (last access: 28 October 2025):

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

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

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

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

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

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: 1 September 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 varies 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.

The (daily) doses recommended in the product information or in the labelled publications were used as the basis for calculation.

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 for glofitamab, all patients are pretreated with a single dose of obinutuzumab (1,000 mg) on day 1, cycle 1⁸.

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.

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 therapies⁹. Furthermore, for the treatment regimens and dosages in relation to the combination therapy R-GDP, the study by Crump et al. (2014)¹⁰ 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)¹¹ 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

⁸ Obinutuzumab is not approved for pretreatment prior to therapy with glofitamab. The application for marketing authorisation was withdrawn. Obinutuzumab is not reimbursable for this indication, which is why the necessary costs cannot be quantified.

⁹ Association of the Scientific-Medical Societies (AWMF). Diagnostics, therapy and follow-up 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.

¹⁰ 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.

¹¹ 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

German Hospital Fee Act (KHEntgG) and the treatment-specific nursing revenue valuation ratio, is taken into account in the inpatient costs.

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 transplant

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Glofitamab	Cycle 1: 2 x per 21-day cycle Cycle 2 - 12: 1 x per 21-day cycle	12	Cycle 1: 2 Cycle 2-12: 1	13
Appropriate comparator therapy				
<i>CAR-T cell therapies</i>				
Axicabtagene ciloleucel	Single dose	1	1	1
Lisocabtagene maraleucel	Single dose	1	1	1
Tisagenlecleucel	Single dose	1	1	1
<i>Induction chemotherapy followed by high-dose chemotherapy with autologous stem cell transplant if there is a response to induction chemotherapy</i>				
<i>Induction chemotherapy</i>				
<i>R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin)¹⁰</i>				
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	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
<i>R-ICE (rituximab + ifosfamide + carboplatin + etoposide)¹¹</i>				
Rituximab	1 x per 21-day cycle (day 1, additionally once on the day before the first cycle)	2 - 3	1	3 – 4

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
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
<i>R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin)^{10,11}</i>				
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
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
<i>High-dose chemotherapy with autologous stem cell transplant</i>				
Stem cell collection from autologous donors with chemotherapy or with most severe complications or comorbidities (CC), age > 15 years	once		16.1 (average length of stay)	16.1
Autologous stem cell transfusion	once		22.3 (average length of stay)	22.3
<i>Induction chemotherapy followed by high-dose chemotherapy with allogeneic stem cell transplant if there is a response to induction chemotherapy</i>				
<i>Induction therapy</i>				
<i>R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin)¹⁰</i>				
Rituximab	1 x per 21-day cycle (day -1)	2 – 3	1	2 – 3

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Gemcitabine	2 x per 21-day cycle (day 1 + 8)	2 – 3	2	4 – 6
Dexamethasone	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
<i>R-ICE (rituximab + ifosfamide + carboplatin + etoposide)¹¹</i>				
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
<i>R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin)^{10,11}</i>				
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
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
<i>High-dose chemotherapy with allogeneic stem cell transplant</i>				
Highly complex and intensive block chemotherapy	once		7.9 (average length of stay)	7.9
Allogeneic stem cell transfusion	once		33.6 (average length of stay)	33.6

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

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Glofitamab	Cycle 1: 2 x per 21-day cycle Cycle 2 - 12: 1 x per 21-day cycle	12	Cycle 1: 2 Cycle 2-12: 1	13
Appropriate comparator therapy				
<i>Polatuzumab vedotin + bendamustine + rituximab</i>				
Polatuzumab vedotin	1 x per 21-day cycle	6.0	1	6.0
Bendamustine	2 x per 21-day cycle	6.0	2	12.0
Rituximab	1 x per 21-day cycle	6.0	1	6.0
<i>Tafasitamab + lenalidomide</i>				
Tafasitamab	<u>Cycle 1:</u> Day 1, 4, 8, 15 and 22 (28-day cycle)	13.0	<u>Cycle 1:</u> 5	33.0
	<u>Cycle 2 + 3:</u> Day 1, 8, 15, 22 (28-day cycle)		<u>Cycle 2 + 3:</u> 4	
	<u>Cycle 4 until disease progression:</u> Day 1 and 15 (28-day cycle)		<u>From cycle 4 onwards:</u> 2	
Lenalidomide	Day 1 – 21 of a 28-day cycle	12.0	21	252.0

