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
Idecabtagene vicleucel (reassessment of an orphan drug after exceeding the EUR 30 million limit: multiple myeloma, at least 3 prior therapies; new therapeutic indication: multiple myeloma, at least 2 prior therapies)

of 19 September 2024

At its session on 19 September 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on idecabtagene vicleucel in the version of the resolution of 16 June 2022 (Federal Gazette, BAnz AT 16.08.2022 B5) is repealed.
2. Annex XII shall be amended in alphabetical order to include the active ingredient idecabtagene vicleucel as follows:

Idecabtagene vicleucel

Resolution of: 19 September 2024
Entry into force on: 19 September 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 March 2024):

Abecma is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Therapeutic indication of the resolution (resolution of 19 September 2024):

See new therapeutic indication according to marketing authorisation.

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

Adults with relapsed and refractory multiple myeloma who have received at least two prior therapies and have demonstrated disease progression on the last therapy; prior treatment includes an immunomodulator, a proteasome inhibitor and an anti-CD-38 antibody

Appropriate comparator therapy:

A patient-individual therapy under selection of:

- 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 [only for subjects who are refractory to a CD38 antibody and lenalidomide]
- Ixazomib in combination with lenalidomide and dexamethasone [only for subjects who are refractory to bortezomib, carfilzomib and a CD38 antibody]
- Panobinostat in combination with bortezomib and dexamethasone
- Carfilzomib in combination with dexamethasone
- Pomalidomide in combination with dexamethasone
  [only for at least double-refractory subjects who are ineligible for triplet therapy and have received at least four prior therapies]
- Lenalidomide in combination with dexamethasone

[only for at least double-refractory subjects who are ineligible for triplet therapy and have received at least four prior therapies]

- Bortezomib in combination with pegylated liposomal doxorubicin
  [only for at least double-refractory subjects who are ineligible for triplet therapy and have received at least four prior therapies]
- Bortezomib in combination with dexamethasone
  [only for at least double-refractory subjects who are ineligible for triplet therapy and have received at least four prior therapies]
- Daratumumab monotherapy
  [only for at least triple-refractory subjects who are ineligible for triplet or doublet therapy and have received at least four prior therapies]
- Cyclophosphamide as monotherapy or in combination with dexamethasone [only for at least triple refractory subjects who are ineligible for triplet or doublet therapy and have received at least four prior therapies]
- Melphalan as monotherapy or in combination with prednisolone or prednisone
  [only for at least triple-refractory subjects who are ineligible for triplet or doublet therapy and have received at least four prior therapies]

taking into account the general condition, the active ingredients and combinations of active ingredients used in the prior therapies and the type and duration of the response to the respective prior therapies

Extent and probability of the additional benefit of idecabtagene vicleucel compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with relapsed and refractory multiple myeloma who have received at least two prior therapies and have demonstrated disease progression on the last therapy; prior treatment includes an immunomodulator, a proteasome inhibitor and an anti-CD-38 antibody

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	↓	Disadvantage in severe UEs.
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		

[1] Data from the dossier assessment of the IQWiG (A24-35) and from the addendum (A24-81), unless otherwise indicated.

KarMMa-3 study:

Idecabtagene vicleucel **vs** patient-individual therapy (PIT) with selection of daratumumab in combination with pomalidomide and dexamethasone (DPd), daratumumab in combination with bortezomib and dexamethasone (DVd), ixazomib in combination with lenalidomide and dexamethasone (IRd), carfilzomib in combination with dexamethasone (Kd), elotuzumab in combination with pomalidomide and dexamethasone (EPd)

Mortality

Endpoint	**Idecabtagene vicleucel**		**PIT with selection of DPd, DVd, IRd, Kd and EPd**		Intervention vs control
	N	Median survival time in months [95% CI][b] *Patients with event n (%)*	N	Median survival time in months [95% CI][b] *Patients with event n (%)*	HR [95%- CI][c] p value[d] Absolute difference (AD)[a]
Overall survival					
	254	41.4 [31.0; n.c.] 106 (42)	132	38.0 [23.4; n.c.] 74 (56)	1.01 [0.73; 1.40] 0.529[e]

