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)
Daratumumab (reassessment after the deadline: multiple myeloma, first-line, unsuitable for stem cell transplantation, combination with bortezomib, melphalan and prednisone)

of 16 May 2024

At its session on 16 May 2024, the Federal Joint Committee (G-BA) 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. Annex XII is amended as follows:

1. The information on daratumumab in the version of the resolution of 22 March 2019 (BAnz AT 16.05.2019 B5) last modified on 19 January 2023 is repealed.
2. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of daratumumab in the version of the resolution of 18 March 2022:

Courtesy translation – only the German version is legally binding.

Daratumumab

Resolution of: 16 May 2024
Entry into force on: 16 May 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 31 August 2018):

Darzalex is indicated in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Therapeutic indication of the resolution (resolution of 16 May 2024):

Darzalex is indicated in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

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

Adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

Appropriate comparator therapy:

– Daratumumab in combination with lenalidomide and dexamethasone

or

– Bortezomib in combination with melphalan and prednisone

or

– Bortezomib in combination with lenalidomide and dexamethasone

or

– Thalidomide in combination with melphalan and prednisone

or

– Bortezomib in combination with cyclophosphamide and dexamethasone [only for patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy; see Annex VI to Section K of the Pharmaceuticals Directive]

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Extent and probability of the additional benefit of daratumumab in combination with bortezomib, melphalan and prednisone over bortezomib, melphalan and prednisone

Indication of a considerable additional benefit

Study results according to endpoints:[1]

Adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑↑	Advantage in overall survival.
Morbidity	↔	No relevant differences for the benefit assessment. In detail, advantage in the fatigue symptom
Health-related quality of life	↔	No relevant differences overall for the benefit assessment. In detail, advantage in the functional scale of global health status.
Side effects	↔	No relevant differences overall for the benefit assessment. In detail, disadvantages with specific AEs.
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		

Open-label, randomised phase III ALCYONE, OCTANS studies

- Daratumumab + bortezomib + melphalan + prednisone (D-VMP) versus bortezomib + melphalan + prednisone (VMP)
- ALCYONE: final data cut-off from 31 May 2023 (after 382 death events), additionally for the endpoint of overall survival: originally planned final data cut-off from 14 October 2021 (after 330 death events)
- OCTANS: final data cut-off from 23 December 2022
- Meta-analytical summary of both studies, except for some specific AEs (ALCYONE only)

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-127) unless otherwise indicated.

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Mortality

Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	N	Median survival time to event in months [95% CI] Patients with event n (%)	N	Median survival time to event in months [95% CI] Patients with event n (%)	HR [95% CI] p value Absolute difference (AD)[a]
Overall survival (originally planned final analysis on overall survival of the ALCYONE[b]study, data cut-off 14.10.2021)					
ALCYONE	350	n.r. 143 (40.9)	356	53.59 [46.32; 60.91] 187 (52.5)	0.66 [0.53; 0.82]; < 0.001[c] AD: n.c.
OCTANS	146	n.r. [54.67; n.c.] 33 (22.6)	74	n.r. [41.49; n.c.] 23 (31.1)	0.60 [0.35; 1.03]; 0.060[c]
Total					0.65 [0.53; 0.80]; < 0.001[d]
Overall survival (final analysis of overall survival of the ALCYONE[e]study, data cut-off 31.05.2023)					
ALCYONE	350	82.96 [72.48; n.c.] 172 (49.1)	356	53.59 [46.32; 60.91] 217 (61.0)	0.65 [0.53; 0.80]; < 0.001[c] AD: +29.37 months
OCTANS	146	n.r. [54.67; n.c.] 33 (22.6)	74	n.r. [41.49; n.c.] 23 (31.1)	0.60 [0.35; 1.03]; 0.060[c]
Total					0.64 [0.53; 0.78]; < 0.001[f]

