

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
Linoseltamab (multiple myeloma, at least 3 prior therapies,
monotherapy)

From 19 March 2026

At their session on 19 March 2026, 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 shall be amended in alphabetical order to include the active ingredient
Linoseltamab as follows:**

Linvoseltamab

Resolution of: 19 March 2026

Entry into force on: 19 March 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

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

Lynozyfic is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, and have demonstrated disease progression on the last therapy.

Therapeutic indication of the resolution (resolution of 19 March 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 three prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Appropriate comparator therapy:

An individualised therapy with 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 subjects who are refractory to a CD38 antibody and lenalidomide are eligible]
- Ixazomib in combination with lenalidomide and dexamethasone [only subjects who are refractory to bortezomib, carfilzomib and a CD38 antibody are eligible]
- Carfilzomib in combination with dexamethasone

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

An additional benefit is not proven.

- b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Appropriate comparator therapy:

An individualised therapy with 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 subjects who are refractory to a CD38 antibody and lenalidomide are eligible]
- Ixazomib in combination with lenalidomide and dexamethasone [only subjects who are refractory to bortezomib, carfilzomib and a CD38 antibody are eligible]
- Panobinostat in combination with bortezomib and dexamethasone
- Carfilzomib in combination with dexamethasone
- Pomalidomide in combination with dexamethasone [only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible]
- Lenalidomide in combination with dexamethasone [only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible]
- Bortezomib in combination with pegylated liposomal doxorubicin [only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible]
- Bortezomib in combination with dexamethasone [only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible]
- 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]
- 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 livoseltamab compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:¹

- a) Adults with relapsed or refractory multiple myeloma who have received three prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

No data are available to allow an assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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		

- b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

No data are available to allow an assessment of the additional benefit.

¹ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-127), unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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 three prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Approx. 150 to 160 patients

- b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Approx. 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 Lynozyfic (active ingredient: livoseltamab) at the following publicly accessible link (last access: 9 February 2026):

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

Treatment with livoseltamab 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 a patient card.

The patient card is intended to explain the risks of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome and when patients should seek urgent medical treatment in the event of signs and symptoms. In addition, the patient card reminds patients that they should stay close to a medical facility and be monitored daily for signs and symptoms for 48 hours after being administered the step-up doses.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is anticipated. The EMA will assess new information on this medicinal product at least annually and update the product information as necessary.

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 three prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Linvoseltamab	€ 212,956.34 – € 279,220.49
Appropriate comparator therapy:	
An individualised therapy with selection of	
Carfilzomib in combination with lenalidomide and dexamethasone	
Carfilzomib	€ 80,035.52
Lenalidomide	€ 464.40
Dexamethasone	€ 193.71
Total	€ 80,693.63
Additionally required SHI services	€ 10.49
Elotuzumab in combination with lenalidomide and dexamethasone	
Elotuzumab	€ 88,227.60
Lenalidomide	€ 464.40
Dexamethasone	€ 186.05
Total	€ 88,878.05
Additionally required SHI services	€ 284.80 – € 289.10
Elotuzumab in combination with pomalidomide and dexamethasone	

Designation of the therapy	Annual treatment costs/ patient
Elotuzumab	€ 88,227.60
Pomalidomide	€ 26,904.41
Dexamethasone	€ 188.86
Total	€ 115,320.87
Additionally required SHI services	€ 184.21 – € 186.94
Daratumumab in combination with bortezomib and dexamethasone	
Daratumumab	€ 121,970.10
Bortezomib	€ 5,610.88
Dexamethasone	€ 147.76
Total	€ 127,728.74
Additionally required SHI services	€ 210.41 – € 213.42
Daratumumab in combination with lenalidomide and dexamethasone	
Daratumumab	€ 133,586.30
Lenalidomide	€ 464.40
Dexamethasone	€ 108.03
Total	€ 134,158.73
Additionally required SHI services	€ 261.25 – € 264.55
Daratumumab in combination with carfilzomib and dexamethasone	
Daratumumab	€ 133,586.30
Carfilzomib	€ 150,998.96
Dexamethasone	€ 174.49
Total	€ 284,759.75
Additionally required SHI services	€ 232.21 – € 235.51
Daratumumab in combination with pomalidomide and dexamethasone	
Daratumumab	€ 133,586.30
Pomalidomide	€ 26,904.41
Dexamethasone	€ 108.03
Total	€ 160,598.74
Additionally required SHI services	€ 261.25 – € 264.55
Isatuximab in combination with carfilzomib and dexamethasone	
Isatuximab	€ 69,257.44
Carfilzomib	€ 150,998.96
Dexamethasone	€ 639.61
Total	€ 220,896.01

