Isatuximab
(newly diagnosed multiple myeloma, eligible for stem cell transplant)

Benefit assessment according to §35a SGB V[1]

EXTRACT

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Isatuximab, Bortezomib, Lenalidomide, Dexamethasone, Multiple Myeloma, Benefit Assessment

Medical and scientific advice

No advisor on medical and scientific questions was involved in the present dossier assessment.

Patient and family involvement

No patients or families were involved in the present dossier assessment.

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Part I: Benefit assessment

I Table of contents

I List of tables[2]

Page

[2] Table numbers start with “2” as numbering follows that of the full dossier assessment.

I List of abbreviations

Abbreviation	Meaning
ACT	appropriate comparator therapy
ASCT	autologous stem cell transplant
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
MRD	minimal residual disease
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)

I 1 Executive summary of the benefit assessment

Background

In accordance with §35a Social Code Book V, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug isatuximab (in combination with bortezomib, lenalidomide and dexamethasone). The assessment is based on a dossier compiled by the pharmaceutical company (hereinafter referred to as the 'company'). That dossier was sent to IQWiG on 13 August 2025.

Research question

The aim of this report is to assess the added benefit of isatuximab in combination with bortezomib, lenalidomide and dexamethasone for induction therapy (hereinafter 'isatuximab + bortezomib + lenalidomide + dexamethasone'), in comparison with the appropriate comparator therapy (ACT), in patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT).

The research question shown in Table 2 was defined in accordance with the ACT specified by the G-BA.

Table 2: Research question for the benefit assessment of isatuximab + bortezomib + lenalidomide + dexamethasone

Therapeutic indication	**ACT**[a]
Adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant	▪ An induction therapy consisting of ▫ bortezomib + thalidomide + dexamethasone (VTd) or ▫ bortezomib + cyclophosphamide + dexamethasone (VCd)[b] or ▫ daratumumab + bortezomib + thalidomide + dexamethasone (D-VTd) or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (D-VRd) ▪ followed by high-dose therapy with melphalan and subsequent autologous stem cell transplantation ▪ followed by consolidation therapy[c] consisting of ▫ daratumumab + bortezomib + thalidomide + dexamethasone (only when using induction therapy with D-VTd)[d] or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (only when using induction therapy with D-VRd)[e] ▪ followed by maintenance treatment consisting of ▫ lenalidomide or ▫ daratumumab + lenalidomide (only when using induction or consolidation therapy with D-VRd)

a. Presented is the ACT specified by the G-BA.
b. Only for patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy; see Appendix VI to Section K of the Pharmaceutical Directive.
c. According to the G-BA, the concept of 'consolidation' therapy must be distinguished from that of 'maintenance treatment', which address different therapeutic goals.
d. Only if D-VTd-based induction therapy is used does consolidation therapy with 2 cycles of D-VTd following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.
e. Only if D-VRd-based induction therapy is used does consolidation therapy with 2 cycles of D-VRd with subsequent maintenance treatment with daratumumab + lenalidomide following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.

ACT: appropriate comparator therapy; C: cyclophosphamide; D: daratumumab; d: dexamethasone; G-BA: Federal Joint Committee; R: lenalidomide; SmPC: summary of product characteristics; T: thalidomide; V: bortezomib

On 12 August 2025, the day on which the company submitted its dossier, the G-BA modified the ACT. When specifying the ACT in its dossier, the company mainly referred to a consultation with the G-BA from 2024. Deviating from this consultation, the company only considered

induction therapy followed by high-dose therapy with melphalan and subsequent ASCT, and the consolidation therapy to be part of the ACT. The company did not consider maintenance treatment to be included in the ACT, as isatuximab + bortezomib + lenalidomide + dexamethasone is exclusively authorized for induction therapy. In addition, the company limited the selection of drugs in induction therapy to quadruple combination therapies (namely daratumumab + bortezomib + thalidomide + dexamethasone or daratumumab + bortezomib + lenalidomide + dexamethasone). The ACT specified by the company did not correspond to the ACT specified by the G-BA on 12 August 2025. Overall, the company's deviations from the ACT remained without consequence, as it did not present any suitable data either versus its ACT or versus the G-BA's ACT. This assessment was carried out versus the current ACT specified by the G-BA.

