Deucravacitinib (plaque psoriasis)

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

EXTRACT

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[1] Translation of Sections I 1 to 2 of the dossier assessment *Deucravacitinib (Plaque-Psoriasis) – Nutzenbewertung gemäß § 35a SGB V*. 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.

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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 one person.

IQWiG thanks the respondent for participating in the written exchange about how she/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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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) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug deucravacitinib. 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 April 2023.

Research question

The aim of the present report is to assess the added benefit of deucravacitinib in comparison with the appropriate comparator therapy (ACT) in patients with moderate to severe plaque psoriasis who are candidates for systemic therapy.

The research questions shown in Table 2 are derived from the ACT specified by the G-BA.

Table 2: Research question of the benefit assessment of deucravacitinib

Research question	Therapeutic indication	ACT[a]
1	Adult patients with moderate to severe plaque psoriasis who are not candidates for conventional treatment as part of initial systemic therapy	Adalimumab or bimekizumab or guselkumab or ixekizumab or secukinumab
2	Adult patients with moderate to severe plaque psoriasis with inadequate response or intolerance to systemic therapy	Adalimumab or bimekizumab or brodalumab or guselkumab or infliximab or ixekizumab or risankizumab or secukinumab or ustekinumab
a. Presented is the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee		

The company deviated from the ACT specified by the G-BA and additionally cited apremilast as ACT for both research questions.

The present benefit assessment was conducted in comparison with the ACT specified by the G-BA.

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

Results

No relevant RCT was identified for assessing the added benefit of deucravacitinib in comparison with the ACT.

The company included the RCTs IM011046 and IM011047 , which compared deucravacitinib with apremilast and placebo, in its study pool. Both RCTs included adult patients with plaque psoriasis who were eligible for phototherapy or systemic therapy. Apremilast and placebo are not part of the ACT specified by the G-BA in either of the present research questions. Both studies were thus unsuitable to derive conclusions on the added benefit of deucravacitinib in comparison with the ACT.

Results on added benefit

No suitable data are available for the assessment of the added benefit of deucravacitinib compared with the ACT in adult patients with moderate to severe plaque psoriasis for whom conventional treatment is not an option in the context of an initial systemic therapy (research question 1), and for those patients who have responded inadequately to systemic therapy (research question 2). There is no hint of an added benefit of deucravacitinib in comparison with the ACT for any of the research questions; 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 deucravacitinib.

[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: Deucravacitinib – probability and extent of added benefit

Research question	**Therapeutic indication**	**ACT[a]**	**Probability and extent of added benefit**
1	Adult patients with moderate to severe plaque psoriasis who are not candidates for conventional treatment as part of initial systemic therapy	Adalimumab or bimekizumab or guselkumab or ixekizumab or secukinumab	Added benefit not proven
2	Adult patients with moderate to severe plaque psoriasis with inadequate response or intolerance to prior systemic therapy	Adalimumab or bimekizumab or brodalumab or guselkumab or infliximab or ixekizumab or risankizumab or secukinumab or ustekinumab	Added benefit not proven
a. Presented is the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee			

The G-BA decides on the added benefit.

I 2 Research question

The aim of the present report is to assess the added benefit of deucravacitinib in comparison with the ACT in patients with moderate to severe plaque psoriasis who are candidates for systemic therapy.

The research questions shown in Table 4 are derived from the ACT specified by the G-BA.

Table 4: Research questions of the benefit assessment of deucravacitinib

Research question	Therapeutic indication	ACT[a]
1	Adult patients with moderate to severe plaque psoriasis who are not candidates for conventional treatment as part of initial systemic therapy	Adalimumab or bimekizumab or guselkumab or ixekizumab or secukinumab
2	Adult patients with moderate to severe plaque psoriasis with inadequate response or intolerance to systemic therapy	Adalimumab or bimekizumab or brodalumab or guselkumab or infliximab or ixekizumab or risankizumab or secukinumab or ustekinumab
a. Presented is the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee		

The company deviated from the ACT specified by the G-BA and additionally cited apremilast as ACT for both research questions.

The present benefit assessment was conducted in comparison with the ACT specified by the G-BA.