Consumption:

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from 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).¹²

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

Designation of the therapy	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					
Glofitamab	Cycle 1: Day 8: 2.5 mg	2.5 mg	1 x 2.5 mg	1	1 x 2.5 mg
	Cycle 1: Day 15: 10 mg	10 mg	1 x 10 mg	1	34 x 10 mg
	Cycle 2 - 12: 30 mg	30 mg	3 x 10 mg	11	
Appropriate comparator therapy					
CAR-T cell therapies					
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			
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 × 10 ⁸ CAR-positive viable T cells (regardless of the body weight)	0.6 - 6 × 10 ⁸ CAR- positive T cells	1 single infusion bag	1	1 single infusion bag

¹² Federal Health Reporting. Average body measurements of the population (2021, both sexes, 15 years and older), www.gbe-bund.de

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
<i>Induction chemotherapy followed by high-dose chemotherapy with autologous stem cell transplant if there is a response to induction chemotherapy</i>					
<i>Induction chemotherapy</i>					
<i>R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin)¹⁰</i>					
Rituximab	375 mg/m ² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	2 – 3	2.0 x 500 mg + 6.0 x 100 mg – 3.0 x 500 mg + 9.0 x 100 mg
Gemcitabine	1,000 mg/m ² = 1,910 mg	1,910 mg	2 x 1,000 mg	4 – 6	8.0 x 1,000 mg – 12.0 x 1,000 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	8 – 12	8.0 x 40 mg – 12.0 x 40 mg
Cisplatin	75 mg/m ² = 143.3 mg	143.3 mg	1 x 100 mg + 1 x 50 mg	2 – 3	2.0 x 100 mg + 2.0 x 50 mg – 3.0 x 100 mg + 3.0 x 50 mg
<i>R-ICE (rituximab + ifosfamide + carboplatin + etoposide)¹¹</i>					
Rituximab	375 mg/m ² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	3 – 4	3.0 x 500 mg + 9.0 x 100 mg – 4.0 x 500 mg + 12.0 x 100 mg
Ifosfamide	5,000 mg/m ² = 9,550 mg	9,550 mg	2 x 5000 mg	2 – 3	4.0 x 5000 mg – 6.0 x 5000 mg
Carboplatin	AUC = 5 (= 641.4 mg); max. 800 mg	641.4 mg – 800 mg	1 x 600 mg + 1 x 50 mg – 1 x 600 mg + 4 x 50 mg	2 – 3	2.0 x 600 mg + 2.0 x 50 mg – 3.0 x 600 mg + 3.0 x 50 mg – 2.0 x 600 mg + 8.0 x 50 mg – 3.0 x 600 mg + 12.0 x 50 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
Etoposide	100 mg/m ² = 191 mg	191 mg	1 x 200 mg	6 – 9	6.0 x 200 mg – 9.0 x 200 mg
<i>R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin)^{10,11}</i>					
Rituximab	375 mg/m ² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	2 – 4	2.0 x 500 mg + 6.0 x 100 mg – 4.0 x 500 mg + 12.0 x 100 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	8 – 12	8.0 x 40 mg – 12.0 x 40 mg
Cytarabine	2 x daily 2,000 mg/m ² = 2 x 3,820 mg	7,640 mg	4 x 2,000 mg	2 – 3	8.0 x 2,000 mg – 12.0 x 2,000 mg
Cisplatin	100 mg/m ² = 191 mg	191 mg	2 x 100 mg	2 – 3	4.0 x 100 mg – 6.0 x 100 mg
<i>Induction chemotherapy followed by high-dose chemotherapy with allogeneic stem cell transplant if there is a response to induction chemotherapy</i>					
<i>Induction therapy</i>					
<i>R-GDP (rituximab + gemcitabine + dexamethasone + cisplatin)¹⁰</i>					
Rituximab	375 mg/m ² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	2 – 3	2.0 x 500 mg + 6.0 x 100 mg – 3.0 x 500 mg + 9.0 x 100 mg
Gemcitabine	1,000 mg/m ² = 1,910 mg	1,910 mg	2 x 1,000 mg	4 – 6	8.0 x 1,000 mg – 12.0 x 1,000 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	8 – 12	8.0 x 40 mg – 12.0 x 40 mg
Cisplatin	75 mg/m ² = 143.3 mg	143.3 mg	1 x 100 mg + 1 x 50 mg	2 – 3	2.0 x 100 mg + 2.0 x 50 mg – 3.0 x 100 mg + 3.0 x 50 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
<i>R-ICE (rituximab + ifosfamide + carboplatin + etoposide)^{10, 11}</i>					
Rituximab	375 mg/m ² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	3 – 4	3.0 x 500 mg + 9.0 x 100 mg – 4.0 x 500 mg + 12.0 x 100 mg
Ifosfamide	5,000 mg/m ² = 9,550 mg	9,550 mg	2 x 5000 mg	2 – 3	4.0 x 5000 mg – 6.0 x 5000 mg
Carboplatin	AUC = 5 (= 641.4 mg); max. 800 mg	641.4 mg – 800 mg	1 x 600 mg + 1 x 50 mg – 1 x 600 mg + 4 x 50 mg	2 – 3	2.0 x 600 mg + 2.0 x 50 mg – 3.0 x 600 mg + 3.0 x 50 mg – 2.0 x 600 mg + 8.0 x 50 mg – 3.0 x 600 mg + 12.0 x 50 mg
Etoposide	100 mg/m ² = 191 mg	191 mg	1 x 200 mg	6 – 9	6.0 x 200 mg – 9.0 x 200 mg
<i>R-DHAP (rituximab + dexamethasone + cytarabine + cisplatin)^{10,11}</i>					
Rituximab	375 mg/m ² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	2 – 4	2.0 x 500 mg + 6.0 x 100 mg – 4.0 x 500 mg + 12.0 x 100 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	8 – 12	8.0 x 40 mg – 12.0 x 40 mg
Cytarabine	2 x daily 2,000 mg/m ² = 2 x 3,820 mg	7,640 mg	4 x 2,000 mg	2 – 3	8.0 x 2,000 mg – 12.0 x 2,000 mg
Cisplatin	100 mg/m ² = 191 mg	191 mg	2 x 100 mg	2 – 3	4.0 x 100 mg – 6.0 x 100 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 transplant