Designation of the therapy	Annual treatment costs/ patient
Isatuximab in combination with pomalidomide and dexamethasone	
Isatuximab	€ 69,257.44
Pomalidomide	€ 26,904.41
Dexamethasone	€ 193.71
Total	€ 96,355.56
Additionally required SHI services	€ 10.49
Pomalidomide in combination with bortezomib and dexamethasone (only subjects, who are refractory to a CD38 antibody and lenalidomide, are eligible)	
Pomalidomide	€ 24,007.01
Bortezomib	€ 8,907.27
Dexamethasone	€ 237.97
Total	€ 33,152.25
Additionally required SHI services	€ 10.49
Ixazomib in combination with lenalidomide and dexamethasone (only subjects, who are refractory to bortezomib, carfilzomib and a CD38 antibody, are eligible)	
Ixazomib	€ 78,851.89
Lenalidomide	€ 464.40
Dexamethasone	€ 193.71
Total	€ 79,510.00
Additionally required SHI services	€ 10.49
Carfilzomib in combination with dexamethasone	
Carfilzomib	€ 150,998.96
Dexamethasone	€ 243.59
Total	€ 151,242.55 €

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 January 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					
Linvoseltamab					
Linvoseltamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	25.3 – 32.6	€ 2,530 – € 3,260
Appropriate comparator therapy					
Carfilzomib in combination with lenalidomide and dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	<u>1st – 12th cycle:</u> 6 <u>From 13th cycle:</u> 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	<u>1st - 2nd cycle:</u> 4 <u>From 3rd cycle:</u> 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	<u>1st - 2nd cycle:</u> 4 <u>From 3rd cycle:</u> 1	19.0	€ 1,900
Daratumumab in combination with bortezomib and dexamethasone					

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
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					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st cycle:</u> 4 <u>From 2nd cycle:</u> 2	28.0	€ 2,800
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Isatuximab in combination with pomalidomide and dexamethasone					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st cycle:</u> 4 <u>From 2nd cycle:</u> 2	28.0	€ 2,800
Pomalidomide in combination with bortezomib and dexamethasone (only for subjects, who are refractory to an anti-CD38 antibody and lenalidomide, are eligible)					
Bortezomib	Surcharge for production of a parenteral	€ 100	<u>1st - 8th cycle:</u> 4	50.8	€ 5,080

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	preparation containing cytostatic agents		From 9 th cycle: 2		
Carfilzomib in combination with dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800

- b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Linvoseltamab	€ 212,956.34 – € 279,220.49
Appropriate comparator therapy:	
An individualised therapy with selection of	
Carfilzomib in combination with lenalidomide and dexamethasone	
Carfilzomib	€ 80,035.52
Lenalidomide	€ 464.40
Dexamethasone	€ 193.71
Total	€ 80,693.63
Additionally required SHI services	€ 10.49
Elotuzumab in combination with lenalidomide and dexamethasone	
Elotuzumab	€ 88,227.60
Lenalidomide	€ 464.40
Dexamethasone	€ 186.05
Total	€ 88,878.05
Additionally required SHI services	€ 284.80 – € 289.10
Elotuzumab in combination with pomalidomide and dexamethasone	
Elotuzumab	€ 88,227.60
Pomalidomide	€ 26,904.41

Designation of the therapy	Annual treatment costs/ patient
Dexamethasone	€ 188.86
Total	€ 115,320.87
Additionally required SHI services	€ 184.21 – € 186.94
Daratumumab in combination with bortezomib and dexamethasone	
Daratumumab	€ 121,970.10
Bortezomib	€ 5,610.88
Dexamethasone	€ 147.76
Total	€ 127,728.74
Additionally required SHI services	€ 210.41 – € 213.42
Daratumumab in combination with lenalidomide and dexamethasone	
Daratumumab	€ 133,586.30
Lenalidomide	€ 464.40
Dexamethasone	€ 108.03
Total	€ 134,158.73
Additionally required SHI services	€ 261.25 – € 264.55
Daratumumab in combination with carfilzomib and dexamethasone	
Daratumumab	€ 133,586.30
Carfilzomib	€ 150,998.96
Dexamethasone	€ 174.49
Total	€ 284,759.75
Additionally required SHI services	€ 232.21 – € 235.51
Daratumumab in combination with pomalidomide and dexamethasone	
Daratumumab	€ 133,586.30
Pomalidomide	€ 26,904.41
Dexamethasone	€ 108.03
Total	€ 160,598.74
Additionally required SHI services	€ 261.25 – € 264.55
Isatuximab in combination with carfilzomib and dexamethasone	
Isatuximab	€ 69,257.44
Carfilzomib	€ 150,998.96
Dexamethasone	€ 639.61
Total	€ 220,896.01
Isatuximab in combination with pomalidomide and dexamethasone	
Isatuximab	€ 69,257.44

