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 pomalidomide and dexamethasone)

of 1 October 2026

Contents

1. Legal basis 2

2. Key points of the resolution 2

2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy 3

2.1.1 Approved therapeutic indication of Belantamab mafodotin (Blenrep) in accordance with the product information 3

2.1.2 Appropriate comparator therapy 3

2.1.3 Extent and probability of the additional benefit 11

2.1.4 Summary of the assessment 13

2.2 Number of patients or demarcation of patient groups eligible for treatment 14

2.3 Requirements for a quality-assured application 14

2.4 Treatment costs 15

3. Bureaucratic costs calculation 42

4. Process sequence 42

Courtesy translation – only the German version is legally binding.

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, and

Courtesy translation – only the German version is legally binding.

the statements submitted in the written statement and oral hearing procedure. 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 pomalidomide and dexamethasone in patients who have received at least one prior therapy including lenalidomide.

Therapeutic indication of the resolution (resolution of 01.10.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

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

Appropriate comparator therapy for belantamab mafodotin in combination with pomalidomide 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.

Courtesy translation – only the German version is legally binding.

- 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; pretreatment includes lenalidomide</u>

Appropriate comparator therapy for belantamab mafodotin in combination with pomalidomide 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),

Courtesy translation – only the German version is legally binding.

- 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

Courtesy translation – only the German version is legally binding.

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".

Courtesy translation – only the German version is legally binding.

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) Adults with relapsed or refractory multiple myeloma who have received one to three prior therapies; pretreatment includes lenalidomide

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

Courtesy translation – only the German version is legally binding.

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 dor 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 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 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; pretreatment includes lenalidomide</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

Courtesy translation – only the German version is legally binding.

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 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 combinations of active ingredients

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

Courtesy translation – only the German version is legally binding.

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

Courtesy translation – only the German version is legally binding.

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; pretreatment includes lenalidomide

An additional benefit is not proven.

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

An additional benefit is not proven.

Justification:

The pharmaceutical company did not identify any studies for direct comparison with the appropriate comparator therapy to demonstrate the additional benefit of belantamab mafodotin in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least one prior therapy, including lenalidomide. In the dossier, the pharmaceutical company additionally presented the results of the pivotal DREAMM-8 study, but do not use these to derive an additional benefit.

DREAMM-8 study

The DREAMM-8 study is an ongoing, open-label, multicentre phase III study comparing belantamab mafodotin in combination with pomalidomide and dexamethasone (BPd) against pomalidomide in combination with bortezomib and dexamethasone (PVd). The study has been ongoing since October 2020 in Asia, Australia, Europe, as well as North and South America. A total of 302 adults with relapsed or refractory multiple myeloma who had already received at least one prior therapy, including lenalidomide, were enrolled in the study. The patients were randomised in a 1:1 ratio to the two study arms (BPd: N = 155; PVd: N = 147). In the dossier, the pharmaceutical company presented the analyses of the total study population, as well as the sub-population refractory to an anti-CD38 antibody and lenalidomide (refractory sub-population, BPd: N = 30; PVd: N = 33) as of the data cut-off from 7 July 2025. The pharmaceutical company did not categorise patients according to the patient

Courtesy translation – only the German version is legally binding.

groups of the appropriate comparator therapy (1 to 3 or ≥ 4 prior therapies). In this regard, only the relevant subgroup analyses are available.

Japanese population of the DREAMM-8 study

The Japanese population of the DREAMM-8 study is based on the study protocol of the global DREAMM-8 study. The pharmaceutical company did not process the data from the study.

On the implementation of the appropriate comparator therapy and the suitability of the refractory sub-population of the DREAMM-8 study

For this therapeutic indication, the GBA determined an individualised therapy for these patient groups. In the DREAMM-8 study, only the combination therapy PVd 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.

Within the context of individualised therapy determined as the appropriate comparator therapy, PVd may be a suitable therapy option only for patients who are refractory to an anti-CD38 antibody and lenalidomide. According to the information provided by the pharmaceutical company, only 21% of the enrolled patients were refractory to an anti-CD38 antibody and lenalidomide.

Consequently, treatment with PVd is not a suitable therapy option for the majority of patients enrolled in the DREAMM-8 study.

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.

Although subgroup results are available for the patient groups defined according to the appropriate comparator therapy (1 to 3 or ≥ 4 prior therapies), there is lack of information on patient characteristics and the type and duration of prior therapies.

To draw reliable conclusions for the benefit assessment, the pharmaceutical company stated in the written statement procedure that further division of the refractory sub-population according to patient groups is inappropriate, given the resulting small sample sizes for the individual groups. This approach is inappropriate.

Furthermore, based on the available information, it is not possible to assess adequately the extent to which PVd constitutes a suitable individualised therapy for the refractory sub-population.