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					
Glofitamab	Cycle 1: Day 8: 2.5 mg	2.5 mg	1 x 2.5 mg	1	1 x 2.5 mg
	Cycle 1: Day 15: 10 mg	10 mg	1 x 10 mg	1	34 x 10 mg
	Cycle 2 - 12: 30 mg	30 mg	3 x 10 mg	11	
Appropriate comparator therapy					
Polatuzumab vedotin + bendamustine + rituximab					
Polatuzumab vedotin	1.8 mg/kg = 139.9 mg	139.9 mg	1 x 140 mg	6.0	6.0 x 140 mg
Bendamustine	90 mg/m ² = 171.9 mg	171.9 mg	1 x 100 mg + 3 x 25 mg	12.0	12.0 x 100 mg + 36.0 x 25 mg
Rituximab	375 mg/m ² = 716.3 mg	716.3 mg	1 x 500 mg + 3 x 100 mg	6.0	6.0 x 500 mg + 18.0 x 100 mg
Tafasitamab + lenalidomide					
Tafasitamab	12 mg/kg = 932.4 mg	932.4 mg	5 x 200 mg	33.0	165.0 x 200 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	252.0	252.0 x 25 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:

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 transplant									
2025	R61G	7.9	1.061	€ 4,394.22	0.7864	€ 250	€ 4,662.27	€ 1,553.14	€ 6,215.41
2025	A04E	33.6	9.004	€ 4,394.22	1.7706	€ 250	€ 39,565.56	€ 14,873.04	€ 54,438.60
High-dose chemotherapy with autologous stem cell transplant									
2025	A42A	16.1	2.095	€ 4,394.22	0.7016	€ 250	€ 9,205.89	€ 2,823.94	€ 12,029.83
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:

Medicinal product to be assessed					
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
Glofitamab 2.5 mg	1 CIS	€ 1,164.89	€ 1.77	€ 0.00	€ 1,163.12
Glofitamab 10 mg	1 CIS	€ 4,531.02	€ 1.77	€ 0.00	€ 4,529.25
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 ¹³	€ 230,621.00
Lisocabtagene maraleucel	1 single infusion bag	€ 227,500.00		€ 0 ¹³	€ 227,500.00
Tisagenlecleucel	1 single infusion bag	€ 239,000.00		€ 0 ¹³	€ 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
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

¹³ The medicinal product is exempt from value added tax at the applied LAUER-TAXE® last revised.

Carboplatin 600 mg	1 CIS	€ 300.84	€ 1.77	€ 13.74	€ 285.33
Carboplatin 50 mg	1 CIS	€ 34.70	€ 1.77	€ 1.11	€ 31.82
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	10 TAB	€ 46.29	€ 1.77	€ 0.00	€ 44.29
Dexamethasone 40 mg	20 TAB	€ 81.59	€ 1.77	€ 0.00	€ 79.59
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
Lenalidomide 25 mg	63 HC	€ 117.32	€ 1.77	€ 8.38	€ 107.17
Polatuzumab vedotin 140 mg	1 PIC	€ 7,493.57	€ 1.77	€ 0.00	€ 7,491.80
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
Rituximab 500 mg	1 CIS	€ 1,777.34	€ 1.77	€ 98.21	€ 1,677.36
Rituximab 100 mg	2 CIS	€ 717.21	€ 1.77	€ 39.08	€ 676.36
Tafasitamab 200 mg	1 PIC	€ 654.48	€ 1.77	€ 35.61	€ 617.10

Abbreviations:

HC = hard capsules; CIS = concentrate for the preparation of an infusion solution; SII = solution for injection/infusion; CII = concentrate for injection or infusion solution; PIF = powder for the preparation of an infusion solution, PIC = powder for the preparation of an infusion solution concentrate; TAB = tablets

LAUER-TAXE® last revised: 1 September 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.

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 and invoiced in accordance with Section 300, a medicinal product dispensing price in the amount of the dispensing price of the pharmaceutical company plus the surcharges in accordance with Sections 2 and 3 of the Pharmaceutical Price Ordinance in the version valid on 31 December 2003 applies to the insured.

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.

Mesna is given in combination with ifosfamide for the prophylaxis of haemorrhagic cystitis.

During treatment with glofitamab, all patients receive antipyretic and antihistamine premedication in all cycles. In cycles 1 to 3, a glucocorticoid is also administered before all glofitamab infusions.

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 is an autologous cell product 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 Medicinal Products Act, no further costs are incurred in this respect for axicabtagene ciloleucel.

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

For tisagenlecleucel, provided the white blood cell count is not below $\leq 1,000 \text{ cells}/\mu\text{l}$ one week prior to infusion, a treatment regimen for lymphocyte depletion, consisting of intravenous administration of fludarabine ($25 \text{ mg/m}^2 = 47.75 \text{ mg}$) and cyclophosphamide ($250 \text{ mg/m}^2 = 477.5 \text{ mg}$) 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. 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.

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.¹⁴

¹⁴ S3 guideline on prevention, diagnosis and therapy of hepatitis B virus infection AWMF registry no.: 021/011 https://register.awmf.org/assets/guidelines/021-011I_S3_Prophylaxe-Diagnostik-Therapie-der-Hepatitis-B-Virusinfektion_2021-07.pdf.