Morbidity

Endpoint	**Idecabtagene vicleucel**		**PIT with selection of DPd, DVd, IRd, Kd and EPd**		Intervention vs control
	N	Median survival time in months [95% CI][b] *Patients with event n (%)*	N	Median survival time in months [95% CI][b] *Patients with event n (%)*	HR [95% CI][c] p value[d] Absolute difference (AD)[a]
Progression-free survival (PFS)					
	254	12.85 [11.30; 15.70] 195 (76.8)	132	4.80 [3.71; 5.91] 119 (90.2)	0.512 [0.404; 0.649] < 0.0001 AD = + 8.05 months
Symptomatology (EORTC QLQ-C30 and EORTC QLQ-MY20)					
There are no usable data.					
Health status (EQ-5D VAS)					
There are no usable data.					

Health-related quality of life

Endpoint	Idecabtagene vicleucel		PIT with selection of DPd, DVd, IRd, Kd and EPd		Intervention vs control
	N	Median survival time in months [95% CI][b] *Patients with event n (%)*	N	Median survival time in months [95% CI][b] *Patients with event n (%)*	HR [95% CI][c] p value[d] Absolute difference (AD)[a]
EORTC QLQ-C30 and EORTC QLQ-MY20					
There are no usable data.					

Side effects[f]

Endpoint	Idecabtagene vicleucel		PIT with selection of DPd, DVd, IRd, Kd and EPd		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
Total adverse events (presented additionally)					
	249	248 (100)	126	125 (99)	
Serious adverse events (SAE)					
	249	104 (42)	126	50 (40)	1.05 [0.81; 1.37] 0.736
Severe adverse events (CTCAE grade 3 or 4)					
	249	230 (92)	126	105 (83)	1.11 [1.02; 1.21] 0.007
Therapy discontinuation due to adverse events					
No data available					
Specific adverse events					
Cytokine release syndrome					
No suitable data					
Severe neurological toxicity[g]					
	249	n.r. 19 (8)	126	n.r. 11 (9)	0.89 [0.42; 1.87] 0.752

Endpoint	Idecabtagene vicleucel		PIT with selection of DPd, DVd, IRd, Kd and EPd		Intervention vs control
	N	*Patients with event n (%)*	N	*Patients with event n (%)*	RR [95% CI] p value
Infusion-related reactions					
No data available					
Severe infections[h]					
	249	n.r. 67 (27)	126	n.r. 36 (29)	0.97 [0.64; 1.45] 0.863
Secondary malignancies[i]					
	249	n.r. 18 (7)	126	n.r. 10 (8)	0.99 [0.45; 2.16] 0.972

[a] Indication of absolute difference (AD) only in case of statistically significant difference; own calculation
[b] Kaplan-Meier estimate
[c] HR and CI: Cox proportional hazards model, stratified by age, number of previous myeloma therapies and cytogenetic abnormalities according to high risk
[d] p value: Log-rank test, stratified by age, number of previous myeloma therapies and high-risk cytogenetic abnormalities
[e] p value: one-sided log-rank test, stratified by age, number of previous myeloma therapies and high-risk cytogenetic abnormalities
[f] Based on evaluations of any events occurring within the first 6 months after infusion of idecabtagene vicleucel or the 1st dose in the control arm and the severe AEs (CTCAE grade ≥ 3, SAEs and AEs of special interest) that occurred in the period from month 7 to 28 days after progression. In addition, severe AEs (CTCAE grade ≥ 3), SAEs and AEs of special interest that occurred during follow-up and were attributed to the study medication by the principal investigator, as well as any AEs that occurred in the control arm within 3 months of change of therapy, were included in the evaluations. A selection of other specific AEs on the basis of frequencies was not made.
[g] Operationalised as nervous system disorders (SOC, severe AEs [CTCAE grade ≥ 3])
[h] Operationalised as infections and infestations (SOC, severe AEs [CTCAE grade ≥ 3])
[i] Operationalised as haematological malignant tumours (sub-SMQ [narrow]), non-haematological malignant tumours (sub-SMQ [narrow]) and myelodysplastic syndrome (ad hoc PT). The following PTs were excluded: plasma cell leukaemia, plasma cell myeloma in remission, plasma cell leukaemia in remission, plasma cell myeloma, plasma cell myeloma relapse, plasma cell myeloma refractory and plasmacytoma.

