

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
Isatuximab

(New therapeutic indication: multiple myeloma, first-line,
suitable for stem cell transplant, combination with
bortezomib, lenalidomide and dexamethasone)

of 19 February 2026

At their session on 19 February 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. In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Isatuximab in accordance with the resolution of 7 August 2025:**

Isatuximab

Resolution of: 19 February 2026
Entry into force on: 19 February 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 18 July 2025):

SARCLISA is indicated in combination with bortezomib, lenalidomide, and dexamethasone, for the induction treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Therapeutic indication of the resolution (resolution of 19 February 2026):

See new therapeutic indication according to marketing authorisation.

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

Adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant; induction treatment

Appropriate comparator therapy:

- An induction therapy consisting of:
 - Bortezomib + thalidomide + dexamethasone (VTd)
or
 - bortezomib + cyclophosphamide + dexamethasone (VCd) [only patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy are eligible; see Annex VI to Section K of the Pharmaceuticals Directive]
or
 - daratumumab + bortezomib + thalidomide + dexamethasone (D-VTd)
or
 - daratumumab + bortezomib + lenalidomide + dexamethasone (D-VRd),

- followed by a high-dose therapy with melphalan and subsequent autologous stem cell transplant

Extent and probability of the additional benefit of isatuximab in combination with bortezomib, lenalidomide and dexamethasone compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:¹

Adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant; induction treatment

There are no assessable data.

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

Adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant; induction treatment

Approx. 1,750 to 1,910 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 Sarclisa (active ingredient: isatuximab) at the following publicly accessible link (last access: 11 February 2026):

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

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

¹ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-105), unless otherwise indicated.

In accordance with the European Medicines Agency (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 on how to manage the risk of isatuximab interfering with blood typing (indirect antihuman globulin test or indirect Coombs test). Isatuximab-induced interference with blood typing may persist for approximately 6 months after the last infusion of the medicinal product; therefore, healthcare professionals should advise patients to carry their patient identification card with them until 6 months after the end of treatment.

4. Treatment costs

Annual treatment costs:

Adults with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant; induction treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Isatuximab in combination with bortezomib, lenalidomide and dexamethasone	
Induction	
Isatuximab	€ 27,208.28
Bortezomib	€ 4,208.16
Lenalidomide	€ 179.12
Dexamethasone	€ 192.90
Total induction	€ 31,788.46
High-dose therapy with melphalan and subsequent autologous stem cell transplant	
Stem cell collection	€ 3,701.58 – € 4,440.07
High-dose therapy with melphalan with autologous stem cell transplant	€ 21,804.65
Total	€ 25,506.23 – € 26,244.72
Total	
Induction + high-dose therapy with melphalan and subsequent autologous stem cell transplant	€ 57,294.69 – € 58,033.18
Appropriate comparator therapy:	
Bortezomib + thalidomide + dexamethasone (VTd)	
Induction	
Bortezomib	€ 2,805.44 – € 4,208.16
Thalidomide	€ 2,213.08 – € 8,382.28
Dexamethasone	€ 159.64 – € 186.26

Designation of the therapy	Annual treatment costs/ patient
Total induction	€ 5,178.16 – € 12,776.70
High-dose therapy with melphalan and subsequent autologous stem cell transplant	
Stem cell collection	€ 3,701.58 – € 4,440.07
High-dose therapy with melphalan with autologous stem cell transplant	€ 21,804.65
Total	€ 25,506.23 – € 26,244.72
Total	
Induction + high-dose therapy with melphalan and subsequent autologous stem cell transplant	€ 30,684.39 – € 39,021.42
Additionally required SHI services	€ 10.49
Bortezomib + cyclophosphamide + dexamethasone (VCd) (only patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy are eligible; see Annex VI to Section K of the Pharmaceuticals Directive)	
Induction	
Bortezomib	€ 2,104.08 – € 2,805.44
Cyclophosphamide	€ 136.35 – € 197.71
Dexamethasone	€ 124.34 – € 159.64
Total induction	€ 2,364.77 – € 3,162.79
High-dose therapy with melphalan and subsequent autologous stem cell transplant	
Stem cell collection	€ 3,701.58 – € 4,440.07
High-dose therapy with melphalan with autologous stem cell transplant	€ 21,804.65
Total	€ 25,506.23 – € 26,244.72
Total	
Induction + high-dose therapy with melphalan and subsequent autologous stem cell transplant	€ 27,871.00 – € 29,407.51
daratumumab + bortezomib + thalidomide + dexamethasone (D-VTd)	
Induction	
Daratumumab	€ 69,697.20
Bortezomib	€ 2,805.44
Thalidomide	€ 2,467.68
Dexamethasone	€ 75.17
Total induction	€ 75,045.49
High-dose therapy with melphalan and subsequent autologous stem cell transplant	
Stem cell collection	€ 3,701.58 – € 4,440.07

Designation of the therapy	Annual treatment costs/ patient
High-dose therapy with melphalan with autologous stem cell transplant	€ 21,804.65
Total	€ 25,506.23 – € 26,244.72
Total	
Induction + high-dose therapy with melphalan and subsequent autologous stem cell transplant	€ 100,551.72 – € 101,290.21
Additionally required SHI services	€ 225.73 – € 228.60
Daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd)	
Induction	
Daratumumab	€ 69,697.20
Bortezomib	€ 2,805.44
Lenalidomide	€ 179.12
Dexamethasone	€ 124.34
Total induction	€ 72,806.10
High-dose chemotherapy and subsequent autologous stem cell transplant	
Stem cell collection	€ 3,701.58 – € 4,440.07
High-dose therapy with melphalan with autologous stem cell transplant	€ 21,804.65
Total	€ 25,506.23 – € 26,244.72
Total	
Induction + high-dose chemotherapy with autologous stem cell transplant	€ 98,312.33 – € 99,050.82
Additionally required SHI services	€ 225.73 – € 228.60

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 December 2025)

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					
Isatuximab in combination with bortezomib, lenalidomide and dexamethasone (induction)					
Isatuximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	5 (cycle 1) 3 (cycle 2 – 3)	11.0	€ 1,100
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	8	24.0	€ 2,400
Appropriate comparator therapy					
Bortezomib + thalidomide + dexamethasone (VTd) (induction)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	16.0 – 24.0	€ 1,600 – € 2,400
Bortezomib + cyclophosphamide + dexamethasone (VCd) (only patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy are eligible; see Annex VI to Section K of the Pharmaceuticals Directive) (induction)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	12.0 – 16.0	€ 1,200 – € 1,600
Cyclophosphamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	3.0 – 4.0	€ 300 – € 400
daratumumab + bortezomib + thalidomide + dexamethasone (D-VTd) (induction)					
Bortezomib	Surcharge for production of a	€ 100	4	16.0	€ 1,600

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral preparation containing cytostatic agents				
Daratumumab in combination with bortezomib, lenalidomide and dexamethasone (D-VRd) (induction)					
Bortezomib	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	4	16.0	€ 1,600

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 eligible for autologous stem cell transplant; induction treatment

- No medicinal product with new active ingredients that can be used in a combination therapy, for which the requirements of Section 35a, paragraph 3, sentence 4 SGB V are fulfilled.

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 February 2026.

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

Berlin, 19 February 2026

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

Prof. Hecken