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							
Glofitamab							
Dexamethasone ¹⁵ 20 mg	10 x 4 mg SFI	€ 16.92	€ 1.77	€ 0.44	€ 14.71	4	€ 29.42
Dimetindene IV 1 mg/ 10 kg = 7.8 mg	5 SFI at 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	13.0	€ 105.30
Paracetamol 500 mg – 1,000 mg	20 TAB at 500 mg	€ 3.47	€ 0.17	€ 0.15	€ 3.15	13	€ 3.15
	- 10 TAB at 1,000 mg	- € 3.32	- € 0.17	- € 0.14	- € 3.01		- € 6.02
Appropriate comparator therapy							
CAR-T cell therapies							
Screening for HBV, HCV and HIV							
HBV test Hepatitis B surface antigen status (GOP 32781)	-	-	-	-	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (GOP 32614)	-	-	-	-	€ 5.43	1.0	€ 5.43
Hepatitis C HCV antibody status (GOP 32618)	-	-	-	-	€ 9.02	1.0	€ 9.02
HIV HIV-1 and HIV-2 antibody status (GOP: 32575)	-	-	-	-	€ 4.09	1.0	€ 4.09
Axicabtagene ciloleucel							
Conditioning chemotherapy for lymphocyte depletion							
Cyclophosphamide 500 mg/m² = 955 mg	6 PSI each 500 mg	€ 85.98	€ 1.77	€ 9.45	€ 74.76	3.0	€ 74.76
Fludarabine 30 mg/m² = 57.3 mg	1 KII at 50 mg	€ 118.54	€ 1.77	€ 5.09	€ 111.68	3.0	€ 670.08
Tisagenlecleucel							
Conditioning chemotherapy for lymphocyte depletion							
Cyclophosphamide 250 mg/m² = 477.5 mg	10 PIJ at 200 mg	€ 70.83	€ 1.77	€ 3.29	€ 65.77	3.0	€ 65.77

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
Fludarabine 25 mg/m ² = 47.75 mg	1 KII at 50 mg	€ 118.54	€ 1.77	€ 5.09	€ 111.68	3.0	€ 670.08
<i>Lisocabtagene maraleucel</i>							
<i>Conditioning chemotherapy for lymphocyte depletion</i>							
Cyclophosphamide 300 mg/m ² = 573 mg	6 PSI each 500 mg	€ 85.98	€ 1.77	€ 9.45	€ 74.76	3.0	€ 74.76
Fludarabine 30 mg/m ² = 57.3 mg	1 KII at 50 mg	€ 118.54	€ 1.77	€ 5.09	€ 111.68	3.0	€ 670.08
<i>Polatuzumab vedotin + bendamustine + rituximab</i>							
Dimetindene IV 1 mg/ 10 kg = 7.8 mg	5 SFI at 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	6.0	€ 52.65
Paracetamol ¹⁵ (500 mg - 1,000 mg, PO)	10 TAB 500 mg	€ 2.96	€ 0.15	€ 0.13	€ 2.68	6.0	€ 2.68
	10 TAB 1000 mg	€ 3.32	€ 0.17	€ 0.14	€ 3.01		€ 3.01
HBV test Hepatitis B surface antigen status (GOP 32781)	-	-	-	-	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (GOP 32614)	-	-	-	-	€ 5.43	1.0	€ 5.43
<i>Induction chemotherapies (R-GDP, R-DHAP, R-ICE) prior to an autologous <u>or</u> allogeneic stem cell transplant</i>							
<i>Rituximab (R-GDP, R-DHAP, R-ICE)</i>							
<i>HBV diagnostics</i>							
HBV test Hepatitis B surface antigen status (GOP 32781)	-	-	-	-	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (GOP 32614)	-	-	-	-	€ 5.43	1.0	€ 5.43
<i>Premedication (R-GDP)</i>							
Dimetindene IV 1 mg/ 10 kg = 7.8 mg	5 SFI at 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	2.0 – 3.0	€ 17.55 – € 35.10