Abbreviations used:
AD = Absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; DPd = daratumumab in combination with pomalidomide and dexamethasone; DVd = daratumumab in combination with bortezomib and dexamethasone; EORTC = European Organisation for Research and Treatment of Cancer; Epd = elotuzumab in combination with pomalidomide and dexamethasone; HR = hazard ratio; IRd = ixazomib in combination with lenalidomide and dexamethasone; n.d.: no data available; Kd = carfilzomib in combination with dexamethasone; CI = confidence interval; N = number of patients analysed; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; QLQ-C30 = Quality of Life Questionnaire Core-30; QLQ-MY20 = Quality of Life Questionnaire Multiple Myeloma Module 20; RCT = randomised controlled trial; SAE: serious adverse events; AE = adverse events; VAS = visual analogue scale; vs = versus

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

Adults with relapsed and refractory multiple myeloma who have received at least 2 prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy

Approx. 4,900 to 5,250 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 Abecma (active ingredient: idecabtagene vicleucel) at the following publicly accessible link (last access: 22 May 2024):

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

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material and a patient emergency card. Training material for all healthcare professionals who will prescribe, dispense, and administer idecabtagene vicleucel includes instructions for identifying, treating, and monitoring cytokine release syndrome and neurological side effects. It also includes instructions on the cell thawing process, availability of 1 dose of tocilizumab at the point of treatment, provision of relevant information to patients, and full and appropriate reporting of side effects.

The patient training programme should explain the risks of cytokine release syndrome and serious neurologic side effects, the need to report symptoms immediately to the treating physician, to remain close to the treatment facility for at least 4 weeks after infusion of idecabtagene vicleucel, and to carry the patient emergency card at all times.

Idecabtagene vicleucel must be used in a qualified treatment centre. For the infusion of idecabtagene vicleucel in multiple myeloma diagnosed with C90.00 and C90.01, the quality assurance measures for the use of CAR-T cells in B-cell neoplasms apply (ATMP Quality Assurance Guideline, Annex 1).

There is limited experience of re-treatment of patients with a second dose of Abecma. The response to re-treatment with Abecma was irregular and of shorter duration compared to the first treatment. In addition, fatal courses were observed in patients who were retreated.

A Direct Healthcare Professional Communication ("Rote-Hand-Brief") which reports on the occurrence of secondary malignancies of T-cell origin, including chimeric antigen receptor (CAR)-positive malignancies, is available for the currently approved CD19- or BCMA-targeted CAR T-cell therapies. Patients who have been treated with CAR-T cell products should therefore be monitored throughout their lives for the occurrence of secondary malignancies.

4. Treatment costs

Annual treatment costs:

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

Adults with relapsed and refractory multiple myeloma who have received at least 2 prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Idecabtagene vicleucel[Fehler! Textmarke nicht definiert.]	€ 240,000.00
Additionally required SHI services[Fehler! Textmarke nicht definiert.]	€ 752.30
Appropriate comparator therapy:	
A patient-individual therapy under selection of:	
Bortezomib in combination with pegylated liposomal doxorubicin (only for at least double-refractory subjects who are ineligible for triplet therapy)	
Bortezomib	€ 5,603.52
Doxorubicin (pegylated, liposomal)	€ 17,454.64
Total	€ 23,058.16
Bortezomib in combination with dexamethasone (only for at least double-refractory subjects who are ineligible for triplet therapy)	
Bortezomib	€ 2,801.76 - € 5,603.52
Dexamethasone	€ 104.18- € 168.97
Total	€ 2,905.94 - € 5,772.49
Carfilzomib in combination with lenalidomide and dexamethasone	
Carfilzomib	€ 80,017.58
Lenalidomide	€ 463.41
Dexamethasone	€ 193.47
Total	€ 80,674.46
Additionally required SHI services	€ 11.40
Carfilzomib in combination with dexamethasone	
Carfilzomib	€ 150,928.12
Dexamethasone	€ 243.11
Total	€ 151,171.23
Cyclophosphamide monotherapy (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)	
Cyclophosphamide	€ 515.75 - € 4,452.39
Cyclophosphamide in combination with dexamethasone	
Cyclophosphamide	Not calculable
Dexamethasone	Not calculable
Total	Not calculable

