GBA
Gemeinsamer
Bundesausschuss

Resolution

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

of 1 October 2026

At their session on 1 October 2026, the Federal Joint Committee (GBA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, information on the active ingredient Belantamab mafodotin shall be added in alphabetical order as follows:

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Belantamab mafodotin

Resolution of: 1 October 2026
Entry into force on: 1 October 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 23 July 2025):

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

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

See therapeutic indication according to marketing authorisation.

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

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

Appropriate comparator therapy:

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),
- 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

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- carfilzomib in combination with dexamethasone

Extent and probability of the additional benefit of belantamab mafodotin in combination with bortezomib and dexamethasone compared with the appropriate comparator therapy:

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

An additional benefit is not proven.

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

An additional benefit is not proven.

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

Appropriate comparator therapy:

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),

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- 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),
- 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).

Extent and probability of the additional benefit of belantamab mafodotin in combination with bortezomib and dexamethasone compared with the appropriate comparator therapy:

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

Hint for a non-quantifiable additional benefit.

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

An additional benefit is not proven.

Study results according to endpoints:[1]

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

[1] Data from the dossier assessment of the IQWiG (A26-28) and from the addendum (A26-102), unless otherwise indicated.

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Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑	Advantage in overall survival.
Morbidity	↔	No relevant difference for the benefit assessment.
Health-related quality of life	↔	No relevant differences for the benefit assessment overall. Disadvantage in cognitive functioning.
Side effects	↓	Disadvantages for SAEs, severe AEs and therapy discontinuation due to AEs and in cases of eye disorders (Ocular Surface Disease Index [OSDI]).
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

DREAMM-7 study:

- Study design: open-label, randomised phase III study, data cut-off from 09.01.2026
- Comparison: belantamab mafodotin + bortezomib + dexamethasone (BVd) **vs** daratumumab + bortezomib + dexamethasone (DVd)
- Relevant sub-population: adults who have received **one to three prior therapies**

Mortality

Endpoint	Belantamab mafodotin + bortezomib + dexamethasone (BVd)		Daratumumab + bortezomib + dexamethasone (DVd)		BVd vs DVd
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
Overall survival					
	213	n.r. [63.0; n.c.] 73 (34)	224	n.r. [47.4; n.c.] 96 (43)	0.71 [0.52; 0.96] 0.025

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Morbidity

Endpoint	Belantamab mafodotin + bortezomib + dexamethasone (BVd)		Daratumumab + bortezomib + dexamethasone (DVd)		BVd vs DVd
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
Progression-free survival[d]					
	213	36.6 [30.5; n.c.] 76 (36)	224	14.5 [11.9; 19.1] 138 (62)	0.44 [0.33; 0.58] < 0.001 AD = + 22.1 months
Symptomatology					
EORTC QLQ-C30 – Time to 1st deterioration[e]					
Fatigue	213	1.4 [1.4; 2.1] 172 (81)	224	1.4 [1.4; 2.1] 161 (72)	1.06 [0.86; 1.32] 0.568
Nausea and vomiting	213	6.2 [4.9; 10.3] 135 (63)	224	8.3 [5.7; 16.6] 112 (50)	1.21 [0.94; 1.56] 0.127
Pain	213	4.2 [3.5; 5.1] 144 (68)	224	3.5 [2.8; 4.2] 137 (61)	0.93 [0.73; 1.17] 0.532
Dyspnoea	213	7.0 [3.5; 9.7] 128 (60)	224	4.1 [2.8; 6.9] 127 (57)	0.90 [0.70; 1.15] 0.396
Insomnia	213	4.2 [2.8; 5.6] 134 (63)	224	3.0 [2.1; 4.9] 128 (57)	0.94 [0.74; 1.20] 0.658
Appetite loss	213	5.3 [4.2; 6.3] 143 (67)	224	6.5 [4.9; 8.5] 125 (56)	1.16 [0.92; 1.48] 0.220
Constipation	213	3.5 [2.6; 8.3] 129 (61)	224	3.5 [2.1; 4.9] 137 (61)	0.82 [0.64; 1.04] 0.099
Diarrhoea	213	6.1 [4.9; 7.0] 136 (64)	224	5.6 [4.9; 6.6] 123 (55)	1.02 [0.80; 1.30] 0.886
PGIC – Time to 1st deterioration[f]					
	213	n.r. [56.9; n.c.] 69 (32)	224	n.r. [48.4; n.c.] 73 (33)	0.92 [0.66; 1.29] 0.643
PGIS – Time to 1st deterioration[g]					
	213	6.9 [5.6; 34.5] 104 (49)	224	8.7 [4.7; 51.1] 100 (45)	0.96 [0.73; 1.26] 0.766

