GBA
Gemeinsamer
Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (GBA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Belantamab mafodotin (multiple myeloma, relapsed or refractory, after at least one prior therapy, in combination with bortezomib and dexamethasone)

of 1 October 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 (GBA) 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 GBA 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 GBA 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 GBA 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 relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient belantamab mafodotin on 1 April 2026 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the GBA (VerfO). Pursuant to Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 of the Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the GBA on 31 March 2026.

The GBA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 July 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The GBA came to a resolution on whether an additional benefit of belantamab mafodotin 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, the

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statements submitted in the written statement and oral hearing procedure, and the addendum to the benefit assessment prepared by IQWiG. In order to determine the extent of the additional benefit, the GBA 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 belantamab mafodotin.

In the light of the above, and taking into account the statements received and the oral hearing, the GBA 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 Belantamab mafodotin (Blenrep) in accordance with the product information

Blenrep is indicated in adults for the treatment of relapsed or refractory multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy.

Therapeutic indication of the resolution (resolution of 1 October 2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

a) <u>Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies</u>

Appropriate comparator therapy for belantamab mafodotin in combination with bortezomib and dexamethasone:

An individualised therapy with the selection of

- carfilzomib in combination with lenalidomide and dexamethasone,
- elotuzumab in combination with lenalidomide and dexamethasone,
- elotuzumab in combination with pomalidomide and dexamethasone (only subjects who have received at least two prior therapies and have shown disease progression during the last therapy are eligible),
- daratumumab in combination with bortezomib and dexamethasone,
- daratumumab in combination with lenalidomide and dexamethasone,
- daratumumab in combination with carfilzomib and dexamethasone,
- daratumumab in combination with pomalidomide and dexamethasone (only subjects who are refractory to lenalidomide or have received at least two prior therapies are eligible),

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

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- isatuximab in combination with carfilzomib and dexamethasone,
- isatuximab in combination with pomalidomide and dexamethasone (only subjects who have received at least two prior therapies and have shown disease progression during the last therapy are eligible),
- pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible),
- ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible) and
- carfilzomib in combination with dexamethasone

b) <u>Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies</u>

Appropriate comparator therapy for belantamab mafodotin in combination with bortezomib and dexamethasone:

An individualised therapy with the selection of

- carfilzomib in combination with lenalidomide and dexamethasone,
- elotuzumab in combination with lenalidomide and dexamethasone,
- elotuzumab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible),
- daratumumab in combination with bortezomib and dexamethasone,
- daratumumab in combination with lenalidomide and dexamethasone,
- daratumumab in combination with carfilzomib and dexamethasone,
- daratumumab in combination with pomalidomide and dexamethasone,
- isatuximab in combination with carfilzomib and dexamethasone,
- isatuximab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible),
- pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible),
- ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible),
- carfilzomib in combination with dexamethasone,
- panobinostat in combination with bortezomib and dexamethasone,
- pomalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy and have shown disease progression during the last therapy, are eligible),
- lenalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible),
- bortezomib in combination with pegylated liposomal doxorubicin (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible),
- bortezomib in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible),

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- daratumumab monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible),
- cyclophosphamide as monotherapy or in combination with dexamethasone (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible) and
- melphalan as monotherapy or in combination with prednisolone or prednisone (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible).

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the GBA 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 according to 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 GBA 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 GBA 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 for the therapeutic indication, or

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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 for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible supportive 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 belantamab mafodotin, the following active ingredients are approved for the present therapeutic indication of relapsed/ refractory multiple myeloma:

Bortezomib, carfilzomib, carmustine, ciltacabtagene autoleucel, cyclophosphamide, daratumumab, dexamethasone, doxorubicin, doxorubicin (pegylated liposomal), elotuzumab, elranatamab, idecabtagene vicleucel, isatuximab, ixazomib, lenalidomide, melphalan, melphalan flufenamide, panobinostat, pomalidomide, prednisolone, prednisone, selinexor, teclistamab, talquetamab and vincristine.

The marketing authorisations are in part linked to (specified) concomitant active ingredients and to the type of the prior therapies.

On 2. In the therapeutic indication of relapsed/ refractory multiple myeloma, autologous and allogeneic stem cell transplants are generally considered as non-medicinal treatment options. However, it is assumed that high-dose chemotherapy with stem cell transplantation is not an option for patients at the time of current therapy. Therefore, a non-medicinal treatment cannot be considered in the present therapeutic indication.

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

- Panobinostat – resolution of 17 March 2016
- Pomalidomide – resolutions of 17 March 2016 and 5 December 2019
- Elotuzumab – resolutions of 1 December 2016 and 16 December 2021
- Carfilzomib – resolutions of 15 February 2018 and 15 July 2021
- Daratumumab – resolutions of 15 February 2018, 3 February 2022 and 15 September 2022
- Ixazomib – resolution of 21 April 2022
- Isatuximab – resolutions of 4 November 2021
- Idecabtagene vicleucel – resolution of 19 September 2024 (amended by the resolution of 19 December 2024)
- Melphalan flufenamide – resolution of 16 March 2023
- Selinexor – resolutions of 16 March 2023
- Teclistamab – resolution of 15 February 2024
- Talquetamab – resolution of 7 March 2024
- Elranatamab – resolution of 4 July 2024
- Ciltacabtagene autoleucel – resolution of 15 May 2025

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic 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".

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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 (see "Information on Appropriate Comparator Therapy"). No written opinions were received.

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

With regard to the selection of treatment options in this therapeutic indication, the guidelines generally refer to a patient-individual treatment decision which is influenced by various factors. In this regard, the S3 guideline places central importance on previously used active ingredients and combinations of active ingredients as well as the type and duration of the response to the respective prior therapies, when selecting a therapy. Particularly among heavily pretreated patients with at least four prior therapies, the general condition is also relevant for the selection of the most suitable patient-individual therapy option.

The therapy recommendations of the S3 guideline differentiate between the treatment setting of the first and third recurrence and from the fourth recurrence onwards. This is due to the heterogeneous patient cohort in the advanced lines of therapy, for whom the substances used in the earlier lines of therapy are increasingly no longer an option and who therefore have a poorer prognosis. Accordingly, despite the overlap between certain therapy options, it is considered appropriate to distinguish between two distinct patient populations based on the number of prior therapies:

a) <u>Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies</u>

With regard to the relapsed/ refractory stage of the disease after one to three prior therapies, the S3 guideline initially states that a triplet therapy with two new substances (monoclonal antibody, immunomodulatory agent, proteasome inhibitor) and a steroid should be used for patients. With reference to the respective approved therapeutic indications of the active ingredients, the guideline also states that all product classes can, in principle, be used and combined in an individualised sequence for the respective combination therapy. This is also done against the background that triplet therapies show a therapeutic benefit compared to doublet therapies, but are not suitable for all patients due to increased therapy toxicity.

On triplet therapies

According to the explanations in the S3 guideline, all approved triplet therapies with two new substances and a steroid can be considered.

Accordingly, the triplet therapies carfilzomib in combination with lenalidomide and dexamethasone, elotuzumab in combination with lenalidomide and dexamethasone, elotuzumab in combination with pomalidomide and dexamethasone, daratumumab in combination with bortezomib and dexamethasone, daratumumab in combination with lenalidomide and dexamethasone, daratumumab in combination with carfilzomib and dexamethasone, daratumumab in combination with pomalidomide and dexamethasone, isatuximab in combination with carfilzomib and dexamethasone, isatuximab in combination with pomalidomide and dexamethasone, pomalidomide in combination with bortezomib and dexamethasone, as well as ixazomib in combination

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with lenalidomide and dexamethasone were included in the appropriate comparator therapy.

The therapy options "daratumumab in combination with pomalidomide and dexamethasone (DPd) (only for subjects who are refractory to lenalidomide or have received at least 2 prior therapies)", "pomalidomide in combination with bortezomib and dexamethasone (PVd) (only for subjects who are refractory to an anti-CD38 antibody and lenalidomide)" and "ixazomib in combination with lenalidomide and dexamethasone (IRd) (only for subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody)" are restricted to patients with a specific refractoriness to the active ingredients or combinations of active ingredients used in prior therapies.

On doublet therapy

In addition to triplet therapies, the dual combination of carfilzomib and dexamethasone is also included in the appropriate comparator therapy. In the benefit assessment, a hint for a considerable additional benefit of this combination therapy compared to bortezomib in combination with dexamethasone was identified for adults after at least one prior therapy (GBA resolution of 15 February 2018).

On individualised therapy

For the reasons set out above, an individualised therapy with the selection of the above-mentioned combinations of active ingredients is determined as the appropriate comparator therapy. The treatment decision is made by especially taking into account the active ingredients and combinations of active ingredients used in the prior therapies, as well as the type and duration of the response to the respective prior therapies.

One criterion for individualised therapy is the duration of the response to the prior therapy. In this regard, according to the generally recognised state of medical knowledge, unsuitability for retreatment with the active ingredients or combinations of active ingredients used in the prior therapy is defined as disease progression during the respective prior therapy or a duration of response of less than 12 months following the completion of the respective prior therapy. Accordingly, treatment using the active ingredients or combinations of active ingredients used in the prior therapy may also represent a suitable treatment option for relapsed patients who have shown a response in the form of a complete remission (CR), a very good partial response (VGPR) and a partial response (PR) lasting more than 12 months after completion of prior therapy.

b) <u>Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies</u>

According to the S3 guideline, all therapy options suitable for the treatment of patients who have received one to three prior therapies are considered for patients who have received at least four prior therapies.

When determining the appropriate comparator therapy for patients who have received at least four prior therapies, administration of a further course of antineoplastic therapy is generally assumed. Best supportive care is therefore not considered an appropriate comparator therapy.

On the approved triplet therapies

In accordance with the S3 guideline, patients with at least four prior therapies should also first be assessed to determine whether triplet therapy is appropriate and possible

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based on the status of the prior therapies. All approved triplet therapies that have already been named under the approved triplet therapies for patients who have received one to three prior therapies are also suitable for patients who have received at least four previous therapies (see patient group a). In addition, the approved triplet therapy comprising panobinostat in combination with bortezomib and dexamethasone is also included as a further relevant therapy option in the appropriate comparator therapy for this patient population.

Panobinostat in combination with bortezomib and dexamethasone is approved for the treatment of adults with relapsed and refractory multiple myeloma who have received at least two prior therapies. By the resolution of 17 March 2016, a non-quantifiable additional benefit of panobinostat in combination with bortezomib and dexamethasone was identified in the orphan benefit assessment procedure. This is based on the results of the PANORAMA-1 approval study, which show no difference in overall survival compared to bortezomib and dexamethasone, but an increase in relevant side effects. The statements made by the clinical experts at the oral hearing on panobinostat showed accordingly that these intensified side effects are to be considered significant and can only be partially influenced by therapy.[2] This is why the restriction applies to adults who have received at least four prior therapies.

Other approved therapy options

In addition, the S3 guideline also refers to doublet therapies, classic cytostatic agents, bispecific antibodies and CAR-T cell therapies for patients who have received at least four prior therapies.

In this regard, carfilzomib in combination with dexamethasone is included as a dual combination in the appropriate comparator therapy.

For at least double-refractory patients who are ineligible for triplet therapy, the dual combinations of pomalidomide in combination with dexamethasone, lenalidomide in combination with dexamethasone, bortezomib in combination with pegylated liposomal doxorubicin and bortezomib in combination with dexamethasone can also be considered. Furthermore, according to the marketing authorisation, the dual combination of pomalidomide in combination with dexamethasone is only indicated for at least double-refractory subjects who have demonstrated disease progression on the last therapy.