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Morbidity

Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value Absolute difference (AD)[a]
Progression-free survival (PFS) [g]					
ALCYONE	350	36.40 [32.13; 45.67] 235 (67.1)	356	19.29 [18.00; 20.66] 294 (82.6)	0.43 [0.36; 0.52]; < 0.0001 AD: + 17.11 months
OCTANS	146	38.67 [30.55; 44.16] 73 (50.0)	74	19.15 [15.13; 22.08] 46 (62.2)	0.35 [0.23; 0.52]; < 0.0001 AD: + 19.52 months
Symptomatology (EORTC QLQ-C30 – time to 1st deterioration[h])					
Fatigue					
ALCYONE	350	45.93 [24.05; 68.83] 137 (39.1)	356	17.05 [11.60; 33.38] 135 (37.9)	0.78 [0.61; 1.00]; 0.049 AD: + 28.88 months
OCTANS	146	17.97 [8.41; 34.86] 74 (50.7)	74	8.80 [5.55; n.c.] 34 (45.9)	0.71 [0.46; 1.09]; 0.117
Total					0.76 [0.61; 0.94]; 0.013[f]
Nausea and vomiting					
ALCYONE	350	77.31 [59.40; n.c.] 109 (31.1)	356	n.r. [33.74; n.c.] 95 (26.7)	0.87 [0.66; 1.16]; 0.344
OCTANS	146	51.19 [33.02; n.c.] 49 (33.6)	74	n.c. [21.78; n.c.] 16 (21.6)	1.18 [0.65; 2.14]; 0.588
Total					0.92 [0.71; 1.19]; 0.521[f]

Courtesy translation – only the German version is legally binding.

Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value Absolute difference (AD)[a]
Pain					
ALCYONE	350	79.47 [44.65; n.c.] 118 (33.7)	356	33.38 [18.14; 39.88] 116 (32.6)	0.75 [0.57; 0.98]; 0.033 AD: +46.09 months
OCTANS	146	44.09 [18.20; n.c.] 62 (42.5)	74	27.43 [11.14; n.c.] 25 (33.8)	1.01 [0.62; 1.64]; 0.966
Total					0.80 [0.64; 1.02]; 0.072[f]
Dyspnoea					
ALCYONE	350	58.32 [34.56; n.c.] 125 (35.7)	356	n.r. [33.64; n.c.] 91 (25.6)	1.07 [0.81; 1.41]; 0.623
OCTANS	146	n.r. [33.71; n.c.] 51 (34.9)	74	n.c. [21.55; n.c.] 18 (24.3)	1.21 [0.69; 2.10]; 0.502
Total					1.10 [0.86; 1.41]; 0.467[f]
Insomnia					
ALCYONE	350	44.16 [31.38; 63.05] 132 (37.7)	356	45.67 [25.10; n.c.] 111 (31.2)	0.90 [0.69; 1.16]; 0.410
OCTANS	146	n.r. [17.35; n.c.] 59 (40.4)	74	17.51 [11.11; n.c.] 29 (39.2)	0.82 [0.52; 1.30]; 0.409
Total					0.88 [0.70; 1.10]; 0.267[f]

Courtesy translation – only the German version is legally binding.

Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value [a]
Appetite loss					
ALCYONE	350	n.r. [36.01; n.c.] 116 (33.1)	356	55.13 [34.59; n.c.] 93 (26.1)	0.98 [0.74; 1.30]; 0.896
OCTANS	146	49.54 [33.02; n.c.] 51 (34.9)	74	n.r. [11.11; n.c.] 23 (31.1)	0.84 [0.51; 1.39]; 0.488
Total					0.94 [0.74; 1.21]; 0.648[f]
Constipation					
ALCYONE	350	n.c. [52.96; n.c.] 108 (30.9)	356	n.r. [39.88; n.c.] 92 (25.8)	0.88 [0.66; 1.18]; 0.394
OCTANS	146	n.r. [32.89; n.c.] 48 (32.9)	74	24.02 [22.05; n.c.] 21 (28.4)	0.85 [0.50; 1.45]; 0.548
Total					0.87 [0.68; 1.13]; 0.297[f]
Diarrhoea					
ALCYONE	350	n.r. [62.39; n.c.] 104 (29.7)	356	n.r. 81 (22.8)	0.96 [0.71; 1.30]; 0.806
OCTANS	146	n.r. [33.68; n.c.] 47 (32.2)	74	n.r. [22.05; n.c.] 15 (20.3)	1.07 [0.58; 1.97]; 0.827
Total					0.98 [0.75; 1.29]; 0.888[f]