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) were used to derive the added benefit. This concurs with the company's inclusion criteria.

Results

Consisting with the findings of the company, no relevant studies on the direct comparison of isatuximab + bortezomib + lenalidomide + dexamethasone in comparison with the ACT were identified in the review.

In Module 4 D, Section 4.4, the company summarized the results of the pivotal RCT GMMG-HD7, but did not use these results to derive an added benefit.

Concurring with the company's assessment, the GMMG-HD7 study was not suitable for deriving conclusions on the added benefit of isatuximab + bortezomib + lenalidomide + dexamethasone in comparison with the ACT for the given research question. The GMMG-HD7 study is described below, and the reasons for its unsuitability for the benefit assessment are provided.

Evidence presented by the company – the GMMG-HD7 study

GMMG-HD7 is an ongoing, open-label RCT comparing isatuximab + bortezomib + lenalidomide + dexamethasone versus bortezomib + lenalidomide + dexamethasone, each followed by high-dose therapy with melphalan with subsequent ASCT and, after re-randomization, maintenance treatment with isatuximab + lenalidomide or lenalidomide monotherapy. Adult patients with newly diagnosed multiple myeloma who were eligible for high-dose therapy and ASCT were included.

A total of 662 patients were included in the GMMG-HD7 study and randomized in a 1:1 ratio.

The study treatment was divided into 2 phases: induction and maintenance. After randomization, patients in both study arms received treatment with bortezomib, lenalidomide and dexamethasone for 3 cycles (1 cycle corresponded to 6 weeks) as induction therapy. In the intervention arm, the treatment was given in combination with isatuximab. This was followed by stem cell mobilization, high-dose therapy with melphalan and an ASCT. Prior to maintenance treatment, all patients were randomized again, either to combination therapy with lenalidomide + isatuximab or to monotherapy with lenalidomide, each administered in a 28-day cycle until disease progression, the occurrence of unacceptable toxicity or up to a maximum of 3 years.

The drug combination used as induction therapy in the comparator arm and maintenance treatment with isatuximab and lenalidomide are not approved in this therapeutic indication.

The primary outcome of the GMMG-HD7 study was the minimal residual disease (MRD) negativity rate and progression-free survival. Secondary outcomes were recorded in the categories of mortality, morbidity, health-related quality of life and side effects.

ACT not implemented in the GMMG-HD7 study

As part of its ACT, the G-BA specified the following options for induction therapy:

- bortezomib + thalidomide + dexamethasone, or
- bortezomib + cyclophosphamide + dexamethasone (only for patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy), or
- daratumumab + bortezomib + thalidomide + dexamethasone, or
- daratumumab + bortezomib + lenalidomide + dexamethasone

Therefore, the induction therapy with bortezomib + lenalidomide + dexamethasone used in the comparator arm of GMMG-HD7 did not correspond to the G-BA's specification.

In its ACT, the G-BA specified the following options for maintenance treatment:

- lenalidomide
- daratumumab + lenalidomide (only when using induction or consolidation therapy with the drug combination daratumumab + bortezomib + lenalidomide + dexamethasone)

Deviating from this, all patients in the GMMG-HD7 study were randomized again after the ASCT for maintenance treatment. The patients were divided into an arm with lenalidomide monotherapy and an arm with isatuximab + lenalidomide combination therapy. This did not correspond to the ACT specified by the G-BA.

In summary, induction therapy and maintenance treatment in the comparator arm did not correspond to the ACT, so there were no data on the comparison of isatuximab + bortezomib + lenalidomide + dexamethasone with the comparator therapy specified by the G-BA.

Results on added benefit

Since no relevant study was available for the benefit assessment, there is no hint of an added benefit of isatuximab + bortezomib + lenalidomide + dexamethasone versus the ACT; an added benefit is therefore not proven.

Probability and extent of added benefit, patient groups with therapeutically important added benefit[3]

Table 3 shows a summary of the probability and extent of the added benefit of isatuximab + bortezomib + lenalidomide + dexamethasone.

