

## Guselkumab (ulcerative colitis)

Addendum to Project A25-74  
(dossier assessment)<sup>1</sup>

A horizontal bar composed of 18 rectangular segments of varying shades of blue and grey. The text 'ADDENDUM (DOSSIER ASSESSMENT)' is centered in white on a dark blue segment.

**ADDENDUM (DOSSIER ASSESSMENT)**

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## List of abbreviations

<b>Abbreviation</b>	<b>Meaning</b>
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
IBDQ	Inflammatory Bowel Disease Questionnaire
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)

## 1 Background

On 7 October 2025, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to conduct supplementary assessments for Project A25-74 (Guselkumab – Benefit assessment according to § 35a Social Code Book V) [1].

The commission comprises the assessment of the analyses on the VEGA study presented by the pharmaceutical company (hereinafter referred to as “the company”) in the commenting procedure [2], taking into account the information provided in the dossier for the following outcomes [3]:

- 90 days without corticosteroids treatment at Week 38 (post-hoc analyses)

The responsibility for this assessment and the assessment result lies exclusively with IQWiG. The assessment is forwarded to the G-BA. The G-BA decides on the added benefit.

## 2 Assessment

For benefit assessment A25-74 [1] of guselkumab in adult patients with moderately to severely active ulcerative colitis, the double-blind, randomized controlled trial (RCT) VEGA, which compared guselkumab with golimumab, was used for research question 1 (patients who have had an inadequate response with, lost response to, or were intolerant to conventional therapy). A detailed description of the VEGA study can be found in benefit assessment A25-74 [1].

In accordance with the commission, the analyses on the 90-day corticosteroid-free status at Week 38 subsequently submitted by the company in the commenting procedure are assessed below, taking into account the information in the dossier.

### **Analysis on the 90-day corticosteroid-free status subsequently submitted with the comments**

Dossier assessment A25-74 described that a steroid-free status at Week 38 should be included as a criterion in the definition of the outcome symptomatic remission, or should at least be recorded separately.

As part of the commenting procedure, the company submitted results for the outcome 90-day corticosteroid-free status at Week 38 as a separate analysis, without reference to symptomatic remission. The operationalization concurs with the required criteria regarding the waiting period (a 3-month waiting period to avoid significant corticosteroid-induced side effects) and the analysis date. However, if steroid-free status is recorded separately, it is of limited informative value unless symptomatic remission is also taken into account (in an appropriate operationalization). However, even following the commenting procedure, there are still no suitable analyses available for the outcome symptomatic remission. In particular, it still seems inappropriate that, in addition to the patient-reported symptoms stool frequency and rectal haemorrhage, abdominal pain was not also used as a further relevant patient-reported symptom for the assessment of remission in the VEGA study. In its comments, the company only presents further analyses of three individual items from the Inflammatory Bowel Disease Questionnaire (IBDQ) that may comprise the symptom abdominal pain.

The outcome symptomatic remission in the company's operationalization was presented as supplementary information in I Appendix B of dossier assessment A25-74 [1]. Regardless of the limitations described above, there were no statistically significant effects.

Against the background described above, the subsequently submitted results regarding the 90-day corticosteroid-free status at Week 38 are presented in Table 1, as requested in the commission. There was no statistically significant difference between guselkumab and golimumab. Overall, therefore, neither the analysis of symptomatic remission (as further

detailed in the appendix to dossier assessment A25-74) nor the analysis of the 90-day corticosteroid-free status subsequently submitted with the comments shows any positive or negative effect of guselkumab compared with golimumab.

Table 1: Results (morbidity, supplementary presentation) – RCT, direct comparison: guselkumab vs. golimumab

Study outcome category outcome	Guselkumab		Golimumab		Guselkumab vs. golimumab
	N	patients with event n (%)	N	patients with event n (%)	RR [95% CI]; p-value <sup>a</sup>
<b>VEGA</b>					
<b>Morbidity (at Week 38)</b>					
90-day corticosteroid-free status	71	66 (93)	72	65 (90.3)	1.03 [0.94; 1.13]; 0.538
a. Cochran-Mantel-Haenszel method with the stratification factor corticosteroid treatment at baseline (yes/no); missing values are taken into account using NRI.					
CI: confidence interval; n: number of patients with (at least one) event; N: number of analysed patients; NRI: non-responder imputation; RCT: randomized controlled trial; RR: relative risk					

## 2.1 Summary

The data subsequently submitted by the company in the commenting procedure do not change the conclusion on the added benefit of guselkumab drawn in dossier assessment A25-74.

The following Table 2 shows the result of the benefit assessment of guselkumab under consideration of dossier assessment A25-74 and the present addendum.

Table 2: Guselkumab – probability and extent of added benefit

Research question	Therapeutic indication	ACT <sup>a, b, c</sup>	Probability and extent of added benefit
Adults with moderately to severely active ulcerative colitis <sup>d</sup>			
1	Patients who have had an inadequate response to, lost response to, or are intolerant to conventional therapy	Adalimumab or golimumab or infliximab <sup>e</sup> or mirikizumab or ozanimod or ustekinumab or vedolizumab	Added benefit not proven
2	Patients who have had an inadequate response with, lost response to, or were intolerant to a biologic agent (TNF $\alpha$ antagonist or integrin inhibitor or interleukin inhibitor)	Adalimumab or filgotinib or golimumab or infliximab or mirikizumab or ozanimod or tofacitinib or upadacitinib or ustekinumab or vedolizumab	Added benefit not proven
<p>a. Presented is 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 of the company according to the inclusion criteria in Module 4 Section 4.2.2 is printed in <b>bold</b>.</p> <p>b. Switching within or between drug classes is permitted. Any potential dose adjustment options are assumed to have already been exhausted. In case of primary failure of TNF-<math>\alpha</math> antagonist treatment, switching to another drug class is indicated. In secondary failure of TNF-<math>\alpha</math> antagonist treatment, a switch within the drug class may be contemplated.</p> <p>c. Guselkumab is assumed to be administered as long-term therapy (induction and maintenance). Hence, drugs which are options only for the initial reduction of disease activity according to the guideline are disregarded below. Corticosteroids are generally deemed appropriate for flare treatment. Continuation of an inadequate therapy does not constitute an implementation of the ACT.</p> <p>d. For patients who continue to be candidates for drug therapy, a decision in favour of surgical resection is presumed to represent an individualized choice for that particular patient if necessary and is not the rule; surgical resection is therefore to be disregarded when determining the ACT.</p> <p>e. If infliximab is used, it should be combined with a thiopurine, if necessary.</p> <p>ACT: appropriate comparator therapy; G-BA: Federal Joint Committee; TNF: tumour necrosis factor</p>			

The G-BA decides on the added benefit.

### 3 References

The reference list contains citations provided by the company in which bibliographical information may be missing.

1. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Guselkumab (Colitis ulcerosa); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2025 [Accessed: 08.10.2025]. URL: <https://doi.org/10.60584/A25-74>.
2. Johnson & Johnson. Stellungnahme zum IQWiG-Bericht Nr. 2074: Guselkumab (Colitis ulcerosa); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung. [Soon available at: <https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1230/#beschluesse> in the document "Zusammenfassende Dokumentation"].
3. Johnson & Johnson. Guselkumab (Tremfya); Dossier zur Nutzenbewertung gemäß § 35a SGB V [online]. 2025 [Accessed: 08.10.2025]. URL: <https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1230/#dossier>.