Designation of the therapy	Annual treatment costs/ patient
Daratumumab monotherapy (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)	
Daratumumab	€ 133,581.01
Additionally required SHI services	€ 321.04- € 588.00
Daratumumab in combination with lenalidomide and dexamethasone	
Daratumumab	€ 133,581.01
Lenalidomide	€ 463.41
Dexamethasone	€ 107.90
Total	€ 134,152.32
Additionally required SHI services	€ 254.23- € 257.53
Daratumumab in combination with pomalidomide and dexamethasone	
Daratumumab	€ 133,581.01
Pomalidomide	€ 34,399.17
Dexamethasone	€ 107.90
Total	€ 168,088.08
Additionally required SHI services	€ 254.23- € 257.53
Daratumumab in combination with bortezomib and dexamethasone	
Daratumumab	€ 121,965.27
Bortezomib	€ 5,603.52
Dexamethasone	€ 147.30
Total	€ 127,716.09
Additionally required SHI services	€ 204.08- € 207.09
Daratumumab in combination with carfilzomib and dexamethasone	
Daratumumab	€ 133,581.01
Carfilzomib	€ 150,928.12
Dexamethasone	€ 174.17
Total	€ 284,683.30
Additionally required SHI services	€ 225.19- € 228.49
Elotuzumab in combination with lenalidomide and dexamethasone	
Elotuzumab	€ 88,213.80
Lenalidomide	€ 463.41
Dexamethasone	€ 185.74
Total	€ 88,862.95
Additionally required SHI services	€ 274.75- € 279.05
Elotuzumab + pomalidomide + dexamethasone	
Elotuzumab	€ 88,213.80

Designation of the therapy	Annual treatment costs/ patient
Pomalidomide	€ 34,399.17
Dexamethasone	€ 188.58
Total	€ 122,801.55
Additionally required SHI services	€ 178.18- € 180.91
Isatuximab in combination with pomalidomide and dexamethasone	
Isatuximab	€ 69,231.68
Pomalidomide	€ 34,399.17
Dexamethasone	€ 193.47
Total	€ 103,824.32
Additionally required SHI services	€ 11.40
Isatuximab in combination with carfilzomib and dexamethasone	
Isatuximab	€ 69,231.68
Carfilzomib	€ 150,928.12
Dexamethasone	€ 630.40
Total	€ 220,790.20
Ixazomib in combination with lenalidomide and dexamethasone (only for subjects who are refractory to bortezomib, carfilzomib and an anti-CD38 antibody)	
Ixazomib	€ 78,848.90
Lenalidomide	€ 463.41
Dexamethasone	€ 193.47
Total	€ 79,505.78
Additionally required SHI services	€ 11.40
Lenalidomide in combination with dexamethasone (only for at least double-refractory subjects who are ineligible for triplet therapy)	
Lenalidomide	€ 463.41
Dexamethasone	€ 312.53
Total	€ 775.94
Additionally required SHI services	€ 11.40
Melphalan monotherapy (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)	
Melphalan	€ 602.16
Melphalan in combination with prednisone or prednisolone (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)	
Melphalan	€ 402.98- € 602.16
Prednisone	€ 133.54- € 199.54
Total	€ 536.52- € 801.70
Prednisolone	€ 62.71- € 93.70