For at least triple refractory subjects, who are ineligible for triplet or doublet therapy, treatment options include daratumumab, cyclophosphamide and melphalan, each as monotherapy, as well as cyclophosphamide in combination with dexamethasone and melphalan in combination with prednisone or prednisolone.

Ineligibility for triplet or doublet therapy should be justified on the basis of the patients' refractoriness and comorbidity and taking into account the toxicity of the respective therapy.

On individualised therapy

For the reasons set out above, an individualised therapy with the selection of the above-mentioned active ingredients or combinations of active ingredients is determined as the appropriate comparator therapy. The treatment decision is made by especially taking into account the general condition, the active ingredients and

[2] Benefit assessment procedure of the GBA for the active ingredient panobinostat, resolution of 17 March 2016

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combinations of active ingredients used in the prior therapies, as well as the type and duration of the response to the respective prior therapies.

On the approved active ingredients that were not determined as the appropriate comparator therapy as part of individualised therapy:

Among the approved active ingredients that have not been determined as the appropriate comparator therapy as part of individualised therapy in the present determination of the appropriate comparator therapy, taking into account the evidence on therapeutic benefit, guideline recommendations and the reality of care:

The CAR-T cell therapies idecabtagene vicleucel and ciltacabtagene autoleucel are approved for the treatment of patients who have received at least two prior therapies and one prior therapy, respectively.

An additional benefit of idecabtagene vicleucel (resolution of 19 September 2024) is not proven.

A hint for a considerable additional benefit of ciltacabtagene autoleucel (resolution of 15 May 2025) compared with daratumumab in combination with pomalidomide and dexamethasone, as well as pomalidomide in combination with bortezomib and dexamethasone was found in adults with relapsed and refractory multiple myeloma, who have received one to three prior therapies, have shown disease progression during their last therapy, and are refractory to lenalidomide. An additional benefit is not proven for adults who have received at least four prior therapies.

According to the information in the S3 guideline, idecabtagene vicleucel may be administered to patients who have received four prior therapies. However, its use is not explicitly recommended. The S3 guideline contains no information on the CAR-T cell therapy ciltacabtagene autoleucel. According to the generally recognised state of medical knowledge, it is not yet possible to make a definitive assessment of the significance of these treatment options. For the present resolution, CAR-T cell therapies are not considered to be an appropriate comparator therapy.

The active ingredient selinexor is approved for the treatment setting after at least one prior therapy in combination with bortezomib and dexamethasone. It was determined by the resolution of 16 March 2023 that an additional benefit of this combination therapy over the appropriate comparator therapy is not proven.

Melphalan flufenamide is a therapy option for the treatment of subjects with at least three prior therapies. The GBA determined by the resolution of 16 March 2023 that an additional benefit of melphalan flufenamide is not proven, as no suitable data were available to enable an assessment of the additional benefit.

Teclistamab is a therapy option for the treatment of subjects who have received at least three prior therapies. By the resolution of 15 February 2024, it was determined that an additional benefit of teclistamab is not proven, as no data were available to enable an assessment of the additional benefit.

Talquetamab is a therapy option for the treatment of subjects who have received at least three prior therapies. As part of a benefit assessment of medicinal products for the treatment of a rare disease, the GBA resolution of 7 March 2024 identified a hint for a non-quantifiable additional benefit of talquetamab since the scientific data does not allow quantification.

The active ingredient elranatamab is approved for the treatment setting after at least three prior therapies. It was determined by the resolution of 4 July 2024 that an

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additional benefit of this monotherapy over the appropriate comparator therapy is not proven.

By the resolution of 16 March 2023, it was identified in the benefit assessment that an additional benefit of the combination of active ingredients selinexor in combination with dexamethasone compared to the appropriate comparator therapy is not proven.

Monotherapy with bortezomib is no longer recommended as a therapy option in relevant guidelines due to its proven inferiority in terms of overall survival.

The use of older chemotherapeutic agents, such as doxorubicin monotherapy, is of secondary importance according to the S3 guideline.

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

Any change to the appropriate comparator therapy requires a decision by the GBA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

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

a) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies

a1) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy

An additional benefit is not proven.

a2) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy

An additional benefit is not proven.

b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies

b1) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy

Hint for a non-quantifiable additional benefit.

b2) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy

An additional benefit is not proven.

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Justification:

To demonstrate the additional benefit of belantamab mafodotin in combination with bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have already received at least one prior therapy, the pharmaceutical company presented the results of the global cohort from the ongoing, open-label, multicentre phase III DREAMM-7 study, which compared belantamab mafodotin in combination with bortezomib and dexamethasone (BVd) against daratumumab in combination with bortezomib and dexamethasone (DVd). The study has been ongoing since May 2020 in Asia, Australia, Europe, as well as North and South America.

A total of 494 adults with relapsed or refractory multiple myeloma who had already received at least one prior therapy were enrolled in the global cohort of the study. Patients whose disease was refractory to daratumumab or another anti-CD38 therapy, or to a twice-weekly bortezomib regimen, were excluded.

Patients were randomised in a 1:1 ratio to the two study arms (BVd: N = 251; DVd: N = 243), stratified by the number of previous lines of therapy (1 vs 2 or 3 vs ≥ 4), prior treatment with bortezomib (yes vs no) and Revised International Staging System (R-ISS) status (I vs II or III).

In the dossier, the pharmaceutical company had not divided the patients according to the patient groups of the appropriate comparator therapy (1 to 3 or ≥ 4 prior therapies).

As part of the written statement procedure, the pharmaceutical company submitted analyses of the latest, pre-specified data cut-off from 09.01.2026 relating to the global cohort of the DREAMM-7 study. These analyses follow the division into patient groups according to the appropriate comparator therapy and form the basis of this assessment.

On the China sub-population and the Japan extension cohort of the DREAMM-7 study

In the analyses presented for the global cohort, the pharmaceutical company has largely failed to take into account the "China sub-population" and the "Japan extension cohort" of the DREAMM-7 study. Consequently, around 13.5% of the total population of the DREAMM-7 study is missing from the analyses of the global cohort.

On the implementation of the appropriate comparator therapy

For this therapeutic indication, the GBA determined an individualised therapy with the selection of the specified active ingredients or combinations of active ingredients as the appropriate comparator therapy for these patient groups. In the DREAMM-7 study, only the combination therapy DVd was used in the comparator arm. The investigators therefore did not have a choice of several treatment options that would have enabled them to make an individualised treatment decision.

In accordance with the appropriate comparator therapy, the treatment decision is made – both for adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for those who have received at least four prior therapies – by taking into account, among other factors, the active ingredients and combinations of active ingredients used in prior therapies, as well as the type and duration of the response to those prior therapies.

In the global cohort of the DREAMM-7 study, 84% of patients in the comparator arm had already received prior therapy with bortezomib. This raises uncertainty as to the extent to which bortezomib constitutes a suitable individualised therapy for these patients in the context of DVd. During the written statement procedure, the pharmaceutical company presented information on the treatment duration of bortezomib-containing prior therapy for patients who received a bortezomib-containing regimen as their last therapy prior to

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enrolment in the study and who achieved at least a partial response. The median treatment duration for these patients was 11.8 months.

This additional information cannot definitively rule out the existing uncertainties. During the oral hearing, the clinical experts emphasised that a bortezomib-based regimen may also be indicated for patients who have already received prior therapy with bortezomib, as resistance to bortezomib is rare. In the overall assessment, this uncertainty is not considered to be so serious as to prevent conclusions being drawn about the additional benefit on the basis of the available study results. The presented results of the DREAMM-7 study are therefore used for this assessment. However, there is uncertainty as to the extent to which bortezomib, as part of DVd, constitutes a suitable individualised therapy for patients in the comparator arm of the DREAMM-7 study who have already received prior therapy with bortezomib. Given the comparator selected in the DREAMM-7 study, the assessment is carried out in accordance with the requirements for the appropriate comparator therapy (individualised therapy), separately for patient groups differentiated according to whether DVd constitutes a suitable individualised therapy or not.

Further limitations of the DREAMM-7 study

With regard to prior therapies used, 67% of patients in the global cohort of the DREAMM-7 study had received prior therapy with a cyclophosphamide-containing regimen. However, in the German healthcare context, cyclophosphamide assumes relatively minor significance in first- and second-line therapy. As prior therapy, only 52% of patients had received lenalidomide, which is considered the therapy standard. In the comparator arm, only around 2% of patients received daratumumab, which is part of the standard first-line therapy in Germany. With regard to the patients' prior therapies in the study, there are therefore significant uncertainties as to the generalisability of the study results to the German healthcare context.

Extent and probability of the additional benefit

a1) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy

Mortality

In the DREAMM-7 study, overall survival was operationalised as the time between randomisation and death from any cause.
For the endpoint of overall survival, there was a statistically significant difference to the advantage of BVd over DVd.

Morbidity

Progression-free survival (PFS)

Progression-free survival was operationalised in the DREAMM-7 study as the time from randomisation to the date of documented disease progression according to IMWG criteria, or the time of death from any cause, whichever occurred first.

For the PFS endpoint, there was a statistically significant advantage of BVd.

The present PFS endpoint is a composite endpoint consisting of endpoints from the "mortality" and "morbidity" categories. The endpoint component "mortality" is already assessed via the endpoint "overall survival" as an independent endpoint. The morbidity component "disease progression" is assessed according to IMWG criteria and thus, not in a

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symptom-related manner but by means of laboratory parametric, imaging, and haematological procedures.

Taking into account the aspects mentioned above, there are different opinions within the GBA regarding the patient relevance of the PFS endpoint. The overall statement on the extent of the additional benefit remains unaffected.

Symptomatology assessed using the EORTC QLQ-C30 symptom scales and the item library-52

In the DREAMM-7 study, symptomatology was assessed using the EORTC QLQ-C30 and the EORTC item library (IL)-52.

The pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. Given the expected disease progression in this therapeutic indication, the time to first deterioration (an increase by ≥ 10 points) is used for the benefit assessment.

The IL-52 corresponds to the disease symptoms scale of the EORTC Quality of Life Questionnaire – Multiple Myeloma 20 (EORTC QLQ-MY20), which comprises a total of 4 scales.

The selective collection of data from one scale of the EORTC QLQ-MY20 in the DREAMM-7 study is inappropriate. The results of the EORTC IL-52 are therefore not used for the benefit assessment.

In the EORTC QLQ-C30, there was no statistically significant difference between the study arms.

Symptomatology assessed using the Patient Global Impression of Symptom Severity (PGIS) and the Patient Global Impression of Change (PGIC)

The PGIS consists of a single question that assesses the symptomatology of cancer on the day of the survey. There are 5 possible answers ("no symptoms", "mild", "moderate", "severe", "very severe"). The pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. Given the expected disease progression in this therapeutic indication, the time to first deterioration (an increase by ≥ 1 point) is used for the benefit assessment.

The PGIC consists of a single question that assesses changes in cancer symptomatology compared with the start of treatment. There are 5 possible answers ("much better", "minimally better", "no change", "minimally worse", "much worse").

The pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. Given the expected disease progression in this therapeutic indication, the time to first deterioration (reaching a scale score of "much worse" or "minimally worse" compared with the start of the study) is used for the benefit assessment.

For both the PGIS and the PGIC, there were no statistically significant differences between the study arms.