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Health status					
EQ-5D VAS – Time to 1st deterioration[h]					
	213	8.4 [5.6; 31.8] 112 (53)	224	13.7 [6.9; 46.5] 99 (44)	1.11 [0.84; 1.45] 0.479

Health-related quality of life

Endpoint	**Belantamab mafodotin + bortezomib + dexamethasone (BVd)**		**Daratumumab + bortezomib + dexamethasone (DVd)**		**BVd vs DVd**
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
EORTC QLQ-C30 – Time to 1st deterioration[i]					
Global health status	213	2.1 [1.7; 2.8] 158 (74)	224	2.8 [2.1; 3.5] 141 (63)	1.16 [0.92; 1.45] 0.206
Physical functioning	213	4.2 [3.1; 7.6] 131 (62)	224	4.5 [3.4; 5.8] 130 (58)	1.01 [0.79; 1.28] 0.980
Role functioning	213	2.2 [2.1; 2.8] 159 (75)	224	2.8 [2.1; 3.5] 146 (65)	1.11 [0.88; 1.39] 0.394
Emotional functioning	213	9.7 [4.9; 22.2] 113 (53)	224	9.7 [4.9; 24.4] 108 (48)	0.98 [0.75; 1.27] 0.862
Cognitive functioning	213	2.1 [2.1; 2.8] 154 (72)	224	4.2 [3.4; 6.2] 127 (57)	1.37 [1.08; 1.73] 0.010 AD = 2.1 months
Social functioning	213	4.4 [3.5; 5.7] 143 (67)	224	3.4 [2.8; 4.8] 143 (64)	0.91 [0.72; 1.14] 0.429

Side effects

Endpoint	**Belantamab mafodotin + bortezomib + dexamethasone (BVd)**		**Daratumumab + bortezomib + dexamethasone (DVd)**		**BVd vs DVd**
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
Total adverse events (presented additionally)					
	212	0.1 [0.1; 0.2] 212 (100)	220	0.1 [0.1; 0.2] 220 (100)	–

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Serious adverse events (SAEs)					
	212	17.1 [8.8; 30.0] 119 (56)	220	44.5 [35.1; n.c.] 84 (38)	1.50 [1.13; 1.98] 0.004 AD = 27.4 months
Severe adverse events (CTCAE grade 3 or 4)					
	212	0.3 [0.3; 0.4] 201 (95)	220	1.0 [0.7; 1.2] 175 (80)	1.97 [1.60; 2.42] < 0.001 AD = - 0.7 months
Therapy discontinuation due to adverse events (≥ 1 active ingredient component)					
	212	n.r. 70 (33)	220	n.r. 41 (19)	1.84 [1.25; 2.70] 0.002
PRO-CTCAE					
	no suitable data				
Eye irritation / dry eyes (OSDI – Time to 1st deterioration[j])					
Total score	212	2.0 [1.4; 2.1] 173 (82)	220	49.0 [21.4; n.c.] 73 (33)	5.26 [3.95; 7.00] < 0.001 AD = - 47.0 months
Ocular symptoms	212	2.1 [2.1; 2.9] 155 (73)	220	n.r. [37.3; n.c.] 59 (27)	4.52 [3.33; 6.13]
Vision-related functioning	212	1.7 [1.4; 2.1] 171 (81)	220	22.1 [11.8; 52.8] 91 (41)	3.75 [2.88; 4.89]
Environmental triggers	212	4.8 [2.9; 6.3] 116 (55)	220	37.9 [24.8; n.c.] 57 (26)	2.71 [1.97; 3.72]
Specific adverse events[k]					
Infusion-related reactions[l]	212	n.r. 6 (3)	220	n.r. 40 (18)	0.14 [0.06; 0.33] < 0.001
Peripheral neuropathy	no suitable data[k]				
Eye disorders (SOC, AEs)	212	1.4 [1.4; 1.9] 170 (80)	220	22.6 [15.5; n.c.] 88 (40)	4.57 [3.49; 5.99] < 0.001 AD = - 20.9 months
Eye disorders (SOC, severe AEs)	212	34.4 [16.8; n.c.] 85 (40)	220	n.r. 15 (7)	7.42 [4.28; 12.86] < 0.001
Gastrointestinal disorders (SOC, SAEs)	212	n.r. 20 (9)	220	n.r. 9 (4)	2.24 [1.02; 4.93] 0.039
Thrombocytopenia (PT, severe AEs)	212	1.5 [0.5; 5.2] 119 (56)	220	n.r. 74 (34)	2.16 [1.62; 2.89] < 0.001
Infections and infestations	212	n.r. [36.3; n.c.] 72 (34)	220	n.r. 43 (20)	1.72 [1.18; 2.51] 0.004

