Bimekizumab (hidradenitis suppurativa)

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

EXTRACT

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

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

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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
AE	adverse event
CTCAE	Common Terminology Criteria for Adverse Events
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
SAE	serious adverse event
SGB	Sozialgesetzbuch (Social Code Book)

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 bimekizumab. 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 17 May 2024.

Research question

The aim of the present report is the assessment of the added benefit of bimekizumab in comparison with adalimumab as appropriate comparator therapy (ACT) in adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic hidradenitis suppurativa therapy.

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

Table 2: Research questions of the benefit assessment of bimekizumab

Therapeutic indication	**ACT**[a]
Adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic hidradenitis suppurativa therapy[b]	Adalimumab
a. Presented is the ACT specified by the G-BA. b. According to the G-BA, it is assumed that conventional therapy options (antimicrobial therapies, in particular a systemic combination therapy of clindamycin and rifampicin) have already been exhausted as part of the pretreatment(s). ACT: appropriate comparator therapy; G-BA: Federal Joint Committee	

The company followed the G-BA's specification on the ACT.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) with a minimum duration of 24 weeks were used for deriving any added benefit.

Results

In line with the company's assessment, the check of completeness of the study pool did not identify any relevant study for assessing the added benefit of bimekizumab versus adalimumab. The company also does not identify any studies that it considers suitable for conducting indirect comparisons. Overall, no suitable data are available for the present benefit assessment.

Results on added benefit

Since no relevant study is available for the benefit assessment, there is no hint of an added benefit of bimekizumab 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 bimekizumab.

Table 3: Bimekizumab – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic hidradenitis suppurativa therapy[b]	Adalimumab	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. According to the G-BA, it is assumed that conventional therapy options (antimicrobial therapies, in particular a systemic combination therapy of clindamycin and rifampicin) have already been exhausted as part of the pretreatment(s).

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee

The G-BA decides on the added benefit.

[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].

I 2 Research question

The aim of the present report is the assessment of the added benefit of bimekizumab in comparison with adalimumab as appropriate comparator therapy (ACT) in adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic hidradenitis suppurativa therapy.

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

Table 4: Research questions of the benefit assessment of bimekizumab

Therapeutic indication	**ACT**[a]
Adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic hidradenitis suppurativa therapy[b]	Adalimumab
a. Presented is the ACT specified by the G-BA. b. According to the G-BA, it is assumed that conventional therapy options (antimicrobial therapies, in particular a systemic combination therapy of clindamycin and rifampicin) have already been exhausted as part of the pretreatment(s). ACT: appropriate comparator therapy; G-BA: Federal Joint Committee	

The company followed the G-BA's specification on the ACT.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. Randomized controlled trials (RCTs) with a minimum duration of 24 weeks were used for deriving any added benefit. This concurs with the company’s inclusion criteria.

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 list on bimekizumab (status: 25 March 2024)
- bibliographical literature search on bimekizumab (last search on 25 March 2024)
- search in trial registries/trial results databases for studies on bimekizumab (last search on 25 March 2024)
- search on the G-BA website for bimekizumab (last search on 25 March 2024)

To check the completeness of the study pool:

- search in trial registries for studies on bimekizumab (last search on 13 June 2024); for search strategies, see I Appendix A of the full dossier assessment

Concurring with the company, the check of the completeness of the study pool identified no RCT that would allow a direct comparison of bimekizumab versus adalimumab.

In Module 4 E of the dossier, the company nevertheless presented the results of the two phase 3 studies HS0003 (BE HEARD I) [3] and HS0004 (BE HEARD II) [4] as the best available evidence. However, the company did not use these for its benefit assessment and justified the exclusion of the BE HEARD I and BE HEARD II studies as well as the phase 2 study HS0001 [5] sponsored by the company, in which bimekizumab is compared with placebo and adalimumab over 12 weeks, on the following grounds: at 12 weeks, the duration of the HS0001 study does not meet the necessary minimum duration of 24 weeks for chronic diseases. The comparator therapy in the BE HEARD I and BE HEARD II studies was placebo, and therefore is not in line with the ACT. As with the HS0001 study, the duration of the phase 3 studies was too short: after 16 weeks, the initial (placebo-controlled) treatment period transitioned into the uncontrolled maintenance period, meaning that no comparative data were collected beyond 16 weeks. Because the treatment duration was too short, the company also did not identify any studies that could be considered for an indirect comparison of bimekizumab with adalimumab using a bridge comparator, nor did it conduct a search for suitable studies with the ACT for the indirect comparison.

Overall, concurring with the company, no suitable data are available for the present benefit assessment.

I 4 Results on added benefit

No suitable data are available in the company's dossier for the assessment of bimekizumab for the treatment of adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic hidradenitis suppurativa therapy. There is no hint of an added benefit of bimekizumab versus adalimumab. An added benefit is therefore not proven.

I 5 Probability and extent of added benefit

Table 5 summarizes the result of the assessment of added benefit of bimekizumab in comparison with the ACT.

Table 5: Bimekizumab – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic hidradenitis suppurativa therapy[b]	Adalimumab	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. According to the G-BA, it is assumed that conventional therapy options (antimicrobial therapies, in particular a systemic combination therapy of clindamycin and rifampicin) have already been exhausted as part of the pretreatment(s).

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee

The assessment described above concurs with that of 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/a24-64.html.