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Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value [a]
Health status (EQ-5D VAS – time to 1st deterioration[i])					
ALCYONE	350	n.r. 72 (20.6)	356	n.r. [55.79; n.c.] 67 (18.8)	0.81 [0.57; 1.14]; 0.217[c]
OCTANS	146	n.r. 37 (25.3)	74	n.r. [32.85; n.c.] 13 (17.6)	1.00 [0.52; 1.91]; 0.995[c]
Total					0.85 [0.62; 1.15]; 0.293[f]

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Health-related quality of life

Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value Absolute difference (AD)[a]
EORTC QLQ-C30 – time to 1st deterioration[j]					
Global health status					
ALCYONE	350	85.78 [68.83; n.c.] 105 (30.0)	356	44.45 [29.44; 66.89] 106 (29.8)	0.72 [0.55; 0.95]; 0.023 AD: + 41.33 months
OCTANS	146	44.09 [32.72; n.c.] 51 (34.9)	74	27.43 [22.05; n.c.] 22 (29.7)	0.78 [0.47; 1.31]; 0.354
Total					0.73 [0.58; 0.93]; 0.012[f]
Physical functioning					
ALCYONE	350	n.r. [61.08; n.c.] 102 (29.1)	356	39.88 [32.66; n.c.] 98 (27.5)	0.76 [0.57; 1.01]; 0.063
OCTANS	146	44.09 [32.92; n.c.] 51 (34.9)	74	n.r. [18.37; n.c.] 19 (25.7)	1.08 [0.63; 1.85]; 0.791
Total					0.82 [0.64; 1.06]; 0.126[f]
Role functioning					
ALCYONE	350	45.90 [28.06; 62.23] 134 (38.3)	356	25.04 [16.85; 39.88] 126 (35.4)	0.83 [0.64; 1.06]; 0.138
OCTANS	146	n.r. [33.68; n.c.] 54 (37.0)	74	27.43 [8.80; n.c.] 27 (36.5)	0.71 [0.43; 1.15]; 0.162
Total					0.80 [0.64; 1.01]; 0.056[f]

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Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value [a]
Emotional functioning					
ALCYONE	350	n.c. [60.62; n.c.] 100 (28.6)	356	55.79 [45.67; n.c.] 79 (22.2)	0.89 [0.65; 1.21]; 0.451
OCTANS	146	n.r. [33.71; n.c.] 45 (30.8)	74	n.r. 15 (20.3)	1.01 [0.55; 1.85]; 0.972
Total					0.91 [0.69; 1.20]; 0.522[f]
Cognitive functioning					
ALCYONE	350	22.67 [11.50; 31.84] 166 (47.4)	356	23.36 [11.76; 25.10] 134 (37.6)	0.98 [0.77; 1.25]; 0.863
OCTANS	146	16.62 [8.77; 28.35] 76 (52.1)	74	20.37 [8.35; n.c.] 29 (39.2)	0.98 [0.63; 1.53]; 0.948
Total					0.98 [0.79; 1.21]; 0.852[f]
Social functioning					
ALCYONE	350	60.35 [28.02; n.c.] 131 (37.4)	356	34.30 [17.91; 61.01] 114 (32.0)	0.89 [0.69; 1.16]; 0.388
OCTANS	146	21.88 [11.24; 33.61] 71 (48.6)	74	21.52 [8.35; n.c.] 28 (37.8)	0.90 [0.57; 1.43]; 0.667
Total					0.89 [0.71; 1.12]; 0.324[f]

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Side effects[k]

Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value [a]
Adverse events (AEs, presented additionally)					
ALCYONE	346	0.20 [0.13; 0.26] 338 (97.7)	354	0.26 [0.26; 0.33] 342 (96.6)	–
OCTANS	144	0.03 [0.03; 0.07] 144 (100.0)	71	0.16 [0.10; 0.20] 71 (100.0)	–
Serious adverse events (SAE)					
ALCYONE	346	35.91 [23.46; 52.27] 186 (53.8)	354	–[l] 117 (33.1)	1.17 [0.91; 1.50]; 0.216
OCTANS	144	20.96 [10.64; n.c.] 75 (52.1)	71	n.c. [n.c.; n.c.] 28 (39.4)	1.12 [0.72; 1.75]; 0.620
Total					1.16 [0.93; 1.44]; 0.187[f]
Severe adverse events (CTCAE grade ≥ 3)					
ALCYONE	346	0.61 [0.49; 0.95] 291 (84.1)	354	0.95 [0.72; 1.08] 277 (78.2)	1.07 [0.90; 1.27]; 0.459
OCTANS	144	0.38 [0.26; 0.46] 133 (92.4)	71	0.66 [0.33; 0.82] 61 (85.9)	1.32 [0.96; 1.82]; 0.084
Total					1.12 [0.96; 1.31]; 0.138[f]

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Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value Absolute difference (AD)[a]
Therapy discontinuations due to adverse events (at least 1 therapy component)					
ALCYONE	346	n.r. 46 (13.3)	354	–[l] 40 (11.3)	0.81 [0.51; 1.29]; 0.382
OCTANS	144	n.r. 20 (13.9)	71	n.c. [n.c.; n.c.] 6 (8.5)	1.38 [0.55; 3.51]; 0.495
Total					0.90 [0.60; 1.36]; 0.623[f]
Specific adverse events					
Reaction in connection with an infusion					
ALCYONE	No suitable data[m]				
OCTANS					
Peripheral neuropathy (HLT, severe AEs)					
ALCYONE	346	n.r. 10 (2.9)	354	n.r. 18 (5.1)	0.55 [0.25; 1.19]; 0.128
OCTANS	144	n.r. 5 (3.5)	71	n.r. 2 (2.8)	1.09 [0.21; 5.66]; 0.919
Total					0.62 [0.31; 1.26]; 0.189
Infections and infestations (SOC, severe AEs)					
ALCYONE	346	n.r. [76.52; n.c.] 108 (31.2)	354	–[l] 53 (15.0)	1.43 [1.002; 2.04]; 0.048 AD: n.c.

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Endpoint Study	**Daratumumab + bortezomib + melphalan + prednisone**		**Bortezomib + melphalan + prednisone**		**Intervention vs control**
	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 (%)	HR [95% CI] p value Absolute difference (AD)[a]
Vascular disorders (SOC, severe AEs)					
ALCYONE	346	n.r. 32 (9.2)	354	n.r. 8 (2.3)	2.38 [1.04; 5.44]; 0.040 AD: n.c.
Respiratory, thoracic and mediastinal disorders (SOC, AEs)					
ALCYONE	346	47.77 [31.08; n.c.] 154 (44.5)	354	n.r. 74 (20.9)	1.94 [1.45; 2.60]; p < 0.001 AD: n.c.

a) HR, CI and p value: Cox proportional hazards model, stratified by ISS stage (I vs II vs III) and age (< 75 years vs ≥ 75 years), in the ALCYONE study also by region (Europe vs other), each calculated by IQWIG; information on absolute difference (AD) only if statistically significant, own calculation
b) Taking into account the originally planned analysis of 330 death events in the ALCYONE study. According to the justification for the resolution of 02.12.2021, the 330 events were reached on 14.10.2021.
c) p value: Log-rank test, stratified by ISS stage (I vs II vs III) and age (< 75 years vs ≥ 75 years), in the ALCYONE study also by region (Europe vs other).
d) Calculation of an FEM meta-analysis by IQWIG
e) Taking into account the final data cut-off of the ALCYONE study after approx. 382 death events (data cut-off on 31.05.2023)
f) FEM meta-analysis of the pharmaceutical company based on the aggregated effect estimates of the ALCYONE and OCTANS studies
g) Information from the dossier of the pharmaceutical company
h) An increase in score by ≥ 10 points compared to the start of the study is considered a clinically relevant deterioration (value range of the scale: 0 to 100).
i) A decrease in score by ≥ 15 points compared to the start of study is considered clinically relevant deterioration (value range of the scale: 0 to 100).
j) A decrease in score by ≥ 10 points compared to the start of study is considered clinically relevant deterioration (value range of the scale: 0 to 100).
k) When interpreting the results on side effects, it should be noted that the significantly shorter planned treatment duration and the associated discontinuation of observation in the comparator arm mean that the HR only represents approximately the first 14 months after randomisation.
l) No plausible information
m) Evaluations unsuitable for comparison between the study arms, as only events in connection with daratumumab administration were collected

