IQWiG Reports – Commission No. A18-78

Tildrakizumab (plaque psoriasis) –

Benefit assessment according to §35a Social Code Book V[1]

Extract

[1] Translation of the executive summary of the dossier assessment *Tildrakizumab (Plaque-Psoriasis) – Nutzenbewertung gemäß § 35a SGB V* (Version 1.0; Status: 13 February 2019). 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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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.

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Executive summary of the benefit assessment

Background

In accordance with §35a Social Code Book (SBG) 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 tildrakizumab. 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 13 November 2018.

Research question

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

The research questions presented in Table 2 result from the ACT specified by the G-BA.

Table 2[2]: Research questions of the benefit assessment for tildrakizumab

Research question	Indication	ACT[a]
1	Adult patients with moderate to severe plaque psoriasis who are eligible for initial systemic therapy	Adalimumab or ciclosporin or ixekizumab or methotrexate or phototherapy (NB-UVB, balneophototherapy) or secukinumab
2	Adult patients with moderate to severe plaque psoriasis who have responded inadequately to systemic therapy	Adalimumab or infliximab or ixekizumab or secukinumab or ustekinumab

a: Presentation of the respective ACT specified by the G-BA. In cases where the ACT specified by the G-BA allows the company to choose a comparator therapy from several options, the respective choice by the company is printed in **bold**.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; NB-UVB: narrow-band ultraviolet-B light (311 nm)

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 for deriving any the added benefit.

Results

Research question 1

For research question 1 (adult patients with moderate to severe plaque psoriasis who are eligible for initial systemic therapy), the company presented results using single arms from various studies. The company selected fumaric acid ester as the comparator therapy.

[2] Table numbers start with "2" as numbering follows that of the full dossier assessment.

Since fumaric acid ester is not an option for an ACT, the data presented by the company are irrelevant for assessing an added benefit of tildrakizumab in comparison with the ACT for research question 1 with respect to the pertinent therapeutic indication. The company did not explain why it referred to a discontinued ACT, thus deviating from the current ACT specified by the G-BA for the therapeutic indication under review (with 6 possible options).

Research question 2

For research question 2 (adult patients with moderate to severe plaque psoriasis who have responded inadequately to systemic therapy), the company selected etanercept as an ACT option and presented the P011 RCT for comparison of tildrakizumab versus etanercept.

Since etanercept is not an ACT option, the RCT presented by the company is irrelevant for assessing an added benefit of tildrakizumab in comparison with the ACT for research question 2 with respect to the pertinent therapeutic indication.

The company began justifying the selection of etanercept as an ACT option with the same line of reasoning it had already used in the dossier for the benefit assessment of dimethyl fumarate (Commission A17-49) for the same indication. The company then presented further arguments in support of the view that etanercept is an alternative ACT.

The company's view that etanercept is an alternative ACT is not shared. The company did not provide any meaningful data, for example in the form of a systematic review of the evidence, to at least suggest equivalence of etanercept with the other biologics. The G-BA has already expressed its opinion on the value of etanercept as an ACT in its justification paper for several assessment procedures for the same indication (for example, Commissions A17-49 and A17-60). The G-BA explicitly states: "Given the availability of more effective, well-documented alternatives, etanercept is not considered an ACT for the pertinent therapeutic indication." More recent systematic reviews also point to the inferiority of etanercept compared to the ACT options mentioned by the G-BA and thus support said options.

All things considered, the arguments presented by the company do not call into question the ACT specified by the G-BA.

Summary

Neither for question 1 nor for question 2 did the company provide relevant data for assessing an added benefit of tildrakizumab versus ACT in adult patients with moderate to severe plaque psoriasis who are eligible for systemic therapy. Consequently, there is no hint of added benefit of tofacitinib 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 presents a summary of the probability and extent of added benefit of tildrakizumab.

Table 3: Tildrakizumab – probability and extent of added benefit

Indication	ACT[a]	Probability and extent of added benefit
Adult patients with moderate to severe plaque psoriasis who are eligible for initial systemic therapy	Adalimumab or ciclosporin or ixekizumab or methotrexate or phototherapy (NB-UVB, balneophototherapy) or secukinumab	Added benefit not proven
Adult patients with moderate to severe plaque psoriasis who have responded inadequately to systemic therapy	Adalimumab or infliximab or ixekizumab or secukinumab or ustekinumab	Added benefit not proven

a: Presentation of the respective ACT specified by the G-BA. In cases where the ACT specified by the G-BA allows the company to choose a comparator therapy from several options, the respective choice by the company is printed in **bold**.

ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; NB-UVB: narrow-band ultraviolet-B light (311 nm)

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. 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].

References for English extract

Please see full dossier assessment for full reference list.

1. Institute for Quality and Efficiency in Health Care. General methods: version 5.0 [online]. 10 July 2017 [Accessed: 4 June 2018]. URL: https://www.iqwig.de/download/General-Methods_Version-5-0.pdf.

2. Skipka G, Wieseler B, Kaiser T, Thomas S, Bender R, Windeler J et al. Methodological approach to determine minor, considerable, and major treatment effects in the early benefit assessment of new drugs. Biom J 2015; 58(1): 43-58

The full report (German version) is published under https://www.iqwig.de/en/projects-results/projects/drug-assessment/a18-78-tildrakizumab-plaque-psoriasis-benefit-assessment-according-to-35a-social-code-book-v.11001.html.