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(SOC, severe AEs)					
Pneumonia (PT, severe AEs)	212	n.r. 29 (14)	220	n.r. 9 (4)	3.26 [1.54; 6.90] 0.001
Physical examinations (SOC, severe AEs)	212	n.r. [47.6; n.c.] 72 (34)	220	n.r. 40 (18)	1.98 [1.35; 2.92] < 0.001
Cardiac disorders (SOC, severe AEs)	212	n.r. 11 (5)	220	n.r. 2 (< 1)	5.51 [1.22; 24.86] 0.013

a. HR (including 95% CI) calculated using the Cox proportional hazards model, with the stratification factors of prior treatment with bortezomib (yes vs no) and stage of the disease (R-ISS I vs II/III). An HR < 1 indicates an advantage for belantamab mafodotin + bortezomib + dexamethasone compared with daratumumab + bortezomib + dexamethasone.
b. Two-tailed p value from the log-rank test with the stratification factors of prior treatment with bortezomib (yes vs no) and stage of the disease (R-ISS I vs II/III).
c. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation.
d. Findings from the statement by the pharmaceutical company, data cut-off: 02.10.2023
e. An increase in the score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
f. Achieving a scale score of "much worse" or "minimally worse" compared with the start of the study is considered as clinically relevant deterioration (5-point scale: "much better", "minimally better", "no change", "minimally worse", "much worse").
g. An increase by ≥ 1 point compared to the start of the study is considered as clinically relevant deterioration (5-point scale from "no symptoms" to "very severe symptoms").
h. A decrease in the score by ≥ 15 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
i. A decrease in the score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
j. An increase in the total score and in the subscales of vision-related functioning and environmental triggers by ≥ 15 points, and in the subscale of ocular symptoms by ≥ 16.67 points (pre-specified criterion) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
k. Selection according to the methodology of the IQWiG; selection using events occurred in the study, based on frequency and differences between treatment arms, and taking into account patient relevance.
l. Operationalised as an infusion-related reaction (PT, AEs)

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; CI = confidence Interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; vs = versus; OSDI = Ocular Surface Disease Index; PRO-CTCAE = Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events; QLQ-C30 = Quality of Life Questionnaire − Core 30; PGIC = Patient Global Impression of Change; PGIS = Patient Global Impression of Severity; R-ISS = Revised International Staging System; VAS = visual analogue scale

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

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available
Morbidity	∅	No data available
Health-related quality of life	∅	No data available
Side effects	∅	No data available
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

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

Hint for a non-quantifiable additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑	Advantage in overall survival.
Morbidity	↔	No relevant difference for the benefit assessment.
Health-related quality of life	↔	No relevant differences for the benefit assessment overall. Disadvantage in cognitive functioning.
Side effects	↓	Disadvantage for eye disorders (Ocular Surface Disease Index [OSDI]).

