IQWiG Reports – Commission No. A22-101

Selinexor (multiple myeloma, ≥ 4 prior therapies) –

Benefit assessment according to §35a Social Code Book V[1]

Extract

[1] Translation of Sections I 1 to I 6 of the dossier assessment *Selinexor (multiples Myelom ≥ 4 Vortherapien) – Nutzenbewertung gemäß § 35a SGB V* (Version 1.0; Status: 22 December 2022). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

Publishing details

Publisher
Institute for Quality and Efficiency in Health Care

Topic
Selinexor (multiple myeloma, ≥ 4 prior therapies) – Benefit assessment according to §35a Social Code Book V

Commissioning agency
Federal Joint Committee

Commission awarded on
29 September 2022

Internal Commission No.
A22-101

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IQWiG thanks the medical and scientific advisor for his contribution to the dossier assessment. However, the advisor was not involved in the actual preparation of the dossier assessment. The responsibility for the contents of the dossier assessment lies solely with IQWiG.

Patient and family involvement

The questionnaire on the disease and its treatment was answered by Hans Josef von Lier.

IQWiG thanks the respondent for participating in the written exchange about how he experienced the disease and its treatment and about the treatment goals. The respondent was not involved in the actual preparation of the dossier assessment.

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Keywords: Selinexor, Multiple Myeloma, Benefit Assessment

Part I: Benefit assessment

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[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
FHAD	Flatiron Health Analytic Database
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)
SPC	Summary of Product Characteristics

I 1 Executive summary of the benefit assessment

Background

In accordance with § 35a Social Code Book (SGB) 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 selinexor + dexamethasone. The assessment is based on a dossier compiled by the pharmaceutical company (hereinafter referred to as the "company"). The dossier was sent to IQWiG on 29 September 2022.

Research question

The aim of this report is to assess the added benefit of selinexor in combination with dexamethasone (hereinafter referred to as "selinexor + dexamethasone") in comparison with individualized therapy as appropriate comparator therapy (ACT) in adult patients with multiple myeloma who have received at least 4 prior therapies and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

The research question presented in Table 2 results from the ACT specified by the G-BA.

Table 2: Research question of the benefit assessment of selinexor + dexamethasone

Therapeutic indication	**ACT[a]**
Adult patients with multiple myeloma who have received at least 4 previous treatments and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy[b]	Individual therapy choosing from: ▪ bortezomib monotherapy ▪ bortezomib + pegylated liposomal doxorubicin ▪ bortezomib + dexamethasone ▪ carfilzomib + lenalidomide + dexamethasone ▪ carfilzomib + dexamethasone ▪ daratumumab + lenalidomide + dexamethasone ▪ daratumumab + bortezomib + dexamethasone ▪ daratumumab monotherapy ▪ elotuzumab + lenalidomide + dexamethasone ▪ elotuzumab + pomalidomide + dexamethasone ▪ isatuximab + pomalidomide + dexamethasone ▪ ixazomib + lenalidomide + dexamethasone ▪ lenalidomide + dexamethasone ▪ panobinostat + bortezomib + dexamethasone ▪ pomalidomide + bortezomib + dexamethasone ▪ pomalidomide + dexamethasone ▪ cyclophosphamide (in combination with other antineoplastic drugs) ▪ melphalan ▪ doxorubicin ▪ carmustine (in combination with other cytostatic drugs and an adrenocortical hormone, especially prednisone) ▪ vincristine ▪ dexamethasone ▪ prednisolone ▪ prednisone ▪ best supportive care taking into account prior therapies as well as the extent and duration of the response.
a. Presented is the ACT specified by the G-BA. b. It is assumed that the special situation of refractory patients is taken into account when choosing the ACT. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee	

The company followed the G-BA by designating individualized therapy as the ACT. However, it deviated from the specifications of the G-BA in that it only named individual drugs for individualized therapy, but not the combination therapies specified by the G-BA and also not isatuximab. The approach of the company is of no consequence for the assessment, as the company did not present any relevant data.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier.

