Lebrikizumab
(atopic dermatitis in adults and adolescents)

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

EXTRACT

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[1] Translation of Sections I 1 to I 6 of the dossier assessment *Lebrikizumab (atopische Dermatitis bei Erwachsenen und Jugendlichen) – Nutzenbewertung gemäß § 35a SGB V*. Please note: This document was translated by an external translator and is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Medical and scientific advice

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
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 (SGB) V, the Federal Joint Committee (G-BA) has commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug lebrikizumab. 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 11 December 2023.

Research question

The aim of the present report is the assessment of the added benefit of lebrikizumab in comparison with dupilumab as ACT in adults and adolescents 12 years and older with moderate to severe atopic dermatitis who are candidates for systemic therapy.

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

Table 2: Research question for the benefit assessment of lebrikizumab

Therapeutic indication	**ACT**[a]
Adults and adolescents 12 years and older[b] with moderate to severe atopic dermatitis who are candidates for systemic therapy	Dupilumab (if applicable, in combination with TCS and/or TCI)
a. Presented is the ACT specified by the G-BA. b. With a body weight of at least 40 kg. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; TCI: topical calcineurin inhibitors; TCS: topical corticosteroids	

The company followed the specification of the G-BA by designating dupilumab as 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 the information retrieval identified no relevant study for the assessment of the added benefit of lebrikizumab in comparison with the ACT dupilumab.

Results on added benefit

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

Table 3: Lebrikizumab – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Adults and adolescents 12 years and older[b] with moderate to severe atopic dermatitis who are candidates for systemic therapy	Dupilumab (if applicable, in combination with TCS and/or TCI)	Added benefit not proven
a. Presented is the ACT specified by the G-BA. b. With a body weight of at least 40 kg. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; TCI: topical calcineurin inhibitors; TCS: topical corticosteroids		

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 lebrikizumab in comparison with dupilumab as ACT in adults and adolescents 12 years and older with moderate to severe atopic dermatitis who are candidates for systemic therapy.

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

Table 4: Research question for the benefit assessment of lebrikizumab

Therapeutic indication	**ACT**[a]
Adults and adolescents 12 years and older[b] with moderate to severe atopic dermatitis who are candidates for systemic therapy	Dupilumab (if applicable, in combination with TCS and/or TCI)
a. Presented is the ACT specified by the G-BA. b. With a body weight of at least 40 kg. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; TCI: topical calcineurin inhibitors; TCS: topical corticosteroids	

The company followed the specification of the G-BA by designating dupilumab as 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 lebrikizumab (status: 5 October 2023)
- bibliographical literature search on lebrikizumab (last search on 5 October 2023)
- search in trial registries/trial results databases for studies on lebrikizumab (last search on 5 October 2023)
- search on the G-BA website for lebrikizumab (last search on 5 October 2023)

To check the completeness of the study pool:

- search in trial registries for studies on lebrikizumab (last search on 21 December 2023); for search strategies, see I Appendix A of the full dossier assessment

The check did not identify any relevant studies for assessing the added benefit of lebrikizumab in comparison with the ACT dupilumab. This concurs with the company's assessment.

In Module 4 A of the dossier, the company nevertheless presents results of 3 RCTs conducted in the therapeutic indication (ADvocate 1, ADvocate 2 [3] and ADhere [3,4]) and the extension study ADjoin [5].

In the ADvocate 1, ADvocate 2 and ADhere studies, lebrikizumab treatment was compared with placebo. In the ADhere study, topical corticosteroids were also administered in both study arms. In all 3 RTCs, the treatment phase was 16 weeks. In the Advocate 1 and Advocate 2 studies, patients who had responded to treatment were subsequently rerandomized and underwent a further treatment phase with lebrikizumab or placebo for 36 weeks. Patients in the ADjoin extension study were then able to continue treatment with lebrikizumab. Patients in the ADhere study were able to switch to the ADjoin extension study immediately after the 16-week treatment phase. Since there was no comparison with the ACT dupilumab in the 4 studies and the 16-week treatment duration in the 3 RTCs was too short, these studies, in agreement with the company, are not assessed as suitable for the assessment of the added benefit of lebrikizumab in the present therapeutic indication.

I 4 Results on added benefit

No suitable data are available for the assessment of the added benefit of lebrikizumab in comparison with the ACT dupilumab in adults and adolescents 12 years and older with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. There is no hint of an added benefit of lebrikizumab 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 lebrikizumab in comparison with the ACT is summarized in Table 5.

Table 5: Lebrikizumab – probability and extent of added benefit

Therapeutic indication	**ACT[a]**	**Probability and extent of added benefit**
Adults and adolescents 12 years and older[b] with moderate to severe atopic dermatitis who are candidates for systemic therapy	Dupilumab (if applicable, in combination with TCS and/or TCI)	Added benefit not proven
a. Presented is the ACT specified by the G-BA. b. With a body weight of at least 40 kg. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; TCI: topical calcineurin inhibitors; TCS: topical corticosteroids		

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/a23-129.html.