Secukinumab (hidradenitis suppurativa)

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 *Secukinumab (Hidradenitis suppurativa) – 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

No feedback was received in the framework of 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) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug secukinumab. 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 12 June 2023.

Research question

The aim of this report is to assess the added benefit of secukinumab in comparison with adalimumab as the appropriate comparator therapy (ACT) in patients with active moderate to severe hidradenitis suppurativa with an inadequate response to conventional systemic therapy.

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

Table 2: Research question of the benefit assessment of secukinumab

Therapeutic indication	**ACT**[a]
Adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic therapy[b]	Adalimumab
a. Presented is the ACT specified by the G-BA. b. According to the G-BA, it is assumed that conventional prior therapies for the treatment of hidradenitis suppurativa (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 of 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 the derivation of added benefit.

Results

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

In addition, the company did not identify any study that could be considered for an indirect comparison with adalimumab via a common comparator. Since no suitable study was available that allowed an indirect comparison of secukinumab with the ACT in the target population

under consideration, the company did not conduct a search for suitable studies for the ACT for the indirect comparison.

Overall, no 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 secukinumab 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 secukinumab.

Table 3: Secukinumab – 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 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 prior therapies for the treatment of hidradenitis suppurativa (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 this report is to assess the added benefit of secukinumab in comparison with adalimumab as the ACT in patients with active moderate to severe hidradenitis suppurativa with an inadequate response to conventional systemic therapy.

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

Table 4: Research question of the benefit assessment of secukinumab

Therapeutic indication	**ACT**[a]
Adult patients with active moderate to severe hidradenitis suppurativa (acne inversa) with an inadequate response to conventional systemic therapy[b]	Adalimumab
a. Presented is the ACT specified by the G-BA. b. According to the G-BA, it is assumed that conventional prior therapies for the treatment of hidradenitis suppurativa (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 of 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. RCTs with a minimum duration of 24 weeks were 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 secukinumab (status: 4 April 2023)
- bibliographical literature search on secukinumab (last search on 4 April 2023)
- search in trial registries/trial results databases for studies on secukinumab (last search on 4 April 2023)
- search on the G-BA website for secukinumab (last search on 4 April 2023)

To check the completeness of the study pool:

- search in trial registries for studies on secukinumab (last search on 21 June 2023); 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 secukinumab versus adalimumab. In addition, the company did not identify any study that could be considered for an indirect comparison with adalimumab via a common comparator. It considered the 2 studies CAIN457M2301 (SUNSHINE) and CAIN457M2302 (SUNRISE) [3] not eligible for the benefit assessment, as the randomized comparison with placebo was 16 weeks, and the study duration was therefore too short for a chronic disease such as hidradenitis suppurativa. The ongoing extension study CAIN457M2301E1 [4] over 52 weeks was also not be eligible for an indirect comparison, according to the company, because it included only patients pretreated with secukinumab from the SUNRISE and SUNSHINE studies. Since no suitable study was available that allowed an indirect comparison of secukinumab with the ACT in the target population under consideration, the company did not conduct a search for suitable studies for the ACT for the indirect comparison.

Overall, no data are available for the present benefit assessment.

I 4 Results on added benefit

No data are available in the company's dossier for the assessment of secukinumab for the treatment of adult patients with active moderate to severe hidradenitis suppurativa with an inadequate response to conventional systemic therapy. There is no hint of an added benefit of secukinumab versus adalimumab. 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 secukinumab in comparison with the ACT is summarized in Table 5.

Table 5: Secukinumab – 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 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 prior therapies for the treatment of hidradenitis suppurativa (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/a23-51.html.