Ixekizumab
(juvenile psoriatic arthritis)

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

EXTRACT

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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

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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
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)

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 ixekizumab. 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 25 September 2025.

Research question

The aim of this report is to assess the added benefit of ixekizumab, alone or in combination with methotrexate, in comparison with the appropriate comparator therapy (ACT) in children and adolescents with active juvenile psoriatic arthritis, 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant to, conventional therapy.

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

Table 2: Research question of the benefit assessment of ixekizumab

Therapeutic indication	**ACT[a]**
Children and adolescents from 6 years of age with active juvenile psoriatic arthritis and a body weight of at least 25 kg who have had an inadequate response to, or who are intolerant to, conventional therapy[b]	etanercept (≥ 12 years) or secukinumab or tofacitinib
a. Presented is the ACT specified by the G-BA. b. It is assumed that (symptomatic) therapy with NSAIDs and or glucocorticoids alone is not (or no longer) an option for the patients covered by the therapeutic indication. The use of glucocorticoids (systemic and/or intra-articular) should be possible as part of a relapse therapy. Unchanged continuation of an inadequate (prior) treatment does not correspond to the ACT. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; NSAID: non-steroidal anti-inflammatory drug	

The company deviated from the ACT defined by the G-BA insofar as it extended the ACT to include the drug baricitinib. The company stated that baricitinib is authorized for the therapeutic indication in question and that its role in health care has been established. The inclusion of this additional option by the company had no consequence for this assessment, as the company did not present any evidence in comparison with it.

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) with a minimum duration of 24 weeks were used to derive the added benefit.

Results

Concurring with the company, the review of the completeness did not identify any relevant studies.

Results on added benefit

Since no relevant study was available for the benefit assessment, there is no hint of an added benefit of ixekizumab 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 probability and extent of the added benefit of ixekizumab.

Table 3: Ixekizumab – probability and extent of added benefit

Therapeutic indication	ACT[a]	Probability and extent of added benefit
Children and adolescents from 6 years of age with active juvenile psoriatic arthritis and a body weight of at least 25 kg who have had an inadequate response to, or who are intolerant to, conventional therapy[b]	etanercept (≥ 12 years) or secukinumab or tofacitinib	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. It is assumed that (symptomatic) therapy with NSAIDs and or glucocorticoids alone is not (or no longer) an option for the patients covered by the therapeutic indication. The use of glucocorticoids (systemic and/or intra-articular) should be possible as part of a relapse therapy. Unchanged continuation of an inadequate (prior) treatment does not correspond to the ACT.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; NSAID: non-steroidal anti-inflammatory drug

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 this report is to assess the added benefit of ixekizumab, alone or in combination with methotrexate, in comparison with the appropriate comparator therapy (ACT) in children and adolescents with active juvenile psoriatic arthritis, 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant to, conventional therapy.

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

Table 4: Research question of the benefit assessment of ixekizumab

Therapeutic indication	**ACT[a]**
Children and adolescents from 6 years of age with active juvenile psoriatic arthritis and a body weight of at least 25 kg who have had an inadequate response to, or who are intolerant to, conventional therapy[b]	etanercept (≥ 12 years) or secukinumab or tofacitinib
a. Presented is the ACT specified by the G-BA. b. It is assumed that (symptomatic) therapy with NSAIDs and or glucocorticoids alone is not (or no longer) an option for the patients covered by the therapeutic indication. The use of glucocorticoids (systemic and/or intra-articular) should be possible as part of a relapse therapy. Unchanged continuation of an inadequate (prior) treatment does not correspond to the ACT. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; NSAID: non-steroidal anti-inflammatory drug	

The company deviated from the ACT defined by the G-BA insofar as it extended the ACT to include the drug baricitinib. The company stated that baricitinib is authorized for the therapeutic indication in question and that its role in health care has been established. The inclusion of this additional option by the company had no consequence for this assessment, as the company did not present any evidence in comparison with it.

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) with a minimum duration of 24 weeks were used to derive the added benefit. This concurred 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 on ixekizumab (status: 17 July 2025)
- Bibliographical literature search on ixekizumab (last search on 22 July 2025)
- Search of trial registries / trial results databases for studies on ixekizumab (last search on 17 July 2025)
- Search on the G-BA website for ixekizumab (last search on 17 July 2025)

To check the completeness of the study pool:

- Search of trial registries for studies on ixekizumab (last search on 2 October 2025); for search strategies, see I Appendix A of the full dossier assessment

Concurring with the company, this review did not identify any relevant studies.

In Module 3 D, the company presented results of the pivotal study COSPIRIT-JIA [3,4] as supplementary information. The COSPIRIT-JIA study is an open-label, randomized study comparing ixekizumab with adalimumab. Children and adolescents with juvenile psoriatic arthritis or enthesitis-related arthritis aged between 2 and 17 years were included; patients with enthesitis-related arthritis had to be at least 6 years old (for the assessment in the therapeutic indication of enthesitis-associated arthritis, see dossier assessment A25-121 [5]). However, the company did not use this study to derive the added benefit.

The company’s approach was appropriate. The treatment in the comparator arm did not concur with the ACT, so no data were available on the comparison of ixekizumab with the comparator therapy specified by the G-BA.

I 4 Results on added benefit

No data were available to assess the added benefit of ixekizumab in comparison with the ACT in children and adolescents with active juvenile psoriatic arthritis, 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant to, conventional therapy. There is no hint of an added benefit of ixekizumab in comparison with the ACT; an added benefit is therefore not proven.

I 5 Probability and extent of added benefit

The result of the assessment of the added benefit of ixekizumab in comparison with the ACT is summarized in Table 5.

Table 5: Ixekizumab – probability and extent of added benefit

Therapeutic indication	**ACT**[a]	**Probability and extent of added benefit**
Children and adolescents from 6 years of age with active juvenile psoriatic arthritis and a body weight of at least 25 kg who have had an inadequate response to, or who are intolerant to, conventional therapy[b]	etanercept (≥ 12 years) or secukinumab or tofacitinib	Added benefit not proven

a. Presented is the ACT specified by the G-BA.
b. It is assumed that (symptomatic) therapy with NSAIDs and or glucocorticoids alone is not (or no longer) an option for the patients covered by the therapeutic indication. The use of glucocorticoids (systemic and/or intra-articular) should be possible as part of a relapse therapy. Unchanged continuation of an inadequate (prior) treatment does not correspond to the ACT.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; NSAID: non-steroidal anti-inflammatory drug

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/a25-120.html.