Designation of the therapy	Annual treatment costs/ patient
Total	€ 465.69- € 695.86
Pomalidomide in combination with bortezomib and dexamethasone (only for subjects who are refractory to an anti-CD38 antibody and lenalidomide)	
Pomalidomide	€ 30,694.64
Bortezomib	€ 8,895.59
Dexamethasone	€ 237.50
Total	€ 39,827.73
Additionally required SHI services	€ 11.40
Pomalidomide in combination with dexamethasone (only for at least double-refractory subjects who are ineligible for triplet therapy)	
Pomalidomide	€ 34,399.17
Dexamethasone	€ 193.47
Total	€ 34,592.64
Additionally required SHI services	€ 11.40
Panobinostat in combination with bortezomib and dexamethasone	
Panobinostat	€ 35,134.16 - € 70,268.32
Bortezomib	€ 5,603.52 - € 8,405.28
Dexamethasone	€ 168.97- € 233.76
Total	€ 40,906.65 - € 78,907.36

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 September 2024)

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					
Idecabtagene vicleucel lymphocyte depletion					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Fludarabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3	€ 300
Appropriate comparator therapy					
Bortezomib in combination with pegylated liposomal doxorubicin (only for at least double-refractory subjects who are ineligible for triplet therapy)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	32.0	€ 3,200
Doxorubicin (pegylated, liposomal)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	Day 4 21-day cycle	8.0	€ 800
Bortezomib in combination with dexamethasone (only for at least double-refractory subjects who are ineligible for triplet therapy)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	16.0 – 32.0	€ 1,600 - € 3,200
Carfilzomib in combination with lenalidomide and dexamethasone					

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	1st - 12th cycle: 6 From 13th cycle: 4	76.0	€ 7,600
Carfilzomib in combination with dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Cyclophosphamide monotherapy (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0 – 365.0	€ 1,300 – € 36,500
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
Elotuzumab in combination with lenalidomide and dexamethasone					
Elotuzumab	Surcharge for the preparation of a parenteral solution	€ 100	1st - 2nd cycle: 4	30.0	€ 3,000

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing monoclonal antibodies		From 3rd cycle: 2		
Elotuzumab + pomalidomide + 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
Isatuximab in combination with pomalidomide and dexamethasone					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1st cycle: 4 From 2nd cycle: 2	28.0	€ 2,800
Isatuximab in combination with carfilzomib and dexamethasone					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1st cycle: 4 From 2nd cycle: 2	28.0	€ 2,800
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
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:	32 – 48	€ 3,200 – € 4,800

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
			2		
Pomalidomide in combination with bortezomib and dexamethasone (only for subjects who are refractory to an anti-CD38 antibody and lenalidomide)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1st - 8th cycle: 4 From 9th cycle: 2	50.8	€ 5,080
Melphalan monotherapy (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)					
Melphalan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
Melphalan in combination with prednisolone or prednisone (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)					
Melphalan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	8.7 – 13.0	€ 870 - € 1,300
Elotuzumab + pomalidomide + 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
Isatuximab in combination with pomalidomide and dexamethasone					
Isatuximab	Surcharge for the preparation of a parenteral solution containing	€ 100	1st cycle: 4 From 2nd cycle: 2	28.0	€ 2,800

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	monoclonal antibodies				
Isatuximab in combination with carfilzomib and dexamethasone					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1st cycle: 4 From 2nd cycle: 2	28.0	€ 2,800
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
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
Pomalidomide in combination with bortezomib and dexamethasone (only for subjects who are refractory to an anti-CD38 antibody and lenalidomide)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1st - 8th cycle: 4 From 9th cycle: 2	50.8	€ 5,080
Melphalan monotherapy (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)					
Melphalan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Melphalan in combination with prednisolone or prednisone (only for at least triple refractory subjects who are ineligible for triplet or doublet therapy)					
Melphalan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	8.7 – 13.0	€ 870 - € 1,300

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 relapsed and refractory multiple myeloma who have received at least 2 prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy

– 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 September 2024.

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

Berlin, 19 September 2024

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

Prof. Hecken