Health status (assessed using EQ-5D VAS)

The health status was assessed using the visual analogue scale (VAS) of the EQ-5D questionnaire.

For the benefit assessment, the pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. The analyses of the time to first deterioration (decrease by ≥ 15 points) are used in accordance with the explanations on the "Symptomatology" section.

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There was no statistically significant difference between the study arms.

Quality of life

Health-related quality of life was assessed in the DREAMM-7 study using the EORTC QLQ-C30. For the benefit assessment, the pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. The analyses of the time to first deterioration are used in accordance with the explanations on the "Symptomatology" section.

For the endpoint of cognitive functioning, the EORTC QLQ-C30 showed a statistically significant difference to the disadvantage of BVd. For the endpoints of global health status, physical functioning, role functioning, emotional functioning and social functioning, there was no statistically significant difference.

With regard to health-related quality of life, no overall advantage or disadvantage is identified for BVd.

Side effects

Cross-endpoint note

As set out in the study protocol, the definition of AEs in the DREAMM-7 study stipulates that progression, signs or symptoms of the investigated disease should not be collected as AEs unless they were more severe than would have been expected given the study participant's condition. The definition of AEs not to be collected in the study covers not only AEs that reflect progression of the underlying disease, but is considerably broader in scope, as it also includes non-specific signs and symptoms of the diseases. It is the responsibility of the principal investigator to determine which events are to be documented as AEs. Particularly in an unblinded study, this may result in the potentially unsystematic and/or incomplete collection of AEs and may also lead to a risk of bias in the results. Given their magnitude, the effects set out below are not called into question in the present data basis despite the current uncertainty.

Total adverse events (AEs) (presented additionally)

In the DREAMM-7 study, adverse events occurred in all patients. The results were only presented additionally.

Serious AEs (SAEs), severe AEs (CTCAE grade ≥ 3), therapy discontinuation due to AEs

For the endpoints of SAEs, severe AEs and therapy discontinuation due to AEs, there was a statistically significant difference to the disadvantage of BVd in each case.

Specific AEs

Detailed analysis of the specific AEs showed a statistically significant difference to the disadvantage of BVd for the endpoints: eye disorders (SOC, AEs and severe AEs), gastrointestinal disorders (SOC, SAEs), thrombocytopenia (PT, severe AEs), infections and infestations (SOC, severe AEs), pneumonia (PT, severe AEs), physical investigations (SOC, severe AEs) and cardiac disorders (SOC, severe AEs).

No suitable data are available for the endpoint of peripheral neuropathy.

For the endpoint of infusion-related reactions, there was a statistically significant difference to the advantage of BVd.

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FACT-G GP5

The "Functional Assessment of Cancer Therapy – General Version – Physical 5" is a single item from the FACT-G within the "physical wellbeing" domain (item GP5: "I am bothered by side effects of treatment").

The effects of side effects may, in principle, be patient-relevant; however, collecting data solely via this single item is considered to be less significant in terms of content. To ensure that the effects of the therapy's side effects can be adequately shown, other instruments which provide for a more comprehensive and targeted assessment are available, e.g. the PRO-CTCAE.

The FACT-G GP5 is therefore not used for benefit assessment.

PRO-CTCAE

In the DREAMM-7 study, side effects were also collected using the PRO-CTCAE instrument. However, it is not clear from the available documents on what basis the events were selected from the PRO-CTCAE system. It is not clear whether the side effects of BVd and DVd are adequately shown. Regardless of this, only descriptive analyses are available. The PRO-CTCAE results are therefore not used for the benefit assessment.

OSDI (Ocular Surface Disease Index)

In the DREAMM-7 study, the OSDI was used to collect patient-reported eye disorders in the endpoint category of side effects. The OSDI comprises 12 questions, which are grouped into 3 subscales (vision-related functioning with 4 questions, ocular symptoms with 5 questions and environmental triggers with 3 questions) and a total score. The questions are answered using a 5-point Likert scale ranging from "always" to "never". The total score and the subscales are converted to values ranging from 0 to 100, with higher values indicating a greater level of burden.

For the benefit assessment, the time to 1st deterioration (an increase by ≥ 15 points) was used for the total score.

There was a statistically significant difference to the disadvantage of BVd.

In summary, with regard to side effects, the statistically significant differences for serious AEs, severe AEs and discontinuation due to AEs, as well as the eye disorders collected using the OSDI, indicate a clear disadvantage for BVd overall.

<u>Overall assessment</u>

Results in the endpoint categories of mortality, morbidity, health-related quality of life and side effects from the global cohort of the DREAMM-7 study comparing BVd with daratumumab in combination with bortezomib and dexamethasone (DVd) are available for the assessment of the additional benefit of belantamab mafodotin in combination with bortezomib and dexamethasone (BVd) for the treatment of adults with relapsed or refractory multiple myeloma, who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy.

For the endpoint of overall survival, there was a statistically significant difference to the advantage of BVd over DVd.

Available results on the endpoints of symptomatology (EORTC QLQ-C30, PGIS, PGIC) and health status (EQ-5D VAS) in the endpoint category of morbidity do not show any statistically significant differences between the study arms.

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Results from the EORTC QLQ-C30 are available for the endpoint category of health-related quality of life. The EORTC QLQ-C30 showed a statistically significant difference to the disadvantage of BVd only in the endpoint of cognitive functioning. For the endpoints of global health status, physical functioning, role functioning, emotional functioning and social functioning, there was no statistically significant difference.

With regard to health-related quality of life, no overall advantage or disadvantage is identified for BVd.

For the endpoints on severe AEs, SAEs and discontinuation due to AEs, as well as the eye disorders collected using the OSDI in the endpoint category of side effects, there was a statistically significant difference to the disadvantage of BVd in each case. In detail, there were predominantly disadvantages for the specific AEs. Given their magnitude, the effects are considered to be sufficiently reliable despite the uncertainties regarding the collection of the AEs in accordance with the study protocol. Overall, a clear disadvantage for BVd in terms of side effects can be observed.

In the overall analysis of the available results, the advantage in terms of the overall survival endpoint is offset by a significant disadvantage in terms of side effects.

The overall assessment takes into account the fact that the pharmaceutical company presented the analyses without the data on the "China sub-population", as well as the "Japan extension cohort", which account for approximately 13.5% of the total study population. This therefore gives rise to a significant degree of uncertainty as to how the effect on overall survival, in particular, would be reflected when these data are taken into account.

Furthermore, there remains uncertainty regarding the comparator therapy, specifically the extent to which bortezomib, as part of DVd, constitutes a suitable individualised therapy for patients in the comparator arm of the DREAMM-7 study who have already received prior therapy with bortezomib.

Based on the data from the global cohort and taking into account the reasons set out above, the GBA conclude in a weighted decision that the statistically significant difference to the advantage of BVd in terms of the overall survival endpoint does not outweigh the significant disadvantage in terms of side effects.

It is therefore concluded that an additional benefit is not proven for adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy.

a2) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy

The DREAMM-7 study is unsuitable for deriving the additional benefit since only the combination of DVd was used in the comparator arm of this study. Consequently, an additional benefit is not proven for adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy.

b1) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy

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Mortality

In the DREAMM-7 study, overall survival was operationalised as the time between randomisation and death from any cause.

For the endpoint of overall survival, there was a statistically significant difference to the advantage of BVd over DVd.

Morbidity

Progression-free survival (PFS)

In the DREAMM-7 study, progression-free survival was operationalised as the time from randomisation to the date of documented disease progression according to IMWG criteria, or the time of death from any cause, whichever occurred first.

For the PFS endpoint, there was a statistically significant advantage of BVd.

The present PFS endpoint is a composite endpoint consisting of endpoints from the "mortality" and "morbidity" categories. The endpoint component "mortality" is already assessed via the endpoint "overall survival" as an independent endpoint. The morbidity component "disease progression" is assessed according to IMWG criteria and thus, not in a symptom-related manner but by means of laboratory parametric, imaging, and haematological procedures.

Taking into account the aspects mentioned above, there are different opinions within the GBA regarding the patient relevance of the PFS endpoint. The overall statement on the extent of the additional benefit remains unaffected.

Symptomatology assessed using the EORTC QLQ-C30 symptom scales and the item library-52

In the DREAMM-7 study, symptomatology was assessed using the EORTC QLQ-C30 and the EORTC item library (IL)-52.

The pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. Given the expected disease progression in this therapeutic indication, the time to first deterioration (an increase by ≥ 10 points) is used for the benefit assessment.

The IL-52 corresponds to the disease symptoms scale of the EORTC Quality of Life Questionnaire – Multiple Myeloma 20 (EORTC QLQ-MY20), which comprises a total of 4 scales.

The selective collection of data from one scale of the EORTC QLQ-MY20 in the DREAMM-7 study is inappropriate. The results of the EORTC IL-52 are therefore not used for the benefit assessment.

In the EORTC QLQ-C30, there was no statistically significant difference between the study arms.

Symptomatology assessed using the Patient Global Impression of Symptom Severity (PGIS) and the Patient Global Impression of Change (PGIC)

The PGIS consists of a single question that assesses the symptomatology of cancer on the day of the survey. There are 5 possible answers ("no symptoms", "mild", "moderate", "severe", "very severe"). The pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. Given the expected disease progression in this therapeutic indication, the time to first deterioration (an increase by ≥ 1 point) is used for the benefit assessment.

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The PGIC consists of a single question that assesses changes in cancer symptomatology compared with the start of treatment. There are 5 possible answers ("much better", "minimally better", "no change", "minimally worse", "much worse").

The pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. Given the expected disease progression in this therapeutic indication, the time to first deterioration (reaching a scale score of "much worse" or "minimally worse" compared with the start of the study) is used for the benefit assessment.

For both the PGIS and the PGIC, there were no statistically significant differences between the study arms.

Health status (assessed using EQ-5D VAS)

The health status was assessed using the visual analogue scale (VAS) of the EQ-5D questionnaire.

For the benefit assessment, the pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. The analyses of the time to first deterioration (decrease by ≥ 15 points) are used in accordance with the explanations on the "Symptomatology" section.

There was no statistically significant difference between the study arms.

Quality of life

Health-related quality of life was assessed in the DREAMM-7 study using the EORTC QLQ-C30. For the benefit assessment, the pharmaceutical company submitted analyses of the time to first deterioration and the time to first improvement in the dossier. The analyses of the time to first deterioration are used in accordance with the explanations on the "Symptomatology" section.

For the endpoint of cognitive functioning, the EORTC QLQ-C30 showed a statistically significant difference to the disadvantage of BVd. For the endpoints of global health status, physical functioning, role functioning, emotional functioning and social functioning, there was no statistically significant difference.

With regard to health-related quality of life, no overall advantage or disadvantage is identified for BVd.

Side effects

Cross-endpoint note

As set out in the study protocol, the definition of AEs in the DREAMM-7 study stipulates that progression, signs or symptoms of the investigated disease should not be collected as AEs unless they were more severe than would have been expected given the study participant's condition. The definition of AEs not to be collected in the study covers not only AEs that reflect progression of the underlying disease, but is considerably broader in scope, as it also includes non-specific signs and symptoms of the diseases. It is the responsibility of the principal investigator to determine which events are to be documented as AEs. Particularly in an unblinded study, this may result in the potentially unsystematic and/or incomplete collection of AEs and may also lead to a risk of bias in the results.

Total adverse events (AEs) (presented additionally)

In the DREAMM-7 study, adverse events occurred in all patients. The results were only presented additionally.