[3] On the basis of the scientific data analysed, IQWiG draws conclusions on the (added) benefit or harm of an intervention for each patient-relevant outcome. Depending on the number of studies analysed, the certainty of their results, and the direction and statistical significance of treatment effects, conclusions on the probability of (added) benefit or harm are graded into 4 categories: (1) “proof”, (2) “indication”, (3) “hint”, or (4) none of the first 3 categories applies (i.e., no data available or conclusions 1 to 3 cannot be drawn from the available data). The extent of added benefit or harm is graded into 3 categories: (1) major, (2) considerable, (3) minor (in addition, 3 further categories may apply: non-quantifiable extent of added benefit, added benefit not proven, or less benefit). For further details see [1,2].

Table 3: Isatuximab + bortezomib + lenalidomide + dexamethasone – probability and extent of added benefit

Therapeutic indication	**ACT**[a]	**Probability and extent of added benefit**
Adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant	▪ An induction therapy consisting of ▫ bortezomib + thalidomide + dexamethasone (VTd) or ▫ bortezomib + cyclophosphamide + dexamethasone (VCd)[b] or ▫ daratumumab + bortezomib + thalidomide + dexamethasone (D-VTd) or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (D-VRd) ▪ followed by high-dose therapy with melphalan and subsequent autologous stem cell transplantation ▪ followed by consolidation therapy[c] consisting of ▫ daratumumab + bortezomib + thalidomide + dexamethasone (only when using induction therapy with D-VTd)[d] or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (only when using induction therapy with D-VRd)[e] ▪ followed by maintenance treatment consisting of ▫ lenalidomide or ▫ daratumumab + lenalidomide (only when using induction or consolidation therapy with D-VRd)	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. Only for patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy; see Appendix VI to Section K of the Pharmaceutical Directive.
c. According to the G-BA, the concept of 'consolidation' therapy must be distinguished from that of 'maintenance treatment', which address different therapeutic goals.
d. Only if D-VTd-based induction therapy is used does consolidation therapy with 2 cycles of D-VTd following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.
e. Only if D-VRd-based induction therapy is used does consolidation therapy with 2 cycles of D-VRd with subsequent maintenance treatment with daratumumab + lenalidomide following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.

ACT: appropriate comparator therapy; C: cyclophosphamide; D: daratumumab; d: dexamethasone; G-BA: Federal Joint Committee; R: lenalidomide; SmPC: summary of product characteristics; T: thalidomide; V: bortezomib

The G-BA decides on the added benefit.

I 2 Research question

The aim of this report is to assess the added benefit of isatuximab in combination with bortezomib, lenalidomide and dexamethasone for induction therapy (hereinafter 'isatuximab + bortezomib + lenalidomide + dexamethasone'), in comparison with the appropriate comparator therapy (ACT), in patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT).

The research question shown in Table 4 was defined in accordance with the ACT specified by the G-BA.

Table 4: Research question for the benefit assessment of isatuximab + bortezomib + lenalidomide + dexamethasone

Therapeutic indication	**ACT**[a]
Adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant	▪ An induction therapy consisting of ▫ bortezomib + thalidomide + dexamethasone (VTd) or ▫ bortezomib + cyclophosphamide + dexamethasone (VCd)[b] or ▫ daratumumab + bortezomib + thalidomide + dexamethasone (D-VTd) or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (D-VRd) ▪ followed by high-dose therapy with melphalan and subsequent autologous stem cell transplantation ▪ followed by consolidation therapy[c] consisting of ▫ daratumumab + bortezomib + thalidomide + dexamethasone (only when using induction therapy with D-VTd)[d] or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (only when using induction therapy with D-VRd)[e] ▪ followed by maintenance treatment consisting of ▫ lenalidomide or ▫ daratumumab + lenalidomide (only when using induction or consolidation therapy with D-VRd)

a. Presented is the ACT specified by the G-BA.
b. Only for patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy; see Appendix VI to Section K of the Pharmaceutical Directive.
c. According to the G-BA, the concept of 'consolidation' therapy must be distinguished from that of 'maintenance treatment', which address different therapeutic goals.
d. Only if D-VTd-based induction therapy is used does consolidation therapy with 2 cycles of D-VTd following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.
e. Only if D-VRd-based induction therapy is used does consolidation therapy with 2 cycles of D-VRd with subsequent maintenance treatment with daratumumab + lenalidomide following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.