Designation of the therapy	Annual treatment costs/ patient
Pomalidomide	€ 26,904.41
Dexamethasone	€ 193.71
Total	€ 96,355.56
Additionally required SHI services	€ 10.49
Pomalidomide in combination with bortezomib and dexamethasone (only subjects, who are refractory to a CD38 antibody and lenalidomide, are eligible)	
Pomalidomide	€ 24,007.01
Bortezomib	€ 8,907.27
Dexamethasone	€ 237.97
Total	€ 33,152.25
Additionally required SHI services	€ 10.49
Ixazomib in combination with lenalidomide and dexamethasone (only subjects, who are refractory to bortezomib, carfilzomib and a CD38 antibody, are eligible)	
Ixazomib	€ 78,851.89
Lenalidomide	€ 464.40
Dexamethasone	€ 193.71
Total	€ 79,510.00
Additionally required SHI services	€ 10.49
Panobinostat in combination with bortezomib and dexamethasone	
Panobinostat	€ 35,136.00 – € 70,272.00
Bortezomib	€ 5,610.88 – € 8,416.32
Dexamethasone	€ 169.43 – € 234.22
Total	€ 40,916.31 – € 78,922.54
Carfilzomib in combination with dexamethasone	
Carfilzomib	€ 150,998.96
Dexamethasone	€ 243.59
Total	€ 151,242.55 €
Pomalidomide in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)	
Pomalidomide	€ 26,904.41
Dexamethasone	€ 193.71
Total	€ 27,098.12
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	€ 464.40

Designation of the therapy	Annual treatment costs/ patient
Dexamethasone	€ 312.92
Total	€ 777.32
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	€ 5,610.88
Doxorubicin (pegylated, liposomal)	€ 17,458.32
Total	€ 23,069.20
Bortezomib in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)	
Bortezomib	€ 2,805.44 – € 5,610.88
Dexamethasone	€ 104.64 – € 169.43
Total	€ 2,910.08 – € 5,780.31
Daratumumab monotherapy (only at least triple-refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)	
Daratumumab	€ 133,586.30
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	€ 590.85 - € 5,347.61
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	€ 605.15
Melphalan in combination with prednisolone or prednisone (only at least triple refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)	
Melphalan	€ 404.99 – € 605.15
Prednisone	€ 134.10 – € 200.38
Total	€ 539.09 – € 805.53
Prednisolone	€ 63.27 – € 94.54
Total	€ 468.26 – € 699.69

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 January 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					
Linvoseltamab					
Linvoseltamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	25.3 – 32.6	€ 2,530 – € 3,260
Appropriate comparator therapy					
Carfilzomib in combination with lenalidomide and dexamethasone					
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1 st – 12 th cycle: 6 From 13 th 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	<u>1st – 2nd cycle: 4</u> <u>From 3rd cycle: 2</u>	30.0	€ 3,000
Elotuzumab in combination with pomalidomide and dexamethasone					
Elotuzumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st – 2nd cycle: 4</u> <u>From 3rd cycle: 1</u>	19.0	€ 1,900
Daratumumab in combination with bortezomib and dexamethasone					

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
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					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st cycle:</u> 4 <u>From 2nd cycle:</u> 2	28.0	€ 2,800
Carfilzomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	6	78.0	€ 7,800
Isatuximab in combination with pomalidomide and dexamethasone					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	<u>1st cycle:</u> 4 <u>From 2nd cycle:</u> 2	28.0	€ 2,800
Pomalidomide in combination with bortezomib and dexamethasone (only for subjects, who are refractory to an anti-CD38 antibody and lenalidomide, are eligible)					
Bortezomib	Surcharge for production of a parenteral	€ 100	<u>1st - 8th cycle:</u> 4	50.8	€ 5,080

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	preparation containing cytostatic agents		From 9 th cycle: 2		
Panobinostat in combination with bortezomib and dexamethasone					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1 st - 8 th cycle: 4 9 th - 16 th 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 (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)					
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	1	8.0	€ 800
Bortezomib in combination with dexamethasone (only at least double-refractory subjects, who are ineligible for triplet therapy, are eligible)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	16.0 – 32.0	€ 1,600 € 3,200

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cyclophosphamide monotherapy (only at least triple refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0 – 365.0	€ 1,300 – € 36,500
Melphalan monotherapy (only at least triple refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
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 at least triple refractory subjects, who are ineligible for triplet or doublet therapy, are eligible)					
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:

- a) Adults with relapsed or refractory multiple myeloma who have received three prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient approved in monotherapy.

- b) Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies and have demonstrated disease progression on the last therapy; pretreatment includes a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient approved in monotherapy.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between statutory 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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product livoseltamab is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5 per cent of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant percentage within the scope of SGB V.

II. The resolution will enter into force on the day of its publication on the G-BA website on 19 March 2026.

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

Berlin, 19 March 2026

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

Prof. Hecken