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
Paracetamol ¹⁵ (500 mg - 1,000 mg, PO)	10 TAB 500 mg	€ 2.96	€ 0.15	€ 0.13	€ 2.68	2.0	€ 2.68
	– 10 TAB 1000 mg	– € 3.32	– € 0.17	– € 0.14	– € 3.01	– 3.0	– € 3.01
<i>Premedication (R-DHAP)</i>							
Dimetindene IV 1 mg/ 10 kg = 7.8 mg	5 SFI at 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	2.0 – 3.0	€ 17.55 – € 35.10
Paracetamol ¹⁵ (500 mg - 1,000 mg, PO)	10 TAB 500 mg	€ 2.96	€ 0.15	€ 0.13	€ 2.68	2.0	€ 2.68
	– 10 TAB 1000 mg	– € 3.32	– € 0.17	– € 0.14	– € 3.01	– 4.0	– € 3.01
<i>Premedication (R-ICE)</i>							
Dimetindene IV 1 mg/ 10 kg = 7.8 mg	5 SFI at 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	2.0 – 3.0	€ 17.55 – € 35.10
Paracetamol ¹⁵ (500 mg - 1,000 mg, PO)	10 TAB 500 mg	€ 2.96	€ 0.15	€ 0.13	€ 2.68	3.0	€ 2.68
	– 10 TAB 1000 mg	– € 3.32	– € 0.17	– € 0.14	– € 3.01	– 4.0	– € 3.01
<i>Cisplatin (R-GDP, R-DHAP)</i>							
Antiemetic treatment: In clinical practice, an appropriate antiemetic treatment is established before and/or after administration of cisplatin. The product information for cisplatin does not provide any specific information on this, which is why the necessary costs cannot be quantified.							
Mannitol 10% Inf. sol., 37.5 g/day	10 x 250 ml INF	€ 87.05	€ 4.35	€ 7.94	€ 74.76	2.0 – 3.0	€ 74.76
Sodium chloride 0.9% Inf. sol., 3 l - 4.4 l/day	10 x 1,000 ml INF	€ 23.10	€ 1.16	€ 1.89	€ 20.05	2.0 – 3.0	€ 40.01 – € 80.02
<i>Mesna (R-ICE)</i>							
Mesna (Bolus with 1,900 mg mesna (= 20% of the ifosfamide dose), followed by 24-hour continuous infusion)	Bolus with 1,900 mg followed by 24-hour continuous infusion with 1,900 mg						
	5 SFI x 1,000 mg	€ 48.54	€ 1.77	€ 1.77	€ 45.00	2.0 – 3.0	€ 90.00 – € 135.00

¹⁵ Fixed reimbursement rate

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
with at least 1,900 mg up to 9,500 mg (= 20% - 100% of the ifosfamide dose), followed by subsequent infusion with up to 4,750 mg mesna (= 0% - 50% of the ifosfamide dose) for 6 - 12 hours	Bolus of 1,900 mg followed by 24-hour continuous infusion of 9,500 mg followed by subsequent infusion of 4,750 mg						
	50 AMP x 400 mg	€ 151.06	€ 1.77	€ 17.68	€ 131.61	2.0 – 3.0	€ 266.06
	5 SFI x 1,000 mg	€ 48.54	€ 1.77	€ 1.77	€ 45.00		-
Tafasitamab + lenalidomide							
HBV diagnostics (lenalidomide)							
HBV test Hepatitis B surface antigen status (GOP 32781)	-	-	-	-	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (GOP 32614)	-	-	-	-	€ 5.43	1.0	€ 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							

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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 transplant

No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

References:

Product information for glofitamab (Columvi); Columvi; last revised: July 2025

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

No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

References:

Product information for glofitamab (Columvi); Columvi; last revised: July 2025

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 27 July 2021, 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 6 June 2025.

On 9 May 2025 the pharmaceutical company submitted a dossier for the benefit assessment of glofitamab to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 6 VerfO.

By letter dated 14 May 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit 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 glofitamab.

The dossier assessment by the IQWiG was submitted to the G-BA on 14 May 2025, and the written statement procedure was initiated with publication on the G-BA website on 15 August 2025. The deadline for submitting statements was 5 September 2025.

The oral hearing was held on 22 September 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 28 October 2025, and the proposed draft resolution was approved.

At their session on 6 November 2025, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
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Subcommittee on Medicinal Products	27 July 2021	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	6 June 2025	New determination of the appropriate comparator therapy
Working group Section 35a	17 September 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	22 September 2025	Conduct of the oral hearing
Working group Section 35a	1 October 2025 15 October 2025	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	28 October 2025	Concluding discussion of the draft resolution
Plenum	6 November 2025	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 6 November 2025

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

Prof. Hecken