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: No data available.
n.a.: not assessable

DREAMM-7 study:

- Study design: open-label, randomised phase III study, data cut-off from 09.01.2026
- Comparison: belantamab mafodotin + bortezomib + dexamethasone (BVd) **vs** daratumumab + bortezomib + dexamethasone (DVd)
- Relevant sub-population: adults who have received **at least four prior therapies**

Mortality

Endpoint	Belantamab mafodotin + bortezomib + dexamethasone (BVd)		Daratumumab + bortezomib + dexamethasone (DVd)		BVd vs DVd
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
Overall survival					
	30	n.r. [31.9; n.c.] 10 (33)	27	16.2 [7.3; 52.4] 19 (70)	0.36 [0.16; 0.81] 0.010

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Morbidity

Endpoint	Belantamab mafodotin + bortezomib + dexamethasone (BVd)		Daratumumab + bortezomib + dexamethasone (DVd)		BVd vs DVd
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
Progression-free survival[d]					
	30	23.4 [7.9; n.c.] 15 (50)	27	6.0 [4.2; 10.4] 20 (74)	0.28 [0.13; 0.60] < 0.001 AD = + 17.4 months
Symptomatology					
EORTC QLQ-C30 – Time to 1st deterioration[e]					
Fatigue	30	1.4 [0.7; 6.2] 22 (73)	27	2.4 [1.4; 3.6] 19 (70)	1.00 [0.54; 1.85] 0.864
Nausea and vomiting	30	6.2 [1.4; n.c.] 15 (50)	27	6.7 [3.5; n.c.] 11 (41)	1.11 [0.50; 2.46] 0.821
Pain	30	3.5 [2.2; 4.9] 21 (70)	27	2.1 [1.4; 4.9] 18 (67)	0.80 [0.43; 1.51] 0.502
Dyspnoea	30	3.4 [1.4; 4.2] 19 (63)	27	4.2 [2.2; n.c.] 14 (52)	1.39 [0.69; 2.78] 0.358
Insomnia	30	3.6 [0.9; n.c.] 17 (57)	27	3.6 [2.1; n.c.] 14 (52)	0.99 [0.48; 2.02] 0.887
Appetite loss	30	4.9 [2.8; 50.2] 17 (57)	27	6.3 [4.2; n.c.] 11 (41)	1.26 [0.58; 2.73] 0.566
Constipation	30	7.6 [1.4; n.c.] 15 (50)	27	5.5 [1.4; n.c.] 13 (48)	0.85 [0.40; 1.82] 0.664
Diarrhoea	30	4.8 [1.4; n.c.] 16 (53)	27	n.r. [2.8; n.c.] 9 (33)	1.55 [0.68; 3.55] 0.309
PGIC – Time to 1st deterioration[f]					
	30	n.r. [2.7; n.c.] 13 (43)	27	6.2 [3.6; 24.0] 13 (48)	0.89 [0.41; 1.94] 0.773
PGIS – Time to 1st deterioration[g]					
	30	n.r. [2.8; n.c.] 12 (40)	27	4.2 [2.4; n.c.] 10 (37)	0.81 [0.35; 1.87] 0.593

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Health status					
EQ-5D VAS – Time to 1st deterioration[h]					
	30	19.4 [2.8; n.c.] 12 (40)	27	9.7 [2.9; n.c.] 9 (33)	0.98 [0.41; 2.33] 0.932

Health-related quality of life

Endpoint	**Belantamab mafodotin + bortezomib + dexamethasone (BVd)**		**Daratumumab + bortezomib + dexamethasone (DVd)**		**BVd vs DVd**
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
EORTC QLQ-C30 – Time to 1st deterioration[i]					
Global health status	30	2.2 [1.4; 3.7] 19 (63)	27	2.8 [2.4; n.c.] 13 (48)	1.81 [0.89; 3.69] 0.093
Physical functioning	30	4.2 [2.1; 8.0] 19 (63)	27	3.6 [2.1; 9.1] 18 (67)	0.92 [0.48; 1.76] 0.797
Role functioning	30	2.8 [2.1; 5.7] 20 (67)	27	2.4 [2.1; 4.0] 19 (70)	0.74 [0.39; 1.40] 0.330
Emotional functioning	30	7.4 [2.8; n.c.] 15 (50)	27	5.6 [2.4; n.c.] 12 (44)	0.97 [0.45; 2.10] 0.943
Cognitive functioning	30	2.1 [1.4; 2.8] 21 (70)	27	6.3 [3.5; n.c.] 11 (41)	2.29 [1.09; 4.83] 0.025 AD = - 4.2 months
Social functioning	30	3.4 [2.1; 7.3] 21 (70)	27	4.3 [1.4; 19.4] 14 (52)	1.29 [0.65; 2.54] 0.471