Study pool and study design

In agreement with the company, no randomized controlled trial (RCT) was identified that directly compared selinexor + dexamethasone with the ACT.

Not having identified any RCTs for a direct comparison, the company conducted an information retrieval for further investigations with selinexor. It identified the studies STORM and XPORT-MM-028. The company conducted no information retrieval for further investigations on the ACT.

In the course of the bibliographic search for selinexor, the company identified the papers Cornell 2021 and Richardson 2021. Cornell 2021 compared the results of the selinexor STORM study with results of the MAMMOTH study, in which patients received conventional therapy. Richardson 2021 compared results of the STORM study with results in patients receiving conventional treatment from the Flatiron Health Analytic Database (FHAD). The company presented a comparison of individual arms of different studies. Since there was no information retrieval for further investigations for the ACT, the study pool is potentially incomplete.

Regardless of the potential incompleteness of the company's study pool, the data submitted by the company are unsuitable for drawing any conclusions on the added benefit of selinexor + dexamethasone in comparison with the ACT for patients in the present therapeutic indication.

Evidence on selinexor presented by the company

Study STORM

The pivotal STORM study is a completed, multicentre, single-arm study. The study included patients with multiple myeloma who had previously received 4 or 5 drugs and were refractory to 2 or 3 drug classes, or had received at least 3 prior treatments (including lenalidomide, pomalidomide, bortezomib, carfilzomib, and daratumumab as well as an alkylating agent). The intervention consisted of selinexor + dexamethasone. Primary outcome of the study was the overall response rate. In its dossier, the company provided a descriptive presentation of the results of the STORM study for the subpopulation corresponding to the therapeutic indication of selinexor.

For the comparison of individual arms of different studies, the company used aggregate data of a subpopulation of the STORM study based on the analyses of the Cornell 2020 publication. These patients were pretreated with the drugs bortezomib, carfilzomib, pomalidomide, lenalidomide and daratumumab as well as an alkylating agent and were refractory to 3 drug classes.

Study XPORT-MM-028

The XPORT-MM-028 study is an ongoing multicentre study comparing different doses of selinexor and dexamethasone, among others. Patients with at least 4 prior therapies and refractoriness to at least 2 proteasome inhibitors, 2 immunomodulators and an anti-CD38 antibody were randomized to the relevant 3 treatment arms with different doses of selinexor +

dexamethasone (Sd part of the study). In the dossier, the company provided a descriptive presentation of the results of those patients who received selinexor + dexamethasone in compliance with the Summary of Product Characteristics (SPC).

Evidence on the ACT presented by the company

Study MAMMOTH

The MAMMOTH study is a retrospective study, which included patients with multiple myeloma who were refractory to daratumumab and/or isatuximab. The study compared patients who had undergone different numbers of prior therapies. For the comparison of individual arms of different studies, the company used aggregate data of a subpopulation of the MAMMOTH study from the Cornell 2020 publication. Patients in this subpopulation were pretreated with 5 drugs and refractory to 3 drug classes.

FHAD

In its dossier, the company also used results from electronic health records of the FHAD. It described that it considered only those patients of the FHAD who corresponded to the therapeutic indication of selinexor + dexamethasone.

Comparison of individual arms of different studies

In the dossier, the company presented comparisons of individual arms of different studies. From the Cornell 2021 publication identified by the company, it reported the results on an unadjusted comparison of a subpopulation of the STORM study with the MAMMOTH study. Furthermore, it conducted a comparison of the STORM study with individual patient data from the FHAD. It presented results for the comparisons only for the outcome of overall survival. The company described that it only had aggregate data from the Cornell 2021 publication for the comparison between STORM and MAMMOTH and that the patient population may also include patients who are not part of the present research question. Besides, information on the ACT is not fully presented in the dossier. The company described that the patients in MAMMOTH and FHAD received individualized therapy, but cited only one drug of each treatment regimen. It is therefore not clear whether the individualized therapy in MAMMOTH and the FHAD corresponds to the combination therapies listed by the G-BA. Overall, the data presented by the company are unsuitable for the derivation of an added benefit.