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Serious AEs (SAEs), severe AEs (CTCAE grade ≥ 3), therapy discontinuation due to AEs

For the endpoints of SAEs and therapy discontinuation due to AEs, there was no statistically significant difference between the study arms in each case.

For the endpoint of severe AEs, there was a significant difference to the disadvantage of BVd.

Due to the potentially unsystematic and/or incomplete collection of the AEs in accordance with the study protocol (see cross-endpoint note), the present results are considered insufficiently reliable for deriving a disadvantage for this endpoint.

Specific AEs

Detailed analysis of the specific AEs showed a statistically significant difference to the disadvantage of BVd for the endpoints: eye disorders (SOC, AEs and severe AEs), fever (PT, AEs) and physical investigations (SOC, severe AEs).

No suitable data are available for the endpoint of peripheral neuropathy.

FACT-G GP5

The "Functional Assessment of Cancer Therapy – General Version – Physical 5" is a single item from the FACT-G within the "physical wellbeing" domain (item GP5: "I am bothered by side effects of treatment").

The effects of side effects may, in principle, be patient-relevant; however, collecting data solely via this single item is considered to be less significant in terms of content. To ensure that the effects of the therapy's side effects can be adequately shown, other instruments which provide for a more comprehensive and targeted assessment are available, e.g. the PRO-CTCAE.

The FACT-G GP5 is therefore not used for benefit assessment.

PRO-CTCAE

In the DREAMM-7 study, side effects were also collected using the PRO-CTCAE instrument. However, it is not clear from the available documents on what basis the events were selected from the PRO-CTCAE system. It is not clear whether the side effects of BVd and DVd are adequately shown. Regardless of this, only descriptive analyses are available. The PRO-CTCAE results are therefore not used for the benefit assessment.

OSDI (Ocular Surface Disease Index)

In the DREAMM-7 study, the OSDI was used to collect patient-reported eye disorders in the endpoint category of side effects. The OSDI comprises 12 questions, which are grouped into 3 subscales (vision-related functioning with 4 questions, ocular symptoms with 5 questions and environmental triggers with 3 questions) and a total score. The questions are answered using a 5-point Likert scale ranging from "always" to "never". The total score and the subscales are converted to values ranging from 0 to 100, with higher values indicating a greater level of burden.

For the benefit assessment, the time to 1st deterioration (an increase by ≥ 15 points) was used for the total score.

There was a statistically significant difference to the disadvantage of BVd.

In summary, with regard to side effects, the eye disorders collected using the OSDI indicate a disadvantage for BVd. Detailed analysis also showed disadvantages for BVd in terms of the specific AEs.

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Overall assessment

Results in the endpoint categories of mortality, morbidity, health-related quality of life and side effects from the global cohort of the DREAMM-7 study comparing BVd with daratumumab in combination with bortezomib and dexamethasone (DVd) are available for the assessment of the additional benefit of belantamab mafodotin in combination with bortezomib and dexamethasone (BVd) for the treatment of adults with relapsed or refractory multiple myeloma, who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy.

For the endpoint of overall survival, there was a statistically significant difference to the advantage of BVd over DVd.

Available results on the endpoints of symptomatology (EORTC QLQ-C30, PGIS, PGIC) and health status (EQ-5D VAS) in the endpoint category of morbidity do not show any statistically significant differences between the study arms.

Results from the EORTC QLQ-C30 are available for the endpoint category of health-related quality of life. The EORTC QLQ-C30 showed a statistically significant difference to the disadvantage of BVd only in the endpoint of cognitive functioning. For the endpoints of global health status, physical functioning, role functioning, emotional functioning and social functioning, there was no statistically significant difference.

With regard to health-related quality of life, no overall advantage or disadvantage is identified for BVd.

For the endpoints of SAEs and discontinuation due to AEs in the endpoint category of side effects, there were no statistically significant differences between the study arms.

For the endpoint of severe AEs, there was a statistically significant difference to the disadvantage of BVd.

Due to the potentially unsystematic and/or incomplete collection of AEs in accordance with the study protocol, the results on side effects are considered insufficiently reliable to conclude that there is a disadvantage for this endpoint. Detailed analysis showed disadvantages for BVd in terms of the specific AEs. In addition, patient-reported eye disorders were collected using the OSDI. The total OSDI score showed a statistically significant difference to the disadvantage of BVd.

In the overall assessment, the advantage of BVd in terms of the overall survival endpoint – based on data from the global cohort and taking into account the effect magnitude – is not called into question by the disadvantage in terms of side effects. The overall assessment takes into account the fact that the pharmaceutical company presented the analyses without the data on the "China sub-population", as well as the "Japan extension cohort", which account for approximately 13.5% of the total study population. This therefore gives rise to a significant degree of uncertainty as to how the effect on overall survival, in particular, would be reflected when these data are taken into account. Furthermore, there remains uncertainty regarding the comparator therapy, specifically the extent to which bortezomib, as part of DVd, constitutes a suitable individualised therapy for patients in the comparator arm of the DREAMM-7 study who have already received prior therapy with bortezomib.
In the overall assessment, the GBA identified an additional benefit of BVd – the extent of which is classified as non-quantifiable – in the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy.

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Reliability of data (probability of the additional benefit)

The present assessment is based on the results of the global cohort of the open-label, randomised, controlled phase III DREAMM-7 study.

The endpoint-specific risk of bias for the results of the patient-reported endpoints on morbidity and health-related quality of life is rated as high due to the open-label study design. In addition, the collection of adverse events (AEs) was potentially unsystematic and incomplete, which also leads to a potential risk of bias in the results.

Furthermore, there are significant uncertainties regarding the transferability of the study results to the German healthcare context. With regard to prior therapies used, 67% of patients in the global cohort of the DREAMM-7 study had received prior therapy with a cyclophosphamide-containing regimen. However, in the German healthcare context, cyclophosphamide assumes relatively minor significance in first- and second-line therapy. As prior therapy, only 52% of patients had received lenalidomide, which is considered the therapy standard. In the comparator arm, only around 2% of patients received daratumumab, which is part of the standard first-line therapy in Germany.

Overall, the reliability of data of the additional benefit identified is classified as a hint.

b2) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy

The DREAMM-7 study is unsuitable for deriving the additional benefit since only the combination of DVd was used in the comparator arm of this study. Consequently, an additional benefit is not proven for adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the medicinal product Blenrep with the active ingredient belantamab mafodotin. The therapeutic indication assessed here is as follows:

"Blenrep is indicated in adults for the treatment of relapsed or refractory multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy."

In the therapeutic indication under consideration, two distinct patient groups which differ in the number of prior therapies are analysed for the benefit assessment.

a) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies

The GBA determined the appropriate comparator therapy to be an individualised therapy with the selection of several therapy options, including daratumumab in combination with bortezomib and dexamethasone, as well as other triplet therapies and a doublet therapy. The treatment decision is made by especially taking into account the active ingredients and combinations of active ingredients used in the prior therapies, as well as the type and duration of the response to the respective prior therapies.

b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies

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The GBA determined the appropriate comparator therapy to be an individualised therapy with the selection of several therapy options, including daratumumab in combination with bortezomib and dexamethasone, as well as other mono, doublet and triplet therapies. The treatment decision is made by especially taking into account the active ingredients and combinations of active ingredients used in the prior therapies, as well as the type and duration of the response to the respective prior therapies.

On patient groups a) and b):

The pharmaceutical company presented the results from the global cohort of the DREAMM-7 study for the benefit assessment of belantamab mafodotin in combination with bortezomib and dexamethasone. The DREAMM-7 study compared belantamab mafodotin in combination with bortezomib and dexamethasone (BVd) against daratumumab in combination with bortezomib and dexamethasone (DVd). As the DREAMM-7 study used only DVd as the comparator, there was no range of therapy options available that would have enabled an individualised treatment decision. Consequently, the assessment is carried out separately for subgroups differentiated according to whether DVd constitutes a suitable individualised therapy or not.

a1) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy

a2) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy

b1) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy

b2) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and for whom daratumumab in combination with bortezomib and dexamethasone does not constitute a suitable individualised therapy

On patient group a1):

For the endpoint of overall survival, there was a statistically significant difference to the advantage of BVd.

Available results on the endpoints of symptomatology (EORTC QLQ-C30, PGIS, PGIC) and health status (EQ-5D VAS) in the endpoint category of morbidity do not show any statistically significant differences between the study arms.

Results from the EORTC QLQ-C30 are available for the endpoint category of health-related quality of life. With regard to health-related quality of life, neither an advantage nor a disadvantage is identified for BVd.

For the endpoints on severe AEs, SAEs and discontinuation due to AEs, as well as the eye disorders collected using the OSDI in the endpoint category of side effects, there was a statistically significant difference to the disadvantage of BVd in each case. In detail, there were predominantly disadvantages for the specific AEs. Given their magnitude, the effects are considered to be sufficiently reliable despite the uncertainties regarding the collection of the AEs in accordance with the study protocol. Overall, a clear disadvantage for BVd in terms of side effects can be observed.

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Based on the data from the global cohort and taking into account the significant uncertainties, the GBA conclude in a weighted decision that the statistically significant difference to the advantage of BVd in terms of the overall survival endpoint does not outweigh the significant disadvantage in terms of side effects. The pharmaceutical company presented the analyses without the data relating to the "China sub-population" and the "Japan extension cohort", which account for approximately 13.5% of the total study population of the DREAMM-7 study. This therefore gives rise to a significant degree of uncertainty as to how the effect on overall survival, in particular, would be reflected when these data are taken into account. Overall, an additional benefit of BVd over DVd is therefore not proven for patient group a1).

On patient group a2):

In the DREAMM-7 study, only treatment with DVd was offered as the comparator. Overall, no data are available for patients, for whom DVd is not a suitable individualised therapy, which is why an additional benefit is not proven for patient group a2).

On patient group b1):

For the endpoint of overall survival, there was a statistically significant difference to the advantage of BVd.

Available results on the endpoints of symptomatology (EORTC QLQ-C30, PGIS, PGIC) and health status (EQ-5D VAS) in the endpoint category of morbidity do not show any statistically significant differences between the study arms.

Results from the EORTC QLQ-C30 are available for the endpoint category of health-related quality of life. With regard to health-related quality of life, neither an advantage nor a disadvantage is identified for BVd.

For the endpoints of SAEs and discontinuation due to AEs in the endpoint category of side effects, there were no statistically significant differences between the study arms.

For the endpoint of severe AEs, there was a significant difference to the disadvantage of BVd. Due to uncertainties regarding the collection of AEs in accordance with the study protocol, the results on the AEs are considered to be insufficiently reliable.

Detailed analysis showed disadvantages for BVd in terms of the specific AEs.

In addition, patient-reported eye disorders were collected using the OSDI. The total OSDI score showed a statistically significant difference to the disadvantage of BVd.

In the overall assessment, the advantage of BVd in terms of the overall survival endpoint – based on data from the global cohort and taking into account the effect magnitude – is not called into question by the disadvantage in terms of side effects.

In the overall assessment, the GBA identified an additional benefit of BVd over DVd for patient group b1). The extent of this benefit is classified as non-quantifiable.

Due to uncertainties regarding the transferability of the study results to the German healthcare context, the reliability of data regarding the identified additional benefit is classified as a hint.

On patient group b2):

In the DREAMM-7 study, only treatment with DVd was offered as the comparator. Overall, no data are available for patients, for whom DVd is not a suitable individualised therapy, which is why an additional benefit is not proven for patient group b2).