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Side effects

Endpoint	Belantamab mafodotin + bortezomib + dexamethasone (BVd)		Daratumumab + bortezomib + dexamethasone (DVd)		BVd vs DVd
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Hazard ratio[a] [95% CI] p value[b] Absolute difference (AD)[c]
Total adverse events (presented additionally)					
	30	0.1 [0.0; 0.2] 30 (100)	26	0.2 [0.0; 0.6] 26 (100)	–
Serious adverse events (SAEs)					
	30	13.2 [4.3; n.c.] 13 (43)	26	14.0 [4.0; n.c.] 13 (50)	0.92 [0.42; 1.98] 0.833
Severe adverse events (CTCAE grade 3 or 4)					
	30	0.3 [0.2; 0.4] 30 (100)	26	0.7 [0.2; 1.2] 23 (88)	1.77 [1.00; 3.13] 0.046
Therapy discontinuation due to adverse events (≥ 1 active ingredient component)					
	30	n.r. [4.3; n.c.] 10 (33)	26	n.r. 6 (23)	1.62 [0.59; 4.46] 0.347
PRO-CTCAE					
	no suitable data				
Eye irritation / dry eyes (OSDI – Time to 1st deterioration[j])					
Total score	30	2.1 [1.4; 2.8] 24 (80)	26	20.0 [3.6; n.c.] 7 (27)	4.02 [1.70; 9.48] < 0.001 AD = - 17.9 months
Ocular symptoms	30	2.2 [1.5; 3.1] 19 (63)	26	29.7 [9.0; n.c.] 6 (23)	3.15 [1.24; 8.02]
Vision-related functioning	30	1.4 [1.4; 2.2] 25 (83)	26	29.7 [2.1; n.c.] 9 (35)	3.35 [1.54; 7.29]
Environmental triggers	30	2.8 [1.4; 6.5] 14 (47)	26	19.6 [4.0; n.c.] 7 (27)	2.37 [0.95; 5.89]
Specific adverse events[k]					
Infusion-related reactions[l]	212	n.r. 6 (3)	220	n.r. 40 (18)	0.14 [0.06; 0.33] < 0.001
Peripheral neuropathy	no suitable data[k]				
Eye disorders (SOC, AEs)	30	1.4 [1.1; 2.4] 26 (87)	26	15.7 [7.5; n.c.] 8 (31)	17.39 [5.75; 52.60] < 0.001 AD = - 14.3 months

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Eye disorders (SOC, severe AEs)	30	4.7 [2.1; n.c.] 16 (53)	26	n.r. 3 (12)	6.93 [2.01; 23.92] < 0.001
Fever (PT, AEs)	30	n.r. 7 (23)	26	n.r. 0 (0)	14.12 [1.72; 1,832.57] 0.010
Physical examinations (SOC, severe AEs)	30	n.r. [2.9; n.c.] 12 (40)	26	n.r. 4 (15)	3.06 [0.99; 9.52] 0.042[m]

a. HR (including 95% CI) calculated using the Cox proportional hazards model, with the stratification factors of prior treatment with bortezomib (yes vs no) and stage of the disease (R-ISS I vs II/III). An HR < 1 indicates an advantage for belantamab mafodotin + bortezomib + dexamethasone compared with daratumumab + bortezomib + dexamethasone.
b. Two-tailed p value from the log-rank test with the stratification factors of prior treatment with bortezomib (yes vs no) and stage of the disease (R-ISS I vs II/III).
c. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation.
d. Findings from the statement by the pharmaceutical company, data cut-off: 02.10.2023
e. An increase in the score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
f. Achieving a scale score of "much worse" or "minimally worse" compared with the start of the study is considered as clinically relevant deterioration (5-point scale: "much better", "minimally better", "no change", "minimally worse", "much worse").
g. An increase by ≥ 1 point compared to the start of the study is considered as clinically relevant deterioration (5-point scale from "no symptoms" to "very severe symptoms").
h. A decrease in the score by ≥ 15 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
i. A decrease in the score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
j. An increase in the total score and in the subscales of vision-related functioning and environmental triggers by ≥ 15 points, and in the subscale of ocular symptoms by ≥ 16.67 points (pre-specified criterion) compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
k. Selection according to the methodology of the IQWiG; selection using events occurred in the study, based on frequency and differences between treatment arms, and taking into account patient relevance.
l. Operationalised as an infusion-related reaction (PT, AEs)
m. Discrepancy between the p value (log-rank test) and the CI (Cox proportional hazards model) due to different calculation methods.