Irrespective of the completeness of the study pool, in the present scenario of indirect comparison without a common comparator, there are no effects for which it can be ruled out with certainty that they result solely from systematic bias due to confounders.

Results on added benefit

Since no suitable data are available for the benefit assessment, there is no hint of an added benefit of selinexor + dexamethasone in comparison with 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 added benefit of selinexor + 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: Selinexor + dexamethasone – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Adult patients with multiple myeloma who have received at least 4 previous treatments and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy	Individual therapy choosing from: ▪ bortezomib monotherapy ▪ bortezomib + pegylated liposomal doxorubicin ▪ bortezomib + dexamethasone ▪ carfilzomib + lenalidomide + dexamethasone ▪ carfilzomib + dexamethasone ▪ daratumumab + lenalidomide + dexamethasone ▪ daratumumab + bortezomib + dexamethasone ▪ daratumumab monotherapy ▪ elotuzumab + lenalidomide + dexamethasone ▪ elotuzumab + pomalidomide + dexamethasone ▪ isatuximab + pomalidomide + dexamethasone ▪ ixazomib + lenalidomide + dexamethasone ▪ lenalidomide + dexamethasone ▪ panobinostat + bortezomib + dexamethasone ▪ pomalidomide + bortezomib + dexamethasone ▪ pomalidomide + dexamethasone ▪ cyclophosphamide (in combination with other antineoplastic drugs) ▪ melphalan ▪ doxorubicin ▪ carmustine (in combination with other cytostatic drugs and an adrenocortical hormone, especially prednisone) ▪ vincristine ▪ dexamethasone ▪ prednisolone ▪ prednisone ▪ best supportive care taking into account prior therapies as well as the extent and duration of the response.	Added benefit not proven

a: Presented is the ACT specified by the G-BA.
b. It is assumed that the special situation of refractory patients is taken into account when choosing the ACT.
ACT: appropriate comparator therapy; G-BA: Federal Joint Committee

The G-BA decides on the added benefit.

I 2 Research question

The aim of this report is to assess the added benefit of selinexor in combination with dexamethasone (hereinafter referred to as "selinexor + dexamethasone") in comparison with individualized therapy as ACT in adult patients with multiple myeloma who have received at least 4 prior therapies and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

The research question presented in Table 4 results from the ACT specified by the G-BA.

Table 4: Research question of the benefit assessment of selinexor + dexamethasone

Therapeutic indication	**ACT**[a]
Adult patients with multiple myeloma who have received at least 4 previous treatments and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy[b]	Individual therapy choosing from: ▪ bortezomib monotherapy ▪ bortezomib + pegylated liposomal doxorubicin ▪ bortezomib + dexamethasone ▪ carfilzomib + lenalidomide + dexamethasone ▪ carfilzomib + dexamethasone ▪ daratumumab + lenalidomide + dexamethasone ▪ daratumumab + bortezomib + dexamethasone ▪ daratumumab monotherapy ▪ elotuzumab + lenalidomide + dexamethasone ▪ elotuzumab + pomalidomide + dexamethasone ▪ isatuximab + pomalidomide + dexamethasone ▪ ixazomib + lenalidomide + dexamethasone ▪ lenalidomide + dexamethasone ▪ panobinostat + bortezomib + dexamethasone ▪ pomalidomide + bortezomib + dexamethasone ▪ pomalidomide + dexamethasone ▪ cyclophosphamide (in combination with other antineoplastic drugs) ▪ melphalan ▪ doxorubicin ▪ carmustine (in combination with other cytostatic drugs and an adrenocortical hormone, especially prednisone) ▪ vincristine ▪ dexamethasone ▪ prednisolone ▪ prednisone ▪ best supportive care taking into account prior therapies as well as the extent and duration of the response.
a. Presented is the ACT specified by the G-BA. b. It is assumed that the special situation of refractory patients is taken into account when choosing the ACT. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee	

The company followed the G-BA by designating individualized therapy as the ACT. However, it deviated from the specifications of the G-BA in that it only named individual drugs for individualized therapy, but not the combination therapies specified by the G-BA and also not isatuximab. The approach of the company is of no consequence for the assessment, as the company did not present any relevant data.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier.