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; EQ-5D VAS = European Quality of Life Questionnaire 5 Dimensions visual analogue scale; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30; FEM = model with common effect (fixed effect analysis); HLT = high level term; HR = hazard ratio; CI = confidence interval; N = number of patients

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evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; SOC = system organ class; SAE: serious adverse event; AE: adverse event; vs = versus

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

Adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

approx. 3,450 – 3,680 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 Darzalex (active ingredient: daratumumab) at the following publicly accessible link (last access: 4 April 2024):

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

Treatment with daratumumab 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 and a patient identification card. The training material for medical professionals and blood banks contains instructions on how to manage the risk of daratumumab interfering with blood typing (indirect antihuman globulin test or indirect Coombs test). Interference with blood typing induced by daratumumab may persist for up to 6 months after the last infusion of the medicinal product; therefore, medical professionals should advise patients to carry their patient identification card with them for up to 6 months after the end of the treatment.

4. Treatment costs

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

Annual treatment costs:

Adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

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Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Daratumumab	€ 127,016.28
Bortezomib	€ 6,794.27
Melphalan	€ 312.20
Prednisone	€ 73.75
Total:	€ 134,196.50
Additionally required SHI costs	€ 300.43 – € 303.51
Appropriate comparator therapy:	
Daratumumab in combination with lenalidomide and dexamethasone	
Daratumumab	€ 136,512.82
Lenalidomide	€ 463.41
Dexamethasone	€ 107.90
Total:	€ 137,084.12
Additionally required SHI costs	€ 346.75 - € 350.05
Bortezomib in combination with melphalan and prednisone	
Bortezomib	€ 8,895.59
Melphalan	€ 312.20
Prednisone	€ 98.34
Total:	€ 9,306.12
Bortezomib in combination with lenalidomide and dexamethasone	
Induction	
Bortezomib	€ 5,603.52
Lenalidomide	€ 190.12
Dexamethasone	€ 168.97
Follow-up treatment	
Lenalidomide	€ 249.53
Dexamethasone	€ 104.18
Total:	€ 6,316.31
Additionally required SHI costs	€ 106.40
Thalidomide in combination with melphalan and prednisone	

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Designation of the therapy	Annual treatment costs/ patient
Thalidomide	€ 27,853.67
Melphalan	€ 346.89
Prednisone	€ 136.88
Total:	€ 28,337.43
Additionally required SHI costs	€ 106.40
Bortezomib in combination with cyclophosphamide and dexamethasone	
Bortezomib	€ 12,187.66
Cyclophosphamide	€ 690.32
Dexamethasone	€ 517.91
Total:	€ 13,395.88

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2024)

Other SHI benefits:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient year	Costs/ patient year
Medicinal product to be assessed					
Daratumumab (in combination with bortezomib, melphalan and prednisone)	Bortezomib: Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4 – 8	38.8	€ 3,880

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Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient year	Costs/ patient year
Appropriate comparator therapy					
Bortezomib (in combination with melphalan and prednisone)	Bortezomib: Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4 – 8	50.8	€ 5,080
Bortezomib (in combination with lenalidomide and dexamethasone)	Bortezomib: Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32	€ 3,200
Bortezomib in combination with cyclophosphamide and dexamethasone	Bortezomib: Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	69.6	€ 6,960
	Cyclophosphamide: Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adults with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant

Courtesy translation – only the German version is legally binding.

– No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 May 2024.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 16 May 2024

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

Prof. Hecken

Courtesy translation – only the German version is legally binding.