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; CI = confidence Interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; vs = versus; OSDI = Ocular Surface Disease Index; PRO-CTCAE = Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events; QLQ-C30 = Quality of Life Questionnaire − Core 30; PGIC = Patient Global Impression of Change; PGIS = Patient Global Impression of Severity; R-ISS = Revised International Staging System; VAS = visual analogue scale

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

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available
Morbidity	∅	No data available
Health-related quality of life	∅	No data available
Side effects	∅	No data available
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

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

Approximately 3,260 to 5,400 patients

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

Approximately 1,100 to 1,180 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Blenrep (active ingredient: belantamab mafodotin) at the following publicly accessible link (last access: 1 July 2026):

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

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

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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.

4. Treatment costs

Annual treatment costs:

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

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Belantamab mafodotin in combination with bortezomib and dexamethasone	
Belantamab mafodotin	€ 203,087.90 – € 236,203.61
Bortezomib	€ 5,635.52
Dexamethasone	€ 170.97
Total	€ 208,894.39 – € 242,010.10
Appropriate comparator therapy:	
An individualised therapy with the selection of	
Carfilzomib in combination with lenalidomide and dexamethasone	
Carfilzomib	€ 80,095.58
Lenalidomide	€ 467.78
Dexamethasone	€ 194.52
Total	€ 80,757.88
Additionally required SHI services	€ 10.49
Elotuzumab in combination with lenalidomide and dexamethasone	
Elotuzumab	€ 88,274.40
Lenalidomide	€ 467.78
Dexamethasone	€ 187.08
Total	€ 88,929.28
Additionally required SHI services	€ 284.80 – € 289.10
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)	

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Designation of the therapy	Annual treatment costs/ patient
Elotuzumab	€ 88,274.40
Pomalidomide	€ 24,755.77
Dexamethasone	€ 189.81
Total	€ 113,219.98
Additionally required SHI services	€ 184.21 – € 186.94
Daratumumab in combination with bortezomib and dexamethasone	
Daratumumab	€ 116,967.06
Bortezomib	€ 5,635.52
Dexamethasone	€ 149.30
Total	€ 122,751.88
Additionally required SHI services	€ 210.41 – € 213.42
Daratumumab in combination with lenalidomide and dexamethasone	
Daratumumab	€ 128,106.78
Lenalidomide	€ 467.78
Dexamethasone	€ 108.48
Total	€ 128,683.04
Additionally required SHI services	€ 261.25 – € 264.55
Daratumumab in combination with carfilzomib and dexamethasone	
Daratumumab	€ 128,106.78
Carfilzomib	€ 151,236.12
Dexamethasone	€ 175.53
Total	€ 279,518.43
Additionally required SHI services	€ 232.21 – € 235.51
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	€ 128,106.78
Pomalidomide	€ 24,755.77
Dexamethasone	€ 108.48
Total	€ 152,971.03
Additionally required SHI services	€ 261.25 – € 264.55
Isatuximab in combination with carfilzomib and dexamethasone	
Isatuximab	€ 67,648.84
Carfilzomib	€ 151,236.12
Dexamethasone	€ 245.19
Total	€ 219,130.15

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Designation of the therapy	Annual treatment costs/ patient
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	€ 67,648.84
Pomalidomide	€ 24,755.77
Dexamethasone	€ 194.52
Total	€ 92,599.13
Additionally required SHI services	€ 10.49
Pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible)	
Pomalidomide	€ 22,089.76
Bortezomib	€ 8,946.39
Dexamethasone	€ 239.53
Total	€ 31,275.68
Additionally required SHI services	€ 10.49
Ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible)	
Ixazomib	€ 78,861.90
Lenalidomide	€ 467.78
Dexamethasone	€ 194.52
Total	€ 79,524.20
Additionally required SHI services	€ 10.49
Carfilzomib in combination with dexamethasone	
Carfilzomib	€ 151,236.12
Dexamethasone	€ 245.19
Total	€ 151,481.31

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 July 2026)