ACT: appropriate comparator therapy; C: cyclophosphamide; D: daratumumab; d: dexamethasone; G-BA: Federal Joint Committee; R: lenalidomide; SmPC: summary of product characteristics; T: thalidomide; V: bortezomib

On 12 August 2025, the day on which the company submitted its dossier, the G-BA modified the ACT to that shown in Table 4. When specifying the ACT in its dossier, the company mainly referred to a consultation with the G-BA from 2024 [3]. Deviating from this consultation, the

company only considered induction therapy followed by high-dose therapy with melphalan and subsequent ASCT, and the consolidation therapy to be part of the ACT. The company did not consider maintenance treatment to be included in the ACT, as isatuximab + bortezomib + lenalidomide + dexamethasone is exclusively authorized for induction therapy. In addition, the company limited the selection of drugs in induction therapy to quadruple combination therapies (namely daratumumab + bortezomib + thalidomide + dexamethasone or daratumumab + bortezomib + lenalidomide + dexamethasone). The ACT specified by the company did not correspond to the ACT specified by the G-BA on 12 August 2025. Overall, the company's deviations from the ACT remained without consequence, as it did not present any suitable data either versus its ACT or versus the G-BA's ACT. This assessment was carried out versus the current ACT specified by the G-BA (see Table 4).

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) were used to derive the added benefit. This concurs with the company's inclusion criteria.

I 3 Information retrieval and study pool

The study pool for the assessment was compiled on the basis of the following information:

Sources used by the company in the dossier:

- Study list for isatuximab + bortezomib + lenalidomide + dexamethasone (status: 3 July 2025)
- Bibliographical literature search for isatuximab + bortezomib + lenalidomide + dexamethasone (last search on 3 July 2025)
- Search of trial registries / trial results databases for studies on isatuximab + bortezomib + lenalidomide + dexamethasone (last search on 3 July 2025)
- Search on the G-BA website for isatuximab + bortezomib + lenalidomide + dexamethasone (last search on 4 July 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on isatuximab + bortezomib + lenalidomide + dexamethasone (last search on 27 August 2025); for search strategies, see I Appendix A of the full dossier assessment

Consisting with the findings of the company, no relevant studies on the direct comparison of isatuximab + bortezomib + lenalidomide + dexamethasone in comparison with the ACT were identified in the review.

In Module 4 D, Section 4.4, the company summarized the results of the pivotal RCT GMMG-HD7 [4], but did not use these results to derive an added benefit.

Concurring with the company's assessment, the GMMG-HD7 study was not suitable for deriving conclusions on the added benefit of isatuximab + bortezomib + lenalidomide + dexamethasone in comparison with the ACT for the given research question. The GMMG-HD7 study is described below, and the reasons for its unsuitability for the benefit assessment are provided.

Evidence presented by the company – the GMMG-HD7 study

GMMG-HD7 is an ongoing, open-label RCT comparing isatuximab + bortezomib + lenalidomide + dexamethasone versus bortezomib + lenalidomide + dexamethasone, each followed by high-dose therapy with melphalan with subsequent ASCT and, after re-randomization, maintenance treatment with isatuximab + lenalidomide or lenalidomide monotherapy. Adult patients with newly diagnosed multiple myeloma who were eligible for high-dose therapy and ASCT were included.

A total of 662 patients were included in the GMMG-HD7 study and randomized in a 1:1 ratio. Randomization for the induction phase was stratified by disease stage (stage I/II versus stage III versus not classified; based on the International Staging System). The study was only conducted in German study centres.

The study treatment was divided into 2 phases: induction and maintenance. After randomization, patients in both study arms received treatment with bortezomib, lenalidomide and dexamethasone for 3 cycles (1 cycle corresponded to 6 weeks) as induction therapy. In the intervention arm, the treatment was given in combination with isatuximab. This was followed by stem cell mobilization, high-dose therapy with melphalan and an ASCT. Prior to maintenance treatment, all patients were randomized again, either to combination therapy with lenalidomide + isatuximab or to monotherapy with lenalidomide, each administered in a 28-day cycle until disease progression, the occurrence of unacceptable toxicity or up to a maximum of 3 years.

The drug combination used as induction therapy in the comparator arm and maintenance treatment with isatuximab and lenalidomide are not approved in this therapeutic indication.

The primary outcome of the GMMG-HD7 study was the minimal residual disease (MRD) negativity rate and progression-free survival. Secondary outcomes were recorded in the categories of mortality, morbidity, health-related quality of life and side effects.