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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 dossier of the pharmaceutical company. These contain a range for the number of patients who have received at least one prior therapy. There are no differentiated data on patient numbers depending on the number of prior therapies (one to three vs at least four). In the procedure for elranatamab (GBA's resolution of 4 July 2024), a number of approx. 1,100 to 1,180 patients was identified for "adults with relapsed and refractory multiple myeloma who have received at least four prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and who have shown disease progression during the last therapy".

As a rule, patients who have received at least four prior therapies are expected to have already received an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody. Consequently, a figure of approximately 1,100 to 1,180 patients is estimated as a rough approximation for patient group b) in the present procedure. Accordingly, patient group a) is the difference between b) and the number of patients in the total population (approximately 1,880 to 2,350 patients).

No data are available on the further division of patient groups into a1) and a2), as well as b1) and b2) according to their suitability for DVd. The active ingredients daratumumab and bortezomib are often used in earlier lines of therapy. Given the several therapy options available for the treatment of relapsed or refractory multiple myeloma, the patient cohort for whom daratumumab in combination with bortezomib and dexamethasone constitutes a suitable individualised therapy is likely to be relatively small.

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 Blenrep (active ingredient: belantamab mafodotin) at the following publicly accessible link (last access: 1 July 2026):

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

Treatment with belantamab mafodotin should only be initiated and monitored by specialists in internal medicine, haematology and oncology experienced in the treatment of patients with multiple myeloma.

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).

The training material contains, in particular, information and warnings about ocular (eye-related) side effects. The training material explains how to carry out eye examinations and contains information on the treatment and prevention of ocular side effects.

Courtesy translation – only the German version is legally binding.

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 July 2026). 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 the maximum treatment duration, if specified in the product information.

For bortezomib in combination with pegylated liposomal doxorubicin, a treatment duration of 8 cycles is assumed, even if the actual treatment duration may differ from patient to patient.

For the cyclophosphamide + dexamethasone combination which was defined as the appropriate comparator therapy, no study that would allow cost representation could be identified. The costs can therefore not be quantified.

When combining melphalan with prednisone or prednisolone, the treatment regimens and dosages follow the underlying product information for melphalan, prednisone or prednisolone.

Treatment with ixazomib in combination with lenalidomide and dexamethasone for more than 24 cycles should be based on an individual risk-benefit assessment, as data on tolerability and toxicity beyond 24 cycles are limited.

Treatment with carfilzomib in combination with lenalidomide and dexamethasone spanning beyond 18 cycles should be based on an individual risk-benefit assessment, as data on the tolerability and toxicity of carfilzomib beyond 18 cycles are limited.

Treatment period:

a) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Belantamab mafodotin in combination with bortezomib and dexamethasone				
Belantamab mafodotin	1 x per 21-day cycle	17.4	1	17.4
Bortezomib	Day 1, 4, 8 and 11: 21-day cycle	8	4	32
Dexamethasone	Day 1, 2, 4, 5, 8, 9, 11 and 12	8	8	64

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	of a 21-day cycle			
Appropriate comparator therapy				
An individualised therapy with the selection of				
Carfilzomib in combination with lenalidomide and dexamethasone				
Carfilzomib	1st – 12th cycle: Day 1, 2, 8, 9, 15, 16 From 13th cycle: Day 1, 2, 15, 16 28-day cycle	13.0	1st – 12th cycle: 6 From 13th cycle: 4	76.0
Lenalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	4	52.0
Elotuzumab in combination with lenalidomide and dexamethasone				
Elotuzumab	1st – 2nd cycle: Day 1, 8, 15, 22 From 3rd cycle: Day 1, 15 28-day cycle	13.0	1st – 2nd cycle 4 From 3rd cycle 2	30.0
Lenalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	4	52.0
Elotuzumab in combination with pomalidomide and dexamethasone (only subjects who have received at least two prior therapies and have shown disease progression during the last therapy are eligible)				
Elotuzumab	1st – 2nd cycle: Day 1, 8, 15, 22 From 3rd cycle: Day 1 28-day cycle	13.0	1st – 2nd cycle: 4 From 3rd cycle: 1	19.0
Pomalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	4	52.0
Daratumumab in combination with bortezomib and dexamethasone				

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Daratumumab	Cycle 1 – 3: Day 1, 8 and 15 of a 21-day cycle Cycle 4 – 8: Day 1 of a 21-day cycle From 9th cycle: Day 1 of a 28-day cycle	21.0	1	21.0
Bortezomib	Day 1, 4, 8 and 11: 21-day cycle	8	4	32
Dexamethasone	Day 1, 2, 4, 5, 8, 9, 11 and 12 of a 21-day cycle	8	Cycle 1 – 3: 6 Cycle 4 – 8: 7	53[3]
Daratumumab in combination with lenalidomide and dexamethasone				
Daratumumab	Cycle 1 – 2: Day 1, 8, 15, 22 Cycle 3 – 6: Day 1, 15 From cycle 7: Day 1 28-day cycle	23.0	1	23.0
Lenalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	Cycle 1 – 2: 0 Cycle 3 – 6: 2 From cycle 7: 3	29.0[4]
Daratumumab in combination with carfilzomib and dexamethasone				
Daratumumab	Cycle 1 – 2: Day 1, 8, 15, 22 Cycle 3 – 6: Day 1, 15 From cycle 7:	13.0	Cycle 1 – 2: 4 cycle: 3 – 6: 2 From cycle 7: 1	23.0

[3] On the days of daratumumab administration, 20 mg of the dexamethasone dose is used as premedication.
[4] On the days of daratumumab administration, 20 mg of the dexamethasone dose is used as premedication and 20 mg on the day after daratumumab administration.

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	Day 1 28-day cycle			
Carfilzomib	Day 1, 2, 8, 9, 15, 16 28-day cycle	13.0	6	78.0
Dexamethasone	Day 1, 2, 8, 9, 15, 16, 22: 28-day cycle	13.0	Cycle 1 – 2: 3 cycle: 3 – 6: 5 From cycle 7: 6	68.0[5]
Daratumumab in combination with pomalidomide and dexamethasone (only subjects who are refractory to lenalidomide or have received at least two prior therapies are eligible)				
Daratumumab	Cycle 1 – 2: Day 1, 8, 15, 22 Cycle 3 – 6: Day 1, 15 From cycle 7: Day 1 28-day cycle	23.0	1	23.0
Pomalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	Cycle 1 – 2: 0 Cycle 3 – 6: 2 From cycle 7: 3	29.0[4]
Isatuximab in combination with carfilzomib and dexamethasone				
Isatuximab	1st cycle: Day 1, 8, 15, 22 From 2nd cycle: Day 1, 15 28-day cycle	13.0	1st cycle: 4 From 2nd cycle: 2	28.0
Carfilzomib	Day 1, 2, 8, 9, 15, 16: 28-day cycle	13.0	6	78.0

[5] On the days of daratumumab administration, the treatment dose of dexamethasone is used as premedication.

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Dexamethasone	Day 1, 2, 8, 9, 15, 16, 22 and 23: 28-day cycle	13.0	8	104.0[6]
Isatuximab in combination with pomalidomide and dexamethasone (only subjects who have received at least two prior therapies and have shown disease progression during the last therapy are eligible)				
Isatuximab	1st cycle: Day 1, 8, 15, 22 From 2nd cycle: Day 1, 15 28-day cycle	13.0	1st cycle: 4 From 2nd cycle: 2	28.0
Pomalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	4	52.0[7]
Pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible)				
Pomalidomide	Day 1 – 14: 21-day cycle	17.4	14	243.6
Bortezomib	1st - 8th cycle: Day 1, 4, 8, 11 From 9th cycle: Day 1, 8 21-day cycle	17.4	1st – 8th cycle: 4 From 9th cycle: 2	50.8
Dexamethasone	1st – 8th cycle: Day 1, 2, 4, 5, 8, 9, 11, 12 From 9th cycle: Day 1, 2, 8, 9 21-day cycle	17.4	1st – 8th cycle: 8 From 9th cycle: 4	101.6
Ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible)				
Ixazomib	Day 1, 8, 15 of a 28-day cycle	13.0	3	39.0
Lenalidomide	Day 1 – 21 of a 28-day cycle	13.0	21	273.0

[6] On the days of isatuximab and/or carfilzomib administration, 20 mg of the dexamethasone dose is administered as premedication.
[7] On the days of isatuximab administration, 40 mg of the dexamethasone dose is administered as premedication.

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Dexamethasone	Day 1, 8, 15, 22 of a 28-day cycle	13.0	4	52.0
Carfilzomib in combination with dexamethasone				
Carfilzomib	Day 1, 2, 8, 9, 15, 16: 28-day cycle	13.0	6	78.0
Dexamethasone	Day 1, 2, 8, 9, 15, 16, 22, 23: 28-day cycle	13.0	8	104.0

b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Belantamab mafodotin in combination with bortezomib and dexamethasone				
Belantamab mafodotin	1 x per 21-day cycle	17.4	1	17.4
Bortezomib	Day 1, 4, 8 and 11: 21-day cycle	8	4	32
Dexamethasone	Day 1, 2, 4, 5, 8, 9, 11 and 12 of a 21-day cycle	8	8	64
Appropriate comparator therapy				
An individualised therapy with the selection of				
Carfilzomib in combination with lenalidomide and dexamethasone				
Carfilzomib	1st – 12th cycle: Day 1, 2, 8, 9, 15, 16 From 13th cycle: Day 1, 2, 15, 16 28-day cycle	13.0	1st – 12th cycle: 6 From 13th cycle: 4	76.0
Lenalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22:	13.0	4	52.0

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	28-day cycle			
Elotuzumab in combination with lenalidomide and dexamethasone				
Elotuzumab	1st – 2nd cycle: Day 1, 8, 15, 22 From 3rd cycle: Day 1, 15 28-day cycle	13.0	1st – 2nd cycle 4 From 3rd cycle 2	30.0
Lenalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	4	52.0
Elotuzumab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible)				
Elotuzumab	1st – 2nd cycle: Day 1, 8, 15, 22 From 3rd cycle: Day 1 28-day cycle	13.0	1st – 2nd cycle: 4 From 3rd cycle: 1	19.0
Pomalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	4	52.0
Daratumumab in combination with bortezomib and dexamethasone				
Daratumumab	Cycle 1 – 3: Day 1, 8 and 15 of a 21-day cycle Cycle 4 – 8: Day 1 of a 21-day cycle From 9th cycle: Day 1 of a 28-day cycle	21.0	1	21.0
Bortezomib	Day 1, 4, 8 and 11:	8	4	32

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	21-day cycle			
Dexamethasone	Day 1, 2, 4, 5, 8, 9, 11 and 12 of a 21-day cycle	8	Cycle 1 – 3: 6 Cycle 4 – 8: 7	53[3]
Daratumumab in combination with lenalidomide and dexamethasone				
Daratumumab	Cycle 1 – 2: Day 1, 8, 15, 22 Cycle 3 – 6: Day 1, 15 From cycle 7: Day 1 28-day cycle	23.0	1	23.0
Lenalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	Cycle 1 – 2: 0 Cycle 3 – 6: 2 From cycle 7: 3	29.0[4]
Daratumumab in combination with carfilzomib and dexamethasone				
Daratumumab	Cycle 1 – 2: Day 1, 8, 15, 22 Cycle 3 – 6: Day 1, 15 From cycle 7: Day 1 28-day cycle	13.0	Cycle 1 – 2: 4 cycle: 3 – 6: 2 From cycle 7: 1	23.0
Carfilzomib	Day 1, 2, 8, 9, 15, 16 28-day cycle	13.0	6	78.0
Dexamethasone	Day 1, 2, 8, 9, 15, 16, 22: 28-day cycle	13.0	Cycle 1 – 2: 3 cycle: 3 – 6: 5 From cycle 7: 6	68.0[5]
Daratumumab in combination with pomalidomide and dexamethasone				
Daratumumab	Cycle 1 – 2:	23.0	1	23.0