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Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed					
Belantamab mafodotin in combination with bortezomib and dexamethasone					
Belantamab mafodotin	Surcharge for the preparation of parenteral solutions containing belantamab mafodotin	€ 100	1	17.4	€ 1,740
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
Appropriate comparator therapy					
Carfilzomib in combination with lenalidomide and dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1st - 12th cycle: 6 From 13th cycle: 4	76.0	€ 7,600
Elotuzumab in combination with lenalidomide and dexamethasone					
Elotuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1st - 2nd cycle: 4 From 3rd cycle: 2	30.0	€ 3,000
Elotuzumab in combination with pomalidomide and dexamethasone					
Elotuzumab	Surcharge for the preparation of a parenteral solution containing	€ 100	1st - 2nd cycle: 4 From 3rd cycle: 1	19.0	€ 1,900

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Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	monoclonal antibodies				
Daratumumab in combination with bortezomib and dexamethasone					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
Daratumumab in combination with carfilzomib and dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Isatuximab in combination with carfilzomib and dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Pomalidomide in combination with bortezomib and dexamethasone					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1st - 8th cycle: 4 From 9th cycle: 2	50.8	€ 5,080
Carfilzomib in combination with dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Belantamab mafodotin in combination with bortezomib and dexamethasone	
belantamab mafodotin	€ 203,087.90 – € 236,203.61
Bortezomib	€ 5,635.52
Dexamethasone	€ 170.97
Total	€ 208,894.39 – € 242,010.10
Appropriate comparator therapy:	
An individualised therapy with the selection of	
Carfilzomib in combination with lenalidomide and dexamethasone	
Carfilzomib	€ 80,095.58
Lenalidomide	€ 467.78
Dexamethasone	€ 194.52
Total	€ 80,757.88
Additionally required SHI services	€ 10.49
Elotuzumab in combination with lenalidomide and dexamethasone	
Elotuzumab	€ 88,274.40
Lenalidomide	€ 467.78
Dexamethasone	€ 187.08
Total	€ 88,929.28
Additionally required SHI services	€ 284.80 – € 289.10
Elotuzumab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible)	
Elotuzumab	€ 88,274.40
Pomalidomide	€ 24,755.77
Dexamethasone	€ 189.81
Total	€ 113,219.98
Additionally required SHI services	€ 184.21 – € 186.94
Daratumumab in combination with bortezomib and dexamethasone	
Daratumumab	€ 116,967.06
Bortezomib	€ 5,635.52
Dexamethasone	€ 149.30
Total	€ 122,751.88
Additionally required SHI services	€ 210.41 – € 213.42
Daratumumab in combination with lenalidomide and dexamethasone	

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Designation of the therapy	Annual treatment costs/ patient
Daratumumab	€ 128,106.78
Lenalidomide	€ 467.78
Dexamethasone	€ 108.48
Total	€ 128,683.04
Additionally required SHI services	€ 261.25 – € 264.55
Daratumumab in combination with carfilzomib and dexamethasone	
Daratumumab	€ 128,106.78
Carfilzomib	€ 151,236.12
Dexamethasone	€ 175.53
Total	€ 279,518.43
Additionally required SHI services	€ 232.21 – € 235.51
Daratumumab in combination with pomalidomide and dexamethasone	
Daratumumab	€ 128,106.78
Pomalidomide	€ 24,755.77
Dexamethasone	€ 108.48
Total	€ 152,971.03
Additionally required SHI services	€ 261.25 – € 264.55
Isatuximab in combination with carfilzomib and dexamethasone	
Isatuximab	€ 67,648.84
Carfilzomib	€ 151,236.12
Dexamethasone	€ 245.19
Total	€ 219,130.15
Isatuximab in combination with pomalidomide and dexamethasone (only subjects who have shown disease progression during the last therapy are eligible)	
Isatuximab	€ 67,648.84
Pomalidomide	€ 24,755.77
Dexamethasone	€ 194.52
Total	€ 92,599.13
Additionally required SHI services	€ 10.49
Pomalidomide in combination with bortezomib and dexamethasone (only subjects who are refractory to an anti-CD38 antibody and lenalidomide are eligible)	
Pomalidomide	€ 22,089.76
Bortezomib	€ 8,946.39
Dexamethasone	€ 239.53
Total	€ 31,275.68
Additionally required SHI services	€ 10.49