ACT not implemented in the GMMG-HD7 study

As part of its ACT, the G-BA specified the following options for induction therapy:

- bortezomib + thalidomide + dexamethasone, or
- bortezomib + cyclophosphamide + dexamethasone (only for patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy), or
- daratumumab + bortezomib + thalidomide + dexamethasone, or
- daratumumab + bortezomib + lenalidomide + dexamethasone

Therefore, the induction therapy with bortezomib + lenalidomide + dexamethasone used in the comparator arm of GMMG-HD7 did not correspond to the G-BA's specification.

In its ACT, the G-BA specified the following options for maintenance treatment:

- lenalidomide
- daratumumab + lenalidomide (only when using induction or consolidation therapy with the drug combination daratumumab + bortezomib + lenalidomide + dexamethasone)

Deviating from this, all patients in the GMMG-HD7 study were randomized again after the ASCT for maintenance treatment. The patients were divided into an arm with lenalidomide monotherapy and an arm with isatuximab + lenalidomide combination therapy. This did not correspond to the ACT specified by the G-BA.

In summary, induction therapy and maintenance treatment in the comparator arm did not correspond to the ACT, so there were no data on the comparison of isatuximab + bortezomib + lenalidomide + dexamethasone with the comparator therapy specified by the G-BA.

I 4 Results on added benefit

No suitable data were available for assessing the added benefit of isatuximab + bortezomib + lenalidomide + dexamethasone in comparison with the ACT in adult patients with newly diagnosed multiple myeloma who are eligible for ASCT. There is no hint of an added benefit of isatuximab + bortezomib + lenalidomide + dexamethasone in comparison with the ACT; an added benefit is therefore not proven.

I 5 Probability and extent of added benefit

Table 5 summarizes the result of the assessment of the added benefit of isatuximab + bortezomib + lenalidomide + dexamethasone in comparison with the ACT.

Table 5: Isatuximab + bortezomib + lenalidomide + dexamethasone – probability and extent of added benefit

Therapeutic indication	ACT[a]	Probability and extent of added benefit
Adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant	▪ An induction therapy consisting of ▫ bortezomib + thalidomide + dexamethasone (VTd) or ▫ bortezomib + cyclophosphamide + dexamethasone (VCd)[b] or ▫ daratumumab + bortezomib + thalidomide + dexamethasone (D-VTd) or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (D-VRd) ▪ followed by high-dose therapy with melphalan and subsequent autologous stem cell transplantation ▪ followed by consolidation therapy[c] consisting of ▫ daratumumab + bortezomib + thalidomide + dexamethasone (only when using induction therapy with D-VTd)[d] or ▫ daratumumab + bortezomib + lenalidomide + dexamethasone (only when using induction therapy with D-VRd)[e] ▪ followed by maintenance treatment consisting of ▫ lenalidomide or ▫ daratumumab + lenalidomide (only when using induction or consolidation therapy with D-VRd)	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. Only for patients with peripheral polyneuropathy or an increased risk of developing peripheral polyneuropathy; see Appendix VI to Section K of the Pharmaceutical Directive.
c. According to the G-BA, the concept of 'consolidation' therapy must be distinguished from that of 'maintenance treatment', which address different therapeutic goals.
d. Only if D-VTd-based induction therapy is used does consolidation therapy with 2 cycles of D-VTd following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.
e. Only if D-VRd-based induction therapy is used does consolidation therapy with 2 cycles of D-VRd with subsequent maintenance treatment with daratumumab + lenalidomide following high-dose therapy and autologous stem cell transplantation correspond to the dosing regimen according to the SmPC for daratumumab and so is part of the ACT.

ACT: appropriate comparator therapy; C: cyclophosphamide; D: daratumumab; d: dexamethasone; G-BA: Federal Joint Committee; R: lenalidomide; SmPC: summary of product characteristics; T: thalidomide; V: bortezomib

The assessment described above concurs with that by the company.

The G-BA decides on the added benefit.

I 6 References for English extract

Please see full dossier assessment for full reference list.

The reference list contains citations provided by the company in which bibliographical information may be missing.

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The full report (German version) is published under https://www.iqwig.de/en/projects/a25-105.html.