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	Day 1, 8, 15, 22 Cycle 3 – 6: Day 1, 15 From cycle 7: Day 1 28-day cycle			
Pomalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	Cycle 1 – 2: 0 Cycle 3 – 6: 2 From cycle 7: 3	29.0[4]
Isatuximab in combination with carfilzomib and dexamethasone				
Isatuximab	1st cycle: Day 1, 8, 15, 22 From 2nd cycle: Day 1, 15 28-day cycle	13.0	1st cycle: 4 From 2nd cycle: 2	28.0
Carfilzomib	Day 1, 2, 8, 9, 15, 16: 28-day cycle	13.0	6	78.0
Dexamethasone	Day 1, 2, 8, 9, 15, 16, 22, 23: 28-day cycle	13.0	8	104.0[6]
Isatuximab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible)				
Isatuximab	1st cycle: Day 1, 8, 15, 22 From 2nd cycle: Day 1, 15 28-day cycle	13.0	1st cycle: 4 From 2nd cycle: 2	28.0
Pomalidomide	Day 1 – 21: 28-day cycle	13.0	21	273.0

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Dexamethasone	Day 1, 8, 15, 22: 28-day cycle	13.0	4	52.0
Pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible)				
Pomalidomide	Day 1 – 14: 21-day cycle	17.4	14	243.6
Bortezomib	1st – 8th cycle: Day 1, 4, 8, 11 From 9th cycle: Day 1, 8 21-day cycle	17.4	1st – 8th cycle: 4 From 9th cycle: 2	50.8
Dexamethasone	1st – 8th cycle: Day 1, 2, 4, 5, 8, 9, 11, 12 From 9th cycle: Day 1, 2, 8, 9 21-day cycle	17.4	1st – 8th cycle: 8 From 9th cycle: 4	101.6
Ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible)				
Ixazomib	Day 1, 8, 15 of a 28-day cycle	13.0	3	39.0
Lenalidomide	Day 1 – 21 of a 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22 of a 28-day cycle	13.0	4	52.0
Carfilzomib in combination with dexamethasone				
Carfilzomib	Day 1, 2, 8, 9, 15, 16: 28-day cycle	13.0	6	78.0
Dexamethasone	Day 1, 2, 8, 9, 15, 16, 22, 23: 28-day cycle	13.0	8	104.0
Panobinostat in combination with bortezomib and dexamethasone				
Panobinostat	1st – 16th cycle: Day 1, 3, 5, 8, 10, 12 21-day cycle	8 – 16	6	48 – 96

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Bortezomib	1st – 8th cycle: Day 1, 4, 8, 11 9th – 16th cycle: Day 1, 8 21-day cycle	8 – 16	1st – 8th cycle: 4 9th – 16th cycle: 2	32 – 48
Dexamethasone	1st – 8th cycle: Day 1, 2, 4, 5, 8, 9, 11, 12 9th – 16th cycle: Day 1, 2, 8, 9 21-day cycle	8 – 16	1st – 8th cycle: 8 9th – 16th cycle: 4	64 – 96
Pomalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy and have shown disease progression during the last therapy, are eligible)				
Pomalidomide	Day 1 – 21 of a 28-day cycle	13.0	21	273.0
Dexamethasone	Day 1, 8, 15, 22 of a 28-day cycle	13.0	4	52.0
Lenalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)				
Lenalidomide	Day 1 – 21 of a 28-day cycle	13.0	21	273.0
Dexamethasone	1st – 4th cycle: Day 1 – 4, 9 – 12, 17 – 20 From 5th cycle: Day 1 – 4 28-day cycle	13.0	1st – 4th cycle: 12 From 5th cycle: 4	84.0
Bortezomib in combination with pegylated liposomal doxorubicin (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)				
Bortezomib	Day 1, 4, 8, 11: 21-day cycle	8	4	32

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Doxorubicin (pegylated, liposomal)	Day 4: 21-day cycle	8	1	8
Bortezomib in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)				
Bortezomib	Day 1, 4, 8, 11: 21-day cycle	4 – 8	4	16 – 32
Dexamethasone	Day 1, 2, 4, 5, 8, 9, 11, 12: 21-day cycle	4 – 8	8	32 – 64
Daratumumab monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)				
Daratumumab	Cycle 1 – 2: Day 1, 8, 15, 22 Cycle 3 – 6: Day 1, 15 From cycle 7: Day 1 28-day cycle	23.0	1	23.0
Cyclophosphamide as monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)				
Cyclophosphamide	Continuously, 1 x daily or continuously, 1 x every 21 – 28 days or continuously, every 2 – 5 days	13.0 – 365.0	1	13.0 – 365.0
Cyclophosphamide in combination with dexamethasone (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)				
No specification possible				
Melphalan as monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)				
Melphalan	Continuously, 1 x every 28 days	13.0	1	13.0

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Melphalan in combination with prednisolone or prednisone (only at least triple refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)				
Melphalan	Day 1 of a 28 – 42-day cycle	8.7 – 13.0	1	8.7 – 13.0
Prednisolone	Day 1 – 4 of a 28 – 42-day cycle	8.7 – 13.0	4	34.8 – 52.0
Melphalan	Day 1 of a 28 – 42-day cycle	8.7 – 13.0	1	8.7 – 13.0
Prednisone	Day 1 – 4 of a 28 – 42-day cycle	8.7 – 13.0	4	34.8 – 52.0

Consumption:

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population" were applied (average body height: 1.73 m; average body weight: 78.3 kg). This results in a body surface area of 1.92 m² (calculated according to Du Bois 1916)[8].

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

As it is not always possible to achieve the exact calculated dose per day with the commercially available dosage strengths, in these cases rounding up or down to the next higher or lower available dose that can be achieved with the commercially available dosage strengths as well as the scalability of the respective dosage form.

a) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies

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					

[8] Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Belantamab mafodotin in combination with bortezomib and dexamethasone					
Belantamab mafodotin	1st cycle 2.5 mg/kg = 195.8 mg From cycle 2: 1.9 mg/kg = 148.8 mg – 2.5 mg/kg = 195.8 mg	1st cycle 195.8 mg From cycle 2: 148.8 mg – 195.8 mg	1st cycle: 2 x 100 mg From cycle 2: 1 x 100 mg + 1 x 70 mg – 2 x 100 mg	17.4	18.4 x 100 mg + 16.4 x 70 mg – 34.8 x 100 mg
Bortezomib	1.3 mg/m² = 2.5 mg	2.5 mg	1 x 2.5 mg	32	32 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	64	64 x 20 mg
Appropriate comparator therapy					
An individualised therapy with the selection of					
Carfilzomib in combination with lenalidomide and dexamethasone					
Carfilzomib	1st cycle Day 1, 2 20 mg/m² = 38.4 mg Thereafter 27 mg/m² = 51.8 mg	1st cycle Day 1, 2 38.4 mg Thereafter 51.8 mg	1st cycle Day 1, 2 1 x 10 mg + 1 x 30 mg Thereafter 1 x 60 mg	76.0	2 x 10 mg + 2 x 30 mg + 74 x 60 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	52.0	52 x 40 mg
Elotuzumab in combination with lenalidomide and dexamethasone					
Elotuzumab	10 mg/kg = 783 mg	783 mg	2 x 400 mg	30.0	60 x 400 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	1st – 2nd cycle Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1, 15: 28 mg	1st – 2nd cycle Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1, 15: 28 mg	1 x 8 mg + 1 x 20 mg or 1 x 40 mg	52.0	30 x 8 mg + 30 x 20 mg + 22 x 40 mg

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Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	Day 8, 22: 40 mg	Day 8, 22: 40 mg			
Elotuzumab in combination with pomalidomide and dexamethasone (only subjects who have received at least two prior therapies and have shown disease progression during the last therapy are eligible)					
Elotuzumab	1st – 2nd cycle Day 1, 8, 15, 22: 10 mg/kg = 783 mg From 3rd cycle Day 1: 20 mg/kg = 1,566 mg	1st – 2nd cycle Day 1, 8, 15, 22: 783 mg From 3rd cycle Day 1: 1,566 mg	1st – 2nd cycle Day 1, 8, 15, 22: 2 x 400 mg From 3rd cycle Day 1: 4 x 400 mg	19.0	60 x 400 mg
Pomalidomide	4 mg	4 mg	1 x 4 mg	273.0	273 x 4 mg
Dexamethasone	1st – 2nd cycle Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1: 28 mg Day 8, 15, 22: 40 mg	1st – 2nd cycle Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1 28 mg Day 8, 15, 22: 40 mg	1 x 8 mg + 1 x 20 mg or 1 x 40 mg	52.0	19 x 8 mg + 19 x 20 mg + 33 x 40 mg
Daratumumab in combination with bortezomib and dexamethasone					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	21.0	21 x 1,800 mg
Bortezomib	1.3 mg/m² = 2.5 mg	2.5 mg	1 x 2.5 mg	32	32 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	53	53 x 20 mg
Daratumumab in combination with lenalidomide and dexamethasone					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	23.0	23 x 1,800 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	29.0	29 x 40 mg
Daratumumab in combination with carfilzomib and dexamethasone					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	23.0	23 x 1,800 mg
Carfilzomib	1st cycle Day 1, 2 20 mg/m² = 38.4 mg	1st cycle Day 1, 2 38.4 mg	1st cycle Day 1, 2 1 x 10 mg + 1 x 30 mg	78.0	154 x 10 mg + 78 x 30 mg + 76 x 60 mg

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Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	Thereafter 56 mg/m² = 107.5 mg	Thereafter 107.5 mg	Thereafter 2 x 10 mg + 1 x 30 mg + 1 x 60 mg		
Dexamethasone	Day 1, 2, 8, 9, 15, 16 20 mg Day 22 40 mg	Day 1, 2, 8, 9, 15, 16 20 mg Day 22 40 mg	Day 1, 2, 8, 9, 15, 16 1 x 20 mg Day 22 1 x 40 mg	68.0	57 x 20 mg + 11 x 40 mg
Daratumumab in combination with pomalidomide and dexamethasone (only subjects who are refractory to lenalidomide or have received at least two prior therapies are eligible)					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	23.0	23 x 1,800 mg
Pomalidomide	4 mg	4 mg	1 x 4 mg	273.0	273 x 4 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	29.0	29 x 40 mg
Isatuximab in combination with carfilzomib and dexamethasone					
Isatuximab	1,400 mg	1,400 mg	1 x 1,400 mg	28.0	28 x 1,400 mg
Carfilzomib	1st cycle Day 1, 2 20 mg/m² = 38.4 mg Thereafter 56 mg/m² = 107.5 mg	1st cycle Day 1, 2 38.4 mg Thereafter 107.5 mg	1st cycle Day 1, 2 1 x 10 mg + 1 x 30 mg Thereafter 2 x 10 mg + 1 x 30 mg + 1 x 60 mg	78.0	154 x 10 mg + 78 x 30 mg + 76 x 60 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	104	104 x 20 mg
Isatuximab in combination with pomalidomide and dexamethasone (only subjects who have received at least two prior therapies and have shown disease progression during the last therapy are eligible)					
Isatuximab	1,400 mg	1,400 mg	1 x 1,400 mg	28.0	28 x 1,400 mg
Pomalidomide	4 mg	4 mg	1 x 4 mg	273.0	273 x 4 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	52.0	52 x 40 mg
Pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible)					
Pomalidomide	4 mg	4 mg	1 x 4 mg	243.6	243.6 x 4 mg
Bortezomib	1.3 mg/m² = 2.5 mg	2.5 mg	1 x 2.5 mg	50.8	50.8 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	101.6	101.6 x 20 mg