Conclusion:

In the DREAMM-8 study, only the combination therapy PVd was used in the comparator arm. For the majority of the patients enrolled, PVd is not the appropriate comparator therapy, as PVd has been determined as a suitable comparator therapy only for patients who are refractory to an anti-CD38 antibody and lenalidomide within the context of individualised therapy. For the patient groups (1 to 3 or ≥ 4 prior therapies), subgroup results are only available for the refractory sub-population. However, information on patient characteristics or on the type and duration of prior therapies is missing.

Consequently, based on the available information, it is not possible to assess adequately the extent to which PVd constitutes a suitable individualised therapy for the refractory sub-population.

Courtesy translation – only the German version is legally binding.

Therefore, the data presented from the DREAMM-8 study do not allow a comparison with the appropriate comparator therapy. Accordingly, the pharmaceutical company did not use the results of the DREAMM-8 study to derive an additional benefit.

Consequently, no suitable data that would allow an assessment of the additional benefit are available for both patient groups. An additional benefit of belantamab mafodotin in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least one prior therapy, including lenalidomide is therefore not proven.

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 pomalidomide and dexamethasone in patients who have received at least one prior therapy including lenalidomide."

In the therapeutic indication to be considered, two patient groups were distinguished by the number of prior therapies.

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

The GBA determined the appropriate comparator therapy to be an individualised therapy with the selection of several therapy options, including pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible), 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; pretreatment includes lenalidomide

The GBA determined the appropriate comparator therapy to be an individualised therapy with the selection of several therapy options, including pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible), 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):

For the benefit assessment of belantamab mafodotin in combination with pomalidomide and dexamethasone, the pharmaceutical company additionally presented the results of the pivotal DREAMM-8 study, but did not use them to derive an additional benefit. The DREAMM-8 study compared belantamab mafodotin in combination with pomalidomide and dexamethasone (BPd) against pomalidomide in combination with bortezomib and dexamethasone (PVd).

For the majority of the patients enrolled, PVd is not the appropriate comparator therapy, as PVd has been determined as a suitable comparator therapy only for patients who are refractory to an anti-CD38 antibody and lenalidomide within the context of individualised

Courtesy translation – only the German version is legally binding.

therapy. For the patient groups (1 to 3 or ≥ 4 prior therapies), subgroup results are only available for the refractory sub-population. There is no information on patient characteristics or the type and duration of prior therapies. Consequently, based on the available information, it is not possible to assess adequately the extent to which PVd constitutes a suitable individualised therapy for the refractory sub-population.

Therefore, the data presented from the DREAMM-8 study do not allow a comparison with the appropriate comparator therapy. Accordingly, the pharmaceutical company did not use the results of the DREAMM-8 study to derive an additional benefit.

Consequently, no suitable data that would allow an assessment of the additional benefit are available for both patient groups. An additional benefit of belantamab mafodotin in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma who have received at least one prior therapy, including lenalidomide is therefore not proven.

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 information provided by the pharmaceutical company on the number of patients in the SHI target population in the present procedure tend to be underestimated. The pharmaceutical company used the number of patients specified in the resolution on the benefit assessment of pomalidomide (GBA's resolution of 5 December 2019) as the basis for their calculations and forecast a lower number of patients for 2026. Even the patient numbers cited in the resolution on the benefit assessment of pomalidomide were considered to be underestimated. They therefore represent a more appropriate estimate than an even lower estimate and form the basis of the resolution (approximately 3,060 to 3,450 patients).

The patient numbers cited in the resolution on the benefit assessment of pomalidomide are not distinguished according to the number of prior therapies (one to three versus 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).

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):

Courtesy translation – only the German version is legally binding.

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.

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.

Courtesy translation – only the German version is legally binding.

Treatment period:

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

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 pomalidomide and dexamethasone				
Belantamab mafodotin	1st cycle: 1 x every 28 days From cycle 2: 1 x every 28 days or 1 x every 56 days	7.0 – 13.0	1	7.0 – 13.0
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
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

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
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				
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	23.0	1	23.0

[3] On the days of daratumumab administration, 20 mg of the dexamethasone dose is used as premedication.

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			
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 (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:	13.0	Cycle 1 – 2:	29.0[3]

[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.

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

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		0 Cycle 3 – 6: 2 From cycle 7: 3	
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 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	17.4	1st – 8th cycle: 4	50.8

[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.

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
	From 9th cycle: Day 1, 8 21-day cycle		From 9th cycle: 2	
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

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

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 pomalidomide and dexamethasone				
Belantamab mafodotin	1st cycle: 1 x every 28 days From cycle 2: 1 x every 28 days or	7.0 – 13.0	1	7.0 – 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
	1 x every 56 days			
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
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 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

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
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: 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]

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
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: 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	13.0	1st cycle: 4 From 2nd cycle: 2	28.0

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
	From 2nd cycle: Day 1, 15 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, 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
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

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
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
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	13.0	21	273.0

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			
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
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

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
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
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

Courtesy translation – only the German version is legally binding.

