Bimekizumab (non-radiographic axial spondyloarthritis)

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
bDMARD	biologic disease-modifying antirheumatic drug
CRP	C-reactive protein
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IL	interleukin
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
MRI	magnetic resonance imaging
NSAID	non-steroidal anti-inflammatory drug
RCT	randomized controlled trial
SGB	Sozialgesetzbuch (Social Code Book)
TNF	tumour necrosis factor

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 3 July 2023.

Research question

The aim of the present report is to assess the added benefit of bimekizumab in comparison with the appropriate comparator therapy (ACT) in adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).

The ACT specified by the G-BA differs depending on the pretreatment of the patients. The resulting research questions are shown in Table 2.

Table 2: Research questions of the benefit assessment of bimekizumab

Research question	Therapeutic indication	ACT[a]
Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated CRP and/or demonstrated by MRI		
1	Patients who have responded inadequately or are intolerant to NSAIDs	A TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab or ixekizumab)
2	Patients who have responded inadequately or are intolerant to prior therapy with bDMARDs	Switch to another bDMARD: TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab of ixekizumab)

a. Presented is the respective ACT specified by the G-BA.

ACT: appropriate comparator therapy; bDMARD: biologic disease-modifying antirheumatic drug; CRP: C-reactive protein; G-BA: Federal Joint Committee; IL: interleukin; MRI: magnetic resonance imaging; NSAID: non-steroidal anti-inflammatory drug; TNF: tumour necrosis factor

The company followed the G-BA's specification of the ACT for both research questions.

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 are used for the derivation of added benefit.

Results

No data are available for assessing the added benefit of bimekizumab in comparison the ACT in adults with active non-radiographic axial spondyloarthritis. This applies both to patients who have responded inadequately or are intolerant to NSAIDs (research question 1) and to patients who have responded inadequately or are intolerant to prior therapy with biologic disease-modifying antirheumatic drugs (bDMARDs) (research question 2). There is no hint of added benefit of bimekizumab in comparison with the ACT for either research question; an added benefit is therefore not proven for either of them.

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

Research question	Therapeutic indication	ACT[a]	Probability and extent of added benefit
Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated CRP and/or demonstrated by MRI			
1	Patients who have responded inadequately or are intolerant to NSAIDs	A TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab or ixekizumab)	Added benefit not proven
2	Patients who have responded inadequately or are intolerant to prior therapy with bDMARDs	Switch to another bDMARD: TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab of ixekizumab)	Added benefit not proven

a. Presented is the respective ACT specified by the G-BA.

ACT: appropriate comparator therapy; bDMARD: biologic disease-modifying antirheumatic drug; CRP: C-reactive protein; G-BA: Federal Joint Committee; IL: interleukin; MRI: magnetic resonance imaging; NSAID: non-steroidal anti-inflammatory drug; TNF: tumour necrosis factor

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 to assess the added benefit of bimekizumab in comparison with the ACT in adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated CRP and/or MRI who have responded inadequately or are intolerant to NSAIDs.

The ACT specified by the G-BA differs depending on the pretreatment of the patients. The resulting research questions are shown in Table 4.

Table 4: Research questions of the benefit assessment of bimekizumab

Research question	Therapeutic indication	ACT[a]
Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated CRP and/or demonstrated by MRI		
1	Patients who have responded inadequately or are intolerant to NSAIDs	A TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab or ixekizumab)
2	Patients who have responded inadequately or are intolerant to prior therapy with bDMARDs	Switch to another bDMARD: TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab of ixekizumab)

a. Presented is the respective ACT specified by the G-BA.

ACT: appropriate comparator therapy; bDMARD: biologic disease-modifying antirheumatic drug; CRP: C-reactive protein; G-BA: Federal Joint Committee; IL: interleukin; MRI: magnetic resonance imaging; NSAID: non-steroidal anti-inflammatory drug; TNF: tumour necrosis factor

The company followed the G-BA's specification of the ACT for both research questions.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier. RCTs with a minimum duration of 24 weeks are used for the derivation of 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: 17 April 2023)
- bibliographical literature search on bimekizumab (last search on 17 April 2023)
- search in trial registries/trial results databases for studies on bimekizumab (last search on 17 April 2023)
- search on the G-BA website for bimekizumab (last search on 17 April 2023)

To check the completeness of the study pool:

- search in trial registries for studies on bimekizumab (last search on 6 July 2023); for search strategies, see I Appendix A of the full dossier assessment

No relevant study was identified from the check.

The company concurred by reporting not to have identified any relevant studies for the present research questions. However, for the therapeutic indication of non-radiographic axial spondyloarthritis to be assessed, the company presented supplementary results of the placebo-controlled BE MOBILE 1 study [3] in Module 4 D, and also mentioned long-term efficacy data from the placebo-controlled BE AGILE study and the associated extension study with bimekizumab [4] in the derivation of the added benefit (Module 4 D, Section 4.4.2). However, it did not use these studies to derive the added benefit. The company's approach is appropriate.

BE MOBILE 1

The BE MOBILE 1 study is a placebo-controlled RCT. It included adult patients who had active non-radiographic axial spondyloarthritis with objective signs of inflammation who had responded inadequately or were intolerant to therapy with NSAIDs. Patients may have received one prior tumour necrosis factor (TNF)-α inhibitor or up to 2 other bDMARDs other than interleukin (IL)-17 inhibitors if they had responded inadequately or were intolerant to these therapies.

The 254 patients were randomized in a 1:1 ratio to treatment with bimekizumab 160 mg every 4 weeks or placebo. The study was divided into a placebo-controlled double-blind phase (16 weeks) and a maintenance phase with bimekizumab (Weeks 16 to 52). This study offers no comparison with the ACT, however, and is therefore irrelevant for the assessment of added benefit.

I 4 Results on added benefit

No data are available for assessing the added benefit of bimekizumab in comparison the ACT in adults with active non-radiographic axial spondyloarthritis. This applies both to patients who have responded inadequately or are intolerant to NSAIDs (research question 1) and to patients who have responded inadequately or are intolerant to prior therapy with bDMARDs (research question 2). There is no hint of added benefit of bimekizumab in comparison with the ACT for either research question; an added benefit is therefore not proven for either of them.

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

Research question	Therapeutic indication	ACT[a]	Probability and extent of added benefit
Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated CRP and/or demonstrated by MRI			
1	Patients who have responded inadequately or are intolerant to NSAIDs	A TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab or ixekizumab)	Added benefit not proven
2	Patients who have responded inadequately or are intolerant to prior therapy with bDMARDs	Switch to another bDMARD: TNF-α inhibitor (adalimumab or certolizumab pegol or etanercept or golimumab) or IL-17 inhibitor (secukinumab of ixekizumab)	Added benefit not proven

a. Presented is the respective ACT specified by the G-BA.

ACT: appropriate comparator therapy; bDMARD: biologic disease-modifying antirheumatic drug; CRP: C-reactive protein; G-BA: Federal Joint Committee; IL: interleukin; MRI: magnetic resonance imaging; NSAID: non-steroidal anti-inflammatory drug; TNF: tumour necrosis factor

The assessment described above concurs with that of the company in each case.

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.

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Allgemeine Methoden; Version 6.1 [online]. 2022 [Accessed: 27.01.2022]. URL: https://www.iqwig.de/methoden/allgemeine-methoden-v6-1.pdf.

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The full report (German version) is published under https://www.iqwig.de/en/projects/a23-62.html.