I 3 Information retrieval and study pool

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

Sources of the company in the dossier:

- study lists on selinexor (status: 26 July 2022)
- bibliographical literature search on selinexor (last search on 22 July 2022)
- search in trial registries/trial results databases for studies on selinexor (last search on 22 July 2022)
- search on the G-BA website for selinexor (last search on 22 July 2022)

To check the completeness of the study pool:

- search in trial registries for studies on selinexor (last search on 11 October 2022); for search strategies, see I Appendix A of the full dossier assessment

Concurring with the company, no RCT on the direct comparison of selinexor + dexamethasone versus the ACT specified by the G-BA was identified from the check of the completeness of the study pool.

Not having identified any RCTs for a direct comparison, the company conducted an information retrieval for further investigations with selinexor. It identified the studies STORM [3] and XPORT-MM-028 [4]. The company conducted no information retrieval for further investigations on the ACT. In the course of the bibliographic search for selinexor, the company identified the papers Cornell 2021 [5] and Richardson 2021 [6]. Cornell 2021 compared the results of the selinexor STORM study with results of the MAMMOTH study [7], in which patients received conventional therapy. Richardson 2021 compared results of the STORM study with results in patients receiving conventional treatment from the FHAD [8]. The company presented a comparison of individual arms of different studies. Since there was no information retrieval for further investigations for the ACT, the study pool is potentially incomplete.

The check for completeness of the study pool on the side of the intervention identified no additional relevant studies. The completeness of the study pool on the side of the ACT was not checked. Regardless of the potential incompleteness of the company's study pool, the data submitted by the company are unsuitable for drawing any conclusions on the added benefit of selinexor + dexamethasone in comparison with the ACT for patients in the present therapeutic indication. This is explained below.

Evidence on selinexor presented by the company

Study STORM

The pivotal STORM study is a completed, multicentre, single-arm study. The study included patients with multiple myeloma who had previously received 4 or 5 drugs and were refractory

to 2 or 3 drug classes, or had received at least 3 prior treatments (including lenalidomide, pomalidomide, bortezomib, carfilzomib, and daratumumab as well as an alkylating agent). The intervention consisted of selinexor + dexamethasone. Primary outcome of the study was the overall response rate. In its dossier, the company provided a descriptive presentation of the results of the STORM study for the subpopulation corresponding to the therapeutic indication of selinexor.

For the comparison of individual arms of different studies, the company used aggregate data of a subpopulation of the STORM study based on the analyses of the Cornell 2021 publication. These patients were pretreated with the drugs bortezomib, carfilzomib, pomalidomide, lenalidomide and daratumumab as well as an alkylating agent and were refractory to 3 drug classes.

Study XPORT-MM-028

The XPORT-MM-028 study is an ongoing multicentre study comparing different doses of selinexor and dexamethasone, among others. Patients with at least 4 prior therapies and refractoriness to at least 2 proteasome inhibitors, 2 immunomodulators and an anti-CD38 antibody were randomized to the relevant 3 treatment arms with different doses of selinexor + dexamethasone (Sd part of the study). In the study, patients with at least 4 prior therapies and refractoriness to at least 2 proteasome inhibitors, 2 immunomodulators and an anti-CD38 antibody were randomized to 3 treatment arms with different doses of selinexor + dexamethasone (Sd part of the study). In the dossier, the company provided a descriptive presentation of the results of those patients who received selinexor + dexamethasone in compliance with the SPC.