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; pretreatment includes lenalidomide

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					
Belantamab mafodotin in combination with pomalidomide and dexamethasone					
Belantamab mafodotin	1st cycle 2.5 mg/kg = 195.8 mg From cycle 2: 1.4 mg/kg = 109.6 mg – 1.9 mg/kg = 148.8 mg	1st cycle 195.8 mg From cycle 2: 109.6 mg – 148.8 mg	1st cycle: 2 x 100 mg From cycle 2: 2 x 70 mg – 1 x 100 mg + 1 x 70 mg	7.0 – 13.0	2 x 100 mg + 12 x 70 mg – 14 x 100 mg + 12 x 70 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
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

[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
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 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					

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
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 (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 +	78.0	154 x 10 mg + 78 x 30 mg + 76 x 60 mg

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
			1 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
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

Courtesy translation – only the German version is legally binding.

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

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 pomalidomide and dexamethasone					
Belantamab mafodotin	1st cycle 2.5 mg/kg = 195.8 mg From cycle 2: 1.4 mg/kg = 109.6 mg – 1.9 mg/kg = 148.8 mg	1st cycle 195.8 mg From cycle 2: 109.6 mg – 148.8 mg	1st cycle: 2 x 100 mg From cycle 2: 2 x 70 mg – 1 x 100 mg + 1 x 70 mg	7.0 – 13.0	2 x 100 mg + 12 x 70 mg – 14 x 100 mg + 12 x 70 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
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	1st – 2nd cycle Day 1, 8, 15, 22: 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

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	From 3rd cycle Day 1, 15: 28 mg Day 8, 22: 40 mg	From 3rd cycle Day 1, 15: 28 mg Day 8, 22: 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 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/m^2 = 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

Courtesy translation – only the German version is legally binding.

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	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
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

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
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
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/m² = 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/m² = 2.5 mg	2.5 mg	1 x 2.5 mg	32	32 x 2.5 mg

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Doxorubicin (pegylated, liposomal)	30 mg/m² = 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/m² = 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/m² = 240 mg/m² = 230.4 mg – 460.8 mg	230.4 mg – 460.8 mg	1 x 500 mg	365.0	365 x 500 mg
	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)					

Courtesy translation – only the German version is legally binding.

Designation of the therapy	Dosage/ application	Costs/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
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 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
Pomalidomide 4 mg	21 HC	€ 2,001.16	€ 1.77	€ 95.10	€ 1,904.29
Dexamethasone 40 mg[9]	50 TAB	€ 188.81	€ 1.77	€ 0.00	€ 187.04
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

[9] Fixed reimbursement rate

Courtesy translation – only the German version is legally binding.

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
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
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

Courtesy translation – only the German version is legally binding.

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 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
Medicinal product to be assessed							
Belantamab mafodotin in combination with **pomalidomide** and dexamethasone							
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
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**Fehler! Textmarke nicht definiert.**, [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

[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

Courtesy translation – only the German version is legally binding.

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
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, **Fehler! Textmarke nicht definiert.**, [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
Paracetamol 500 - 1,000 mg, PO**Fehler! Textmarke nicht definiert.**, [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**Fehler! Textmarke nicht definiert.**	50 TAB x 20 mg	€ 118.88	€ 1.77	€ 0.00	€ 117.11	21.0	€ 49.19
Dexamethasone 40 mg, PO**Fehler! Textmarke nicht definiert.**	50 TAB x 40 mg	€ 188.03	€ 1.77	€ 0.00	€ 186.26	2.0	€ 7.45
Paracetamol 500 - 1,000 mg, PO**Fehler! Textmarke nicht definiert.**, [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

Courtesy translation – only the German version is legally binding.

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
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**Fehler! Textmarke nicht definiert.**	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**Fehler! Textmarke nicht definiert.**	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**Fehler! Textmarke nicht definiert.**[, 11]	100 FCT x 20 mg	€ 20.18	€ 1.77	€ 0.70	€ 17.71	19.0	€ 3.36
Paracetamol 500 – 1,000 mg, PO**Fehler! Textmarke nicht definiert.**[, 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	19.0	€ 2.99 – € 5.72
Elotuzumab in combination with lenalidomide and dexamethasone							
Premedication in combination with lenalidomide and dexamethasone							
Dexamethasone 8 mg, IV**Fehler! Textmarke nicht definiert.**	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**Fehler! Textmarke nicht definiert.**	100 TAB x 20 mg	€ 20.18	€ 1.77	€ 0.70	€ 17.71	30.0	€ 5.31

Courtesy translation – only the German version is legally binding.

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**Fehler! Textmarke nicht definiert.**[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 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.

Courtesy translation – only the German version is legally binding.

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 once the positive opinion was granted. 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 31 March 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.

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.

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

Courtesy translation – only the German version is legally binding.

Working group Section 35a	18.08.2026; 15.09.2026	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

Courtesy translation – only the German version is legally binding.