The assessment is conducted by means of patient-relevant outcomes on the basis of the data presented by the company in the dossier. RCTs with a minimum duration of 24 weeks were used for deriving 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 deucravacitinib (status: 13 March 2023)
- bibliographical literature search on deucravacitinib (last search on 7 March 2023)
- search in trial registries/trial results databases for studies on deucravacitinib (last search on 13 March 2023)
- search on the G-BA website for deucravacitinib (last search on 7 March 2023)

To check the completeness of the study pool:

- search in trial registries for studies on deucravacitinib (last search on 25 April 2023); for search strategies, see I Appendix A

The check did not identify any relevant studies for assessing the added benefit of deucravacitinib in comparison with the ACT. This deviates from the approach of the company, which identified the RCTs IM011046 and IM011047 and used them for its assessment.

The studies IM011046 and IM011047 compare deucravacitinib with apremilast and placebo. They are thus unsuitable for assessing the added benefit of deucravacitinib in comparison with the ACT specified by the G-BA. This is explained below.

Evidence provided by the company

Studies IM011046 and IM011047

Both studies, IM011046 and IM011047, are double-blind, randomized, multicentre studies that enrolled adult patients with plaque psoriasis who were eligible for phototherapy or systemic therapy. Moreover, at least 10% of the body surface area had to be affected at baseline and a Psoriasis Area and Severity Index (PASI) score ≥ 12 and a Static Physician's Global Assessment (sPGA) score ≥ 3 had to be present. The IM011046 study included a total of 666 patients and the IM011047 study included a total of 1020 patients. These were randomized in a 2:1:1 ratio to the treatment arms deucravacitinib, apremilast or placebo.

Approach of the company

The company used the two studies IM011046 and IM011047 for assessing the added benefit of deucravacitinib in adult patients with moderate to severe plaque psoriasis - both for patients for whom conventional treatment is not an option in the context of an initial systemic therapy (research question 1) and for those patients who have responded inadequately to

systemic therapy or have not tolerated it (research question 2). For this purpose, the company presented results for the comparison of deucravacitinib with apremilast.

Studies IM011046 and IM011047 unsuitable for the assessment of the added benefit

The approach of the company is not appropriate. For both research question 1 and research question 2, Apremilast is not part of the comparator therapies specified by the G-BA. The studies are thus not suitable to derive conclusions on the added benefit of deucravacitinib compared with the respective ACT - neither for adult patients with moderate to severe plaque psoriasis for whom conventional treatment is not an option in the context of an initial systemic therapy (research question 1), nor for those patients who have responded inadequately to systemic therapy or have not tolerated it (research question 2).

I 4 Results on added benefit

No suitable data are available for the assessment of the added benefit of deucravacitinib compared with the ACT in adult patients with moderate to severe plaque psoriasis for whom conventional treatment is not an option in the context of an initial systemic therapy (research question 1), and for those patients who have responded inadequately to systemic therapy or have not tolerated it (research question 2). There is no hint of an added benefit of deucravacitinib in comparison with the ACT for any of the research questions; in each case, 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 for deucravacitinib in comparison with the ACT.

Table 5: Deucravacitinib – probability and extent of added benefit

Research question	Therapeutic indication	ACT[a]	Probability and extent of added benefit
1	Adult patients with moderate to severe plaque psoriasis who are not candidates for conventional treatment as part of initial systemic therapy	Adalimumab or bimekizumab or guselkumab or ixekizumab or secukinumab	Added benefit not proven
2	Adult patients with moderate to severe plaque psoriasis with inadequate response or intolerance to systemic therapy	Adalimumab or bimekizumab or brodalumab or guselkumab or infliximab or ixekizumab or risankizumab or secukinumab or ustekinumab	Added benefit not proven

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

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

The assessment described above deviates from that of the company, which derived proof of considerable added benefit for patients of both research questions.

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 [Zugriff: 27.01.2022]. URL: https://www.iqwig.de/methoden/allgemeine-methoden-v6-1.pdf.

2. Skipka G, Wieseler B, Kaiser T et al. Methodological approach to determine minor, considerable, and major treatment effects in the early benefit assessment of new drugs. Biom J 2016; 58(1): 43-58. https://dx.doi.org/10.1002/bimj.201300274.

The full report (German version) is published under https://www.iqwig.de/en/projects/A23-34.html.