IQWiG Reports – Commission No. A18-52

Tofacitinib (ulcerative colitis) –

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

Extract

[1] Translation of the executive summary of the dossier assessment *Tofacitinib (Colitis ulcerosa) – Nutzenbewertung gemäß § 35a SGB V* (Version 1.0; Status: 28 November 2018). 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.

Publishing details

Publisher:
Institute for Quality and Efficiency in Health Care

Topic:
Tofacitinib (ulcerative colitis) – Benefit assessment according to §35a Social Code Book V

Commissioning agency:
Federal Joint Committee

Commission awarded on:
24 August 2018

Internal Commission No.:
A18-52

Address of publisher:
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Keywords: tofacitinib, colitis – ulcerative, benefit assessment

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 tofacitinib. 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 24 August 2018.

Research question

This aim of this report is to assess the added benefit of tofacitinib in comparison with the appropriate comparator therapy (ACT) in adult patients with moderate to severe active ulcerative colitis who did not adequately respond to, no longer respond to, or did not tolerate conventional therapy or a biologic agent.

For the benefit assessment, 2 research questions resulted, for which the G-BA specified the ACTs presented in Table 2.

Table 2[2]: Research questions of the benefit assessment of tofacitinib in patients with moderate to severe ulcerative colitis

Research question	Indication	ACT[a]
1	Patients who did not adequately respond to conventional therapy, no longer respond to it, do not tolerate it, or have a contraindication	TNF-α antagonist (adalimumab or infliximab or golimumab) under consideration of the marketing authorization and prior treatment(s)
2	Patients who did not adequately respond to a biologic agent such as a TNF-α antagonist or integrin inhibitor, no longer respond to it, or do not tolerate this treatment	TNF-α antagonist (adalimumab or infliximab or golimumab) or integrin inhibitor (vedolizumab), each under consideration of the marketing authorization and prior treatment(s)
a: Presentation of the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; TNF-α: tumour necrosis factor α		

The company followed the G-BA's specification of the ACT.

The assessment was conducted using 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 12 months were used to derive any added benefit. This deviates from the inclusion criteria of the company, which considered a minimum study duration of 20 weeks adequate.

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

Results

The company did not present any studies which permit a direct comparison with the ACT for either of the 2 research questions.

On the basis of its information retrieval for studies permitting an indirect comparison, the company identified the OCTAVE SUSTAIN study for tofacitinib. The company stated, however, that due to the study design of OCTAVE SUSTAIN, it was impossible to carry out an indirect comparison with the specified ACT. Therefore, the company did not look for RCTs with the ACT and did not perform an indirect comparison.

Overall, the company therefore did not present any data for assessing the added benefit of tofacitinib in comparison with the ACT. Consequently, there is no hint of an 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 the added benefit of tofacitinib.

Table 3: Tofacitinib in patients with moderate to severe active ulcerative colitis – probability and extent of added benefit

Indication	ACT[a]	Probability and extent of added benefit
Patients who did not adequately respond to conventional therapy, no longer respond to it, do not tolerate it, or have a contraindication	TNF-α antagonist (adalimumab or infliximab or golimumab) under consideration of the marketing authorization and prior treatment(s)	Added benefit not proven
Patients who did not adequately respond to a biologic agent such as a TNF-α antagonist or integrin inhibitor, no longer respond to it, or do not tolerate this treatment	TNF-α antagonist (adalimumab or infliximab or golimumab) or integrin inhibitor (vedolizumab), each under consideration of the marketing authorization and prior treatment(s)	Added benefit not proven
a: Presentation of the respective ACT specified by the G-BA. ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; TNF-α: tumour necrosis factor α		

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].

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/a18-52-tofacitinib-colitis-benefit-assessment-according-to-35a-social-code-book-v.10485.html.