Evidence on the ACT presented by the company

Study MAMMOTH

The MAMMOTH study [7] is a retrospective study, which included patients with multiple myeloma who were refractory to daratumumab and/or isatuximab. The study compared patients who had undergone different numbers of prior therapies. For the comparison of individual arms of different studies, the company used aggregate data of a subpopulation of the MAMMOTH study from the Cornell 2021 publication. Patients in this subpopulation were pretreated with 5 drugs and refractory to 3 drug classes.

FHAD

In its dossier, the company also used results from electronic health records of the FHAD. It described that it considered only those patients of the FHAD who corresponded to the therapeutic indication of selinexor + dexamethasone.

Comparison of individual arms of different studies

In the dossier, the company presented comparisons of individual arms of different studies. From the Cornell 2021 publication [5] identified by the company, it reported the results on an

unadjusted comparison of a subpopulation of the STORM study with the MAMMOTH study. Furthermore, it conducted a comparison of the STORM study with individual patient data from the FHAD. It presented results for the comparisons only for the outcome of overall survival. The company did not present a comparison including the XPORT-MM-028 study. The company described that it only had aggregate data from the Cornell 2021 publication for the comparison between STORM and MAMMOTH and that the patient population may also include patients who are not part of the present research question. Besides, information on the ACT is not fully presented in the dossier. The company described that the patients in MAMMOTH and FHAD received individualized therapy, but cited only one drug of each treatment regimen. It is therefore not clear whether the individualized therapy in MAMMOTH and the FHAD corresponds to the combination therapies listed by the G-BA. Overall, the data presented by the company are unsuitable for the derivation of an added benefit.

Irrespective of the potential incompleteness of the study pool and the described limitations, in the present scenario of indirect comparison without a common comparator, there are also no effects for which it can be ruled out with certainty that they result solely from systematic bias due to confounders.

I 4 Results on added benefit

Since no suitable data are available for the benefit assessment, there is no hint of an added benefit of selinexor + 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 selinexor + dexamethasone in comparison with the ACT.

Table 5: Selinexor + dexamethasone – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Adult patients with multiple myeloma who have received at least 4 previous treatments and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy[b]	Individual therapy choosing from: ▪ bortezomib monotherapy ▪ bortezomib + pegylated liposomal doxorubicin ▪ bortezomib + dexamethasone ▪ carfilzomib + lenalidomide + dexamethasone ▪ carfilzomib + dexamethasone ▪ daratumumab + lenalidomide + dexamethasone ▪ daratumumab + bortezomib + dexamethasone ▪ daratumumab monotherapy ▪ elotuzumab + lenalidomide + dexamethasone ▪ elotuzumab + pomalidomide + dexamethasone ▪ isatuximab + pomalidomide + dexamethasone ▪ ixazomib + lenalidomide + dexamethasone ▪ lenalidomide + dexamethasone ▪ panobinostat + bortezomib + dexamethasone ▪ pomalidomide + bortezomib + dexamethasone ▪ pomalidomide + dexamethasone ▪ cyclophosphamide (in combination with other antineoplastic drugs) ▪ melphalan ▪ doxorubicin ▪ carmustine (in combination with other cytostatic drugs and an adrenocortical hormone, especially prednisone) ▪ vincristine ▪ dexamethasone ▪ prednisolone ▪ prednisone ▪ best supportive care taking into account prior therapies as well as the extent and duration of the response.	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. It is assumed that the special situation of refractory patients is taken into account when choosing the ACT.
ACT: appropriate comparator therapy; G-BA: Federal Joint Committee

As the company did not provide any suitable data for the assessment of the added benefit of selinexor + dexamethasone in comparison with the ACT in adult patients with multiple myeloma who have received at least 4 prior therapies and whose disease is refractory to at least 2 proteasome inhibitors, 2 immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy, an added benefit of selinexor + dexamethasone for these patients is not proven.

This assessment deviates from that by the company, which derived a hint of a non-quantifiable added benefit on the basis of comparisons of individual arms from different studies.

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/a22-101.html.