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Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible)					
Ixazomib	4 mg	4 mg	1 x 4 mg	39.0	39 x 4 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	52.0	52 x 40 mg
Carfilzomib in combination with dexamethasone					
Carfilzomib	1st cycle Day 1, 2 20 mg/m² = 38.4 mg Thereafter 56 mg/m² = 107.5 mg	1st cycle Day 1, 2 38.4 mg Thereafter 107.5 mg	1st cycle Day 1, 2 1 x 10 mg + 1 x 30 mg Thereafter 2 x 10 mg + 1 x 30 mg + 1 x 60 mg	78.0	154 x 10 mg + 78 x 30 mg + 76 x 60 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	104.0	104 x 20 mg

b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies

Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Belantamab mafodotin in combination with bortezomib and dexamethasone					
Belantamab mafodotin	1st cycle 2.5 mg/kg = 195.8 mg From cycle 2: 1.9 mg/kg = 148.8 mg – 2.5 mg/kg = 195.8 mg	1st cycle 195.8 mg From cycle 2: 148.8 mg – 195.8 mg	1st cycle: 2 x 100 mg From cycle 2: 1 x 100 mg + 1 x 70 mg – 2 x 100 mg	17.4	18.4 x 100 mg + 16.4 x 70 mg – 34.8 x 100 mg
Bortezomib	1.3 mg/m² = 2.5 mg	2.5 mg	1 x 2.5 mg	32	32 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	64	64 x 20 mg
Appropriate comparator therapy					
An individualised therapy with the selection of					

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Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Carfilzomib in combination with lenalidomide and dexamethasone					
Carfilzomib	1st cycle Day 1, 2 20 mg/m² = 38.4 mg Thereafter 27 mg/m² = 51.8 mg	1st cycle Day 1, 2 38.4 mg Thereafter 51.8 mg	1st cycle Day 1, 2 1 x 10 mg + 1 x 30 mg Thereafter 1 x 60 mg	76.0	2 x 10 mg + 2 x 30 mg + 74 x 60 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	52.0	52 x 40 mg
Elotuzumab in combination with lenalidomide and dexamethasone					
Elotuzumab	10 mg/kg = 783 mg	783 mg	2 x 400 mg	30.0	60 x 400 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	1st – 2nd cycle Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1, 15: 28 mg Day 8, 22: 40 mg	1st – 2nd cycle Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1, 15: 28 mg Day 8, 22: 40 mg	1 x 8 mg + 1 x 20 mg or 1 x 40 mg	52.0	30 x 8 mg + 30 x 20 mg + 22 x 40 mg
Elotuzumab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible)					
Elotuzumab	1st – 2nd cycle Day 1, 8, 15, 22: 10 mg/kg = 783 mg From 3rd cycle Day 1: 20 mg/kg = 1,566 mg	1st – 2nd cycle Day 1, 8, 15, 22: 783 mg From 3rd cycle Day 1: 1,566 mg	1st – 2nd cycle Day 1, 8, 15, 22: 2 x 400 mg From 3rd cycle Day 1: 4 x 400 mg	19.0	60 x 400 mg
Pomalidomide	4 mg	4 mg	1 x 4 mg	273.0	273 x 4 mg
Dexamethasone	1st – 2nd cycle	1st – 2nd cycle	1 x 8 mg + 1 x 20 mg	52.0	19 x 8 mg + 19 x 20 mg +

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Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1: 28 mg Day 8, 15, 22: 40 mg	Day 1, 8, 15, 22: 28 mg From 3rd cycle Day 1 28 mg Day 8, 15, 22: 40 mg	or 1 x 40 mg		33 x 40 mg
Daratumumab in combination with bortezomib and dexamethasone					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	21.0	21 x 1,800 mg
Bortezomib	1.3 mg/m² = 2.5 mg	2.5 mg	1 x 2.5 mg	32	32 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	53	53 x 20 mg
Daratumumab in combination with lenalidomide and dexamethasone					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	23.0	23 x 1,800 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	29.0	29 x 40 mg
Daratumumab in combination with carfilzomib and dexamethasone					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	23.0	23 x 1,800 mg
Carfilzomib	1st cycle day 1, 2 20 mg/m² = 38.4 mg Thereafter 56 mg/m² = 107.5 mg	1st cycle day 1, 2 38.4 mg Thereafter 107.5 mg	1st cycle day 1, 2 1 x 10 mg + 1 x 30 mg Thereafter 2 x 10 mg + 1 x 30 mg + 1 x 60 mg	78.0	154 x 10 mg + 78 x 30 mg + 76 x 60 mg
Dexamethasone	Day 1, 2, 8, 9, 15, 16 20 mg Day 22 40 mg	Day 1, 2, 8, 9, 15, 16 20 mg Day 22 40 mg	Day 1, 2, 8, 9, 15, 16 1 x 20 mg Day 22 1 x 40 mg	68.0	57 x 20 mg + 11 x 40 mg
Daratumumab in combination with pomalidomide and dexamethasone					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	23.0	23 x 1,800 mg
Pomalidomide	4 mg	4 mg	1 x 4 mg	273.0	273 x 4 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	29.0	29 x 40 mg

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Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Isatuximab in combination with carfilzomib and dexamethasone					
Isatuximab	1,400 mg	1,400 mg	1 x 1,400 mg	28.0	28 x 1,400 mg
Carfilzomib	1st cycle Day 1, 2 20 mg/m² = 38.4 mg Thereafter 56 mg/m² = 107.5 mg	1st cycle Day 1, 2 38.4 mg Thereafter 107.5 mg	1st cycle Day 1, 2 1 x 10 mg + 1 x 30 mg Thereafter 2 x 10 mg + 1 x 30 mg + 1 x 60 mg	78.0	154 x 10 mg + 78 x 30 mg + 76 x 60 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	104	104 x 20 mg
Isatuximab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible)					
Isatuximab	1,400 mg	1,400 mg	1 x 1,400 mg	28.0	28 x 1,400 mg
Pomalidomide	4 mg	4 mg	1 x 4 mg	273.0	273 x 4 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	52.0	52 x 40 mg
Pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible)					
Pomalidomide	4 mg	4 mg	1 x 4 mg	243.6	243.6 x 4 mg
Bortezomib	1.3 mg/m² = 2.5 mg	2.5 mg	1 x 2.5 mg	50.8	50.8 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	101.6	101.6 x 20 mg
Ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible)					
Ixazomib	4 mg	4 mg	1 x 4 mg	39.0	39 x 4 mg
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	52.0	52 x 40 mg
Carfilzomib in combination with dexamethasone					
Carfilzomib	1st cycle Day 1, 2 20 mg/m² = 38.4 mg Thereafter 56 mg/m² = 107.5 mg	1st cycle Day 1, 2 38.4 mg Thereafter 107.5 mg	1st cycle Day 1, 2 1 x 10 mg + 1 x 30 mg Thereafter 2 x 10 mg + 1 x 30 mg + 1 x 60 mg	78.0	154 x 10 mg + 78 x 30 mg + 76 x 60 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	104.0	104 x 20 mg

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Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Panobinostat in combination with bortezomib and dexamethasone					
Panobinostat	20 mg	20 mg	1 x 20 mg	48 – 96	48 x 20 mg – 96 x 20 mg
Bortezomib	1.3 mg/m^2 = 2.5 mg	2.5 mg	1 x 2.5 mg	32 – 48	32 x 2.5 mg – 48 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	64 – 96	64 x 20 mg – 96 x 20 mg
Pomalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy and have shown disease progression during the last therapy, are eligible)					
Pomalidomide	4 mg	4 mg	1 x 4 mg	273.0	273 x 4 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	52.0	52 x 40 mg
Lenalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)					
Lenalidomide	25 mg	25 mg	1 x 25 mg	273.0	273 x 25 mg
Dexamethasone	40 mg	40 mg	1 x 40 mg	84.0	84 x 40 mg
Bortezomib in combination with pegylated liposomal doxorubicin (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)					
Bortezomib	1.3 mg/m^2 = 2.5 mg	2.5 mg	1 x 2.5 mg	32	32 x 2.5 mg
Doxorubicin (pegylated, liposomal)	30 mg/m^2 = 57.6 mg	57.6 mg	1 x 20 mg + 1 x 50 mg	8	8 x 20 mg + 8 x 50 mg
Bortezomib in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)					
Bortezomib	1.3 mg/m^2 = 2.5 mg	2.5 mg	1 x 2.5 mg	16 – 32	16 x 2.5 mg – 32 x 2.5 mg
Dexamethasone	20 mg	20 mg	1 x 20 mg	32 – 64	32 x 20 mg – 64 x 20 mg
Daratumumab monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
Daratumumab	1,800 mg	1,800 mg	1 x 1,800 mg	23.0	23 x 1,800 mg
Cyclophosphamide as monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
Cyclophosphamide	120 mg/m^2 = 240 mg/m^2 = 230.4 mg – 460.8 mg	230.4 mg – 460.8 mg	1 x 500 mg	365.0	365 x 500 mg

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Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	400 mg/m² – 600 mg/m² = 768 mg – 1,152 mg	768 mg – 1,152 mg	1 x 1,000 mg – 1 x 1,000 mg + 1 x 200 mg	73.0 – 182.5	73 x 1,000 mg – 182.5 x 1,000 mg + 182.5 x 200 mg
	800 mg/m² – 1,600 mg/m² = 1,536 mg – 3,072 mg	1,536 mg – 3,072 mg	1 x 1,000 mg + 3 x 200 mg – 3 x 1,000 mg + 1 x 200 mg	13.0 – 17.4	13 x 1,000 mg + 39 x 200 mg – 52.2 x 1,000 mg + 17.4 x 200 mg
Cyclophosphamide in combination with dexamethasone (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
No specification possible					
Melphalan as monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
Melphalan	0.4 mg/kg = 31.3 mg	31.3 mg	1 x 50 mg	13.0	13 x 50 mg
Melphalan in combination with prednisolone or prednisone (only at least triple refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
Melphalan	15 mg/m² = 28.8 mg	28.8 mg	1 x 50 mg	8.7 – 13.0	8.7 x 50 mg – 13 x 50 mg
Prednisone	2 mg/kg = 156.6 mg	156.6 mg	3 x 50 mg + 1 x 5 mg	34.8 – 52.0	104.4 x 50 mg + 34.8 x 5 mg – 156 x 50 mg + 52 x 5 mg
Prednisolone	2 mg/kg = 156.6 mg	156.6 mg	3 x 50 mg + 1 x 5 mg	34.8 – 52.0	104.4 x 50 mg + 34.8 x 5 mg – 156 x 50 mg + 52 x 5 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

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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.