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Designation of the therapy	Annual treatment costs/ patient
Ixazomib in combination with lenalidomide and dexamethasone (only subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody are eligible)	
Ixazomib	€ 78,861.90
Lenalidomide	€ 467.78
Dexamethasone	€ 194.52
Total	€ 79,524.20
Additionally required SHI services	€ 10.49
Carfilzomib in combination with dexamethasone	
Carfilzomib	€ 151,236.12
Dexamethasone	€ 245.19
Total	€ 151,481.31
Panobinostat in combination with bortezomib and dexamethasone	
Panobinostat	€ 37,243.28 - € 74,486.56
Bortezomib	€ 5,635.52 – € 8,453.28
Dexamethasone	€ 170.97 – € 235.76
Total	€ 43,049.77 – € 83,175.60
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	€ 24,755.77
Dexamethasone	€ 194.52
Total	€ 24,950.29
Additionally required SHI services	€ 10.49
Lenalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)	
Lenalidomide	€ 467.78
Dexamethasone	€ 314.23
Total	€ 782.01
Additionally required SHI services	€ 10.49
Bortezomib in combination with pegylated liposomal doxorubicin (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)	
Bortezomib	€ 5,635.52
Doxorubicin (pegylated, liposomal)	€ 17,470.64
Total	€ 23,106.16
Bortezomib in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)	
Bortezomib	€ 2,817.76 – € 5,635.52
Dexamethasone	€ 106.18 – € 170.97

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Designation of the therapy	Annual treatment costs/ patient
Total	€ 2,923.94 – € 5,806.49
Daratumumab monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)	
Daratumumab	€ 128,106.78
Additionally required SHI services	€ 326.79 – € 600.19
Cyclophosphamide as monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)	
Cyclophosphamide	€ 567.50 – € 5,492.89
Cyclophosphamide in combination with dexamethasone (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)	
Cyclophosphamide	Not calculable
Dexamethasone	Not calculable
Total	Not calculable
Melphalan as monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)	
Melphalan	€ 615.29
Melphalan in combination with prednisolone or prednisone (only at least triple refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)	
Melphalan	€ 411.77 – € 615.29
Prednisone	€ 135.98 – € 203.19
Total	€ 547.75 – € 818.48
Prednisolone	€ 65.15 – € 97.35
Total	€ 476.92 – € 712.64

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 July 2026)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed					
Belantamab mafodotin in combination with bortezomib and dexamethasone					
belantamab mafodotin	Surcharge for the preparation of parenteral solutions containing belantamab mafodotin	€ 100	1	17.4	€ 1,740

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Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
Appropriate comparator therapy					
Carfilzomib in combination with lenalidomide and dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1st – 12th cycle: 6 From 13th cycle: 4	76.0	€ 7,600
Elotuzumab in combination with lenalidomide and dexamethasone					
Elotuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1st - 2nd cycle: 4 From 3rd cycle: 2	30.0	€ 3,000
Elotuzumab in combination with pomalidomide and dexamethasone					
Elotuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1st - 2nd cycle: 4 From 3rd cycle: 1	19.0	€ 1,900
Daratumumab in combination with bortezomib and dexamethasone					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
Daratumumab in combination with carfilzomib and dexamethasone					

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Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Isatuximab in combination with carfilzomib and dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Pomalidomide in combination with bortezomib and dexamethasone					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1st - 8th cycle: 4 From 9th cycle: 2	50.8	€ 5,080
Panobinostat in combination with bortezomib and dexamethasone					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1st - 8th cycle: 4 9th – 16th cycle: 2	32 – 48	€ 3,200 – € 4,800
Carfilzomib in combination with dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Bortezomib in combination with pegylated liposomal doxorubicin					
Bortezomib	Surcharge for production of a parenteral preparation	€ 100	4	32.0	€ 3,200

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Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Doxorubicin (pegylated, liposomal)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	8.0	€ 800
Bortezomib in combination with dexamethasone					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	16.0 – 32.0	€ 1,600 – € 3,200
Cyclophosphamide as monotherapy					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0 – 365.0	€ 1,300 – € 36,500
Melphalan as monotherapy					
Melphalan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
Melphalan in combination with prednisolone or prednisone					
Melphalan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	8.7 – 13.0	€ 870 – € 1,300

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II. The resolution will enter into force on the day of its publication on the GBA website on 1 October 2026.

The justification for this resolution will be published on the GBA website at www.g-ba.de.

Berlin, 1 October 2026

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

Dr Optendrenk

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