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					
Belantamab mafodotin 70 mg	1 PCI	€ 5,055.36	€ 1.77	€ 285.38	€ 4,768.21
Belantamab mafodotin 100 mg	1 PCI	€ 7,196.91	€ 1.77	€ 407.68	€ 6,787.46
Bortezomib 2.5 mg	1 PSI	€ 186.14	€ 1.77	€ 8.26	€ 176.11
Dexamethasone 20 mg[9]	50 TAB	€ 119.65	€ 1.77	€ 0.00	€ 117.88
Dexamethasone 20 mg[9]	20 TAB	€ 54.86	€ 1.77	€ 0.00	€ 53.09
Appropriate comparator therapy					
Bortezomib 2.5 mg	1 PSI	€ 186.14	€ 1.77	€ 8.26	€ 176.11
Carfilzomib 10 mg	1 PIF	€ 197.80	€ 1.77	€ 10.28	€ 185.75
Carfilzomib 30 mg	1 PIF	€ 569.20	€ 1.77	€ 30.84	€ 536.59
Carfilzomib 60 mg	1 PIF	€ 1,126.31	€ 1.77	€ 61.69	€ 1,062.85
Cyclophosphamide 200 mg	10 PSI	€ 72.92	€ 1.77	€ 3.37	€ 67.78
Cyclophosphamide 500 mg	6 PSI	€ 88.39	€ 1.77	€ 9.66	€ 76.96
Cyclophosphamide 1,000 mg	6 PSI	€ 149.29	€ 1.77	€ 7.60	€ 139.92
Daratumumab 1,800 mg	1 SFI	€ 5,571.63	€ 1.77	€ 0.00	€ 5,569.86
Dexamethasone 8 mg[9]	100 TAB	€ 124.19	€ 1.77	€ 8.87	€ 113.55
Dexamethasone 20 mg[9]	10 TAB	€ 33.19	€ 1.77	€ 0.00	€ 31.42
Dexamethasone 20 mg[9]	20 TAB	€ 54.86	€ 1.77	€ 0.00	€ 53.09
Dexamethasone 20 mg[9]	50 TAB	€ 119.65	€ 1.77	€ 0.00	€ 117.88
Dexamethasone 40 mg[9]	50 TAB	€ 188.81	€ 1.77	€ 0.00	€ 187.04
Doxorubicin PEG-liposomal 20 mg	1 CIS	€ 722.26	€ 1.77	€ 89.87	€ 630.62
Doxorubicin PEG-liposomal 50 mg	1 CIS	€ 1,779.67	€ 1.77	€ 224.69	€ 1,553.21
Elotuzumab 400 mg	1 PIC	€ 1,558.69	€ 1.77	€ 85.68	€ 1,471.24
Isatuximab 1,400 mg	1 SFI	€ 2,560.71	€ 1.77	€ 142.91	€ 2,416.03
Ixazomib 4 mg	3 HC	€ 6,432.07	€ 1.77	€ 364.00	€ 6,066.30
Lenalidomide 25 mg[9]	63 HC	€ 118.10	€ 1.77	€ 8.38	€ 107.95
Melphalan 50 mg	1 DSS	€ 51.27	€ 1.77	€ 2.17	€ 47.33
Panobinostat 20 mg	6 HC	€ 4,657.18	€ 1.77	€ 0.00	€ 4,655.41
Pomalidomide 4 mg	21 HC	€ 2,001.16	€ 1.77	€ 95.10	€ 1,904.29
Prednisolone 5 mg[9]	100 TAB	€ 16.21	€ 1.77	€ 0.33	€ 14.11

[9] Fixed reimbursement rate

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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
Prednisolone 50 mg[9]	50 TAB	€ 32.21	€ 1.77	€ 1.59	€ 28.85
Prednisone 5 mg[9]	100 TAB	€ 17.52	€ 1.77	€ 0.43	€ 15.32
Prednisone 50 mg[9]	50 TAB	€ 68.83	€ 1.77	€ 4.49	€ 62.57
Abbreviations: HC = hard capsules; CIS = concentrate for the preparation of an infusion solution; SFI = solution for injection; PSI = powder for solution for injection; PIF = powder for the preparation of an infusion solution; PCI = powder for the preparation of an infusion solution concentrate; TAB = tablets; DSS = dry substance with solvent					

LAUER-TAXE® last revised: 15 July 2026

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.

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).

Patients receiving therapy with daratumumab, lenalidomide and pomalidomide should be tested for the presence of HBV infection before initiating the respective treatment.

Diagnostics to rule out chronic hepatitis B requires sensibly coordinated steps[10]. 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.

Overall, the diagnosis of suspected chronic hepatitis B necessitates additionally required SHI services which usually differ between the medicinal product to be assessed and the appropriate comparator therapy, and are consequently considered as additionally required SHI services in the resolution.

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

[10] 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

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exception list) are not subject to the current medicinal products price regulation. Instead, in accordance with Section 129, paragraph 5aSGB 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.

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 year	Costs/ patient/ year
Appropriate comparator therapy							
Daratumumab in combination with lenalidomide and dexamethasone							
Premedication							
Dexamethasone 40 mg, PO[9]	50 TAB x 40 mg	€ 188.03	€ 1.77	€ 0.00	€ 186.26	23.0	€ 85.68
Paracetamol 500 - 1,000 mg, PO[11, 11]	20 TAB x 500 mg 10 TAB x 1,000 mg	€ 3.47 € 3.32	€ 0.17 € 0.17	€ 0.15 € 0.14	€ 3.15 € 3.01	23.0	€ 3.62 – € 6.92
Dimetindene 1 mg/ 10 kg = 7.8 mg, IV	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	23.0	€ 161.46
Daratumumab in combination with bortezomib and dexamethasone							
Premedication							
Dexamethasone 20 mg, PO[9]	50 TAB x 20 mg	€ 118.88	€ 1.77	€ 0.00	€ 117.11	21.0	€ 49.19
Paracetamol 500 - 1,000 mg, [9, 11] PO	20 TAB x 500 mg 10 TAB x 1,000 mg	€ 3.47 € 3.32	€ 0.17 € 0.17	€ 0.15 € 0.14	€ 3.15 € 3.01	21.0	€ 3.31 – € 6.32
Dimetindene 1 mg/ 10 kg = 7.8 mg, IV	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	21.0	€ 147.42
Daratumumab in combination with pomalidomide and dexamethasone							
Premedication							
Dexamethasone 40 mg, PO	50 TAB x 40 mg	€ 188.03	€ 1.77	€ 0.00	€ 186.26	23.0	€ 85.68

[11] 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.

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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 year	Costs/ patient/ year
Paracetamol 500 - 1,000 mg, PO[11, 11]	20 TAB x 500 mg 10 TAB x 1,000 mg	€ 3.47 € 3.32	€ 0.17 € 0.17	€ 0.15 € 0.14	€ 3.15 € 3.01	23.0	€ 3.62 – € 6.92
Dimetindene 1 mg/ 10 kg = 7.8 mg, IV	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	23.0	€ 161.46
Daratumumab in combination with carfilzomib and dexamethasone							
Dexamethasone 20 mg, PO[9]	50 TAB x 20 mg	€ 118.88	€ 1.77	€ 0.00	€ 117.11	21.0	€ 49.19
Dexamethasone 40 mg, PO[9]	50 TAB x 40 mg	€ 188.03	€ 1.77	€ 0.00	€ 186.26	2.0	€ 7.45
Paracetamol 500 - 1,000 mg, PO[11, 11]	20 TAB x 500 mg 10 TAB x 1,000 mg	€ 3.47 € 3.32	€ 0.17 € 0.17	€ 0.15 € 0.14	€ 3.15 € 3.01	23.0	€ 3.62 – € 6.92
Dimetindene 1 mg/ 10 kg = 7.8 mg, IV	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	23.0	€ 161.46
Daratumumab monotherapy							
Premedication							
Methyl prednisolone 60 mg - 100 mg, IV	3 PII x 32 mg	€ 26.48	€ 1.77	€ 6.88	€ 17.83	23.0	€ 273.39 – € 546.79
Postmedication							
Methyl prednisolone 20 mg, PO[9]	100 TAB x 4 mg 100 TAB x 16 mg	€ 29.35 € 73.84	€ 1.77 € 1.77	€ 1.43 € 4.95	€ 26.15 € 67.12	46.0	€ 42.91
Elotuzumab in combination with pomalidomide and dexamethasone							
Premedication in combination with pomalidomide and dexamethasone							
Dexamethasone 8 mg, IV[9]	10 SFI x 8 mg	€ 20.38	€ 1.77	€ 0.72	€ 17.89	19.0	€ 33.99
Dimetindene 1 mg/ 10 kg BW, IV	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	19.0	€ 133.38
Famotidine 20 mg, PO[9]	100 FCT x 20 mg	€ 20.18	€ 1.77	€ 0.70	€ 17.71	19.0	€ 3.36
Paracetamol 500 – 1,000 mg,	20 TAB x 500 mg	€ 3.47	€ 0.17	€ 0.15	€ 3.15	19.0	€ 2.99 –

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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 year	Costs/ patient/ year
PO[11, 11]	10 TAB x 1,000 mg	€ 3.32	€ 0.17	€ 0.14	€ 3.01		€ 5.72
Elotuzumab in combination with lenalidomide and dexamethasone							
Premedication in combination with lenalidomide and dexamethasone							
Dexamethasone 8 mg, IV[9]	10 SFI x 8 mg	€ 20.38	€ 1.77	€ 0.72	€ 17.89	30.0	€ 53.67
Dimetindene 1 mg/ 10 kg = 7.8 mg, IV	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	30.0	€ 210.60
Famotidine 20 mg, PO[9]	100 TAB x 20 mg	€ 20.18	€ 1.77	€ 0.70	€ 17.71	30.0	€ 5.31
Paracetamol 500 – 1,000 mg, PO[11, 11]	20 TAB x 500 mg 10 TAB x 1,000 mg	€ 3.47 € 3.32	€ 0.17 € 0.17	€ 0.15 € 0.14	€ 3.15 € 3.01	30.0	€ 4.73 - € 9.03
Daratumumab, **pomalidomide**, **lenalidomide**							
HBV screening							
HBV test Hepatitis B surface antigen status (FSI 32781)	-	-	-	-	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (FSI 32614)	-	-	-	-	€ 5.43	1.0	€ 5.43
Abbreviations: FCT = film-coated tablets; SFI = solution for injection; PII = powder and solvent for solution for injection or infusion; 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 01.10.2009 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-apply 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

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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.

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

The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 26 November 2024.

A review of the appropriate comparator therapy took place. The Subcommittee on Medicinal Products newly determined the appropriate comparator therapy at their session on 9 September 2025.

On 31 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of belantamab mafodotin to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 1 April 2026 in conjunction with the resolution of the GBA 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 GBA commissioned the IQWiG to assess the dossier concerning the active ingredient belantamab mafodotin.

The dossier assessment by the IQWiG was submitted to the GBA on 29 June 2026, and the written statement procedure was initiated with publication on the GBA website on 1 July 2026. The deadline for submitting written statements was 22 July 2026.

The oral hearing was held on 10 August 2026.

By letter of 11 August 2026, the IQWiG was commissioned with a supplementary assessment of data submitted in the written statement procedure. The addendum prepared by the IQWiG was submitted to the GBA on 11 September 2026.

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 were discussed at the Subcommittee's session on 22 September 2026, and deliberation of the draft resolution was concluded.

At their session on 1 October 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

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Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	26 November 2024	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	9 September 2025	New determination of the appropriate comparator therapy
Working group Section 35a	4 August 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	10 August 2026	Conduct of the oral hearing, commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	18 August 2026 15 September 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	22 September 2026	Concluding discussion of the draft resolution
Plenum	1 October 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 1 October 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk

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