Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Guselkumab (new therapeutic indication: ulcerative colitis, pretreated)

of 20 November 2025

At their session on 20 November 2025, the Federal Joint Committee (G-BA) resolved not to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Guselkumab in accordance with the resolution of 20 May 2021:

Guselkumab

Resolution of: 20 November 2025
Entry into force on: 20 November 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 24 April 2025):

Tremfya is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biologic treatment.

Therapeutic indication of the resolution (resolution of 20 November 2025):

See new therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

a) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to conventional therapy

Appropriate comparator therapy:

- Adalimumab or golimumab or infliximab or mirikizumab or ozanimod or ustekinumab or vedolizumab

Extent and probability of the additional benefit of guselkumab compared to golimumab:

An additional benefit is not proven.

b) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to a biologic agent (TNF-α antagonist or integrin inhibitor or interleukin inhibitor)

Appropriate comparator therapy:

- Adalimumab or filgotinib or golimumab or infliximab or mirikizumab or ozanimod or tofacitinib or upadacitinib or ustekinumab or vedolizumab

Extent and probability of the additional benefit of guselkumab compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

[1] Data from the dossier assessment of the IQWiG (A25-74) and from the addendum (A25-132), unless otherwise indicated.

a) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to conventional therapy

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant differences for the benefit assessment.
Morbidity	↔	No relevant differences for the benefit assessment. Advantage in the PGIC.
Health-related quality of life	↔	No relevant differences for the benefit assessment. Advantages in the "Sleep impairment" and "Participation in social roles and activities" domains of the PROMIS-29.
Side effects	↔	No relevant differences for the benefit assessment.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: No data available.
n.a.: not assessable

VEGA study: double-blind RCT; guselkumab vs golimumab

Mortality (until week 50)

Endpoint	Guselkumab		Golimumab		Guselkumab vs golimumab
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value[a]
Overall mortality[b]	71	1 (1.4)	72	0 (0)	-

Morbidity (at week 38)

Endpoint	Guselkumab		Golimumab		Guselkumab vs golimumab
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value[a]
Symptomatic remission[c]	71	50 (70.4)	72	44 (61.1)	1.15 [0.91; 1.46]; 0.240
90-day corticosteroid-free period *(presented additionally)*	71	66 (93)	72	65 (90.3)	1.03 [0.94; 1.13]; 0.538
Bowel symptoms (IBDQ – improvement[d])	71	53 (74.6)	72	43 (59.7)	1.25 [0.99; 1.58]; 0.060
Systemic symptoms (IBDQ – improvement[d])	71	50 (70.4)	72	40 (55.6)	1.27 [0.98; 1.64]; 0.069
Fatigue (PROMIS Fatigue SF 7a – improvement[e])	71	34 (47.9)	72	27 (37.5)	1.28 [0.87; 1.88]; 0.213
Symptomatology (PGIC – improvement[f])	71	63 (88.7)	72	53 (73.6)	1.21 [1.03; 1.42]; 0.023

Health-related quality of life (at week 38)

Endpoint	Guselkumab		Golimumab		Guselkumab vs golimumab
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value[a]
IBDQ total score (improvement[d])	71	52 (73.2)	72	43 (59.7)	1.23 [0.97; 1.55]; 0.089
Bowel symptoms	71	53 (74.6)	72	43 (59.7)	1.25 [0.99; 1.58]; –
Systemic symptoms	71	50 (70.4)	72	40 (55.6)	1.27 [0.98; 1.64]; –
Emotional functioning	71	49 (69.0)	72	43 (59.7)	1.16 [0.90; 1.48]; –
Social functioning	71	53 (74.6)	72	44 (61.1)	1.22 [0.97; 1.54]; –
PROMIS-29 – improvement					
Physical Health Summary (PHS) score	n.d.				
Mental Health Summary (MHS) score	n.d.				
Physical functioning[g]	71	36 (50.7)	72	31 (43.1)	1.18 [0.83; 1.68]; 0.364

Anxiety [h]	71	38 (53.5)	72	32 (44.4)	1.20 [0.86; 1.69]; 0.281
Depressiveness[h]	71	33 (46.5)	72	29 (40.3)	1.15 [0.79; 1.67]; 0.457
Exhaustion[h]	71	36 (50.7)	72	29 (40.3)	1.26 [0.88; 1.81]; 0.215
Sleep impairment[h]	71	34 (47.9)	72	22 (30.6)	1.56 [1.03; 2.39]; 0.038
Participation in social roles and activities[g]	71	48 (67.6)	72	36 (50.0)	1.35 [1.02; 1.79]; 0.036
Impairment due to pain[h]	71	43 (60.6)	72	36 (50.0)	1.21 [0.90; 1.63]; 0.208
Pain severity[h]	71	20 (28.2)	72	17 (23.6)	1.19 [0.68; 2.07]; 0.538

Side effects (until week 50)[i]

Endpoint	**Guselkumab**		**Golimumab**		**Guselkumab vs golimumab**
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value[a]
AEs (presented additionally)	71	45 (63.4)	72	46 (63.9)	–
SAEs	71	4 (5.6)	72	3 (4.2)	1.36 [0.32; 5.83]; 0.682
Therapy discontinuation due to AEs	71	1 (1.4)	72	1 (1.4)	1.01 [0.06; 15.91]; 0.993
Infections[j]	71	17 (23.9)	72	23 (31.9)	0.75 [0.44; 1.28]; 0.287

a. Cochran-Mantel-Haenszel method with the stratification factor of treatment with corticosteroids at baseline (yes/ no). Missing values are taken into account using NRI (for endpoints on morbidity and health-related quality of life).
b. The results on overall mortality are based on the data on fatal AEs.
c. Defined as the percentage of patients with an SF (stool frequency) score of 0 or 1 ("normal or slightly increased number of daily bowel movements") at week 38 and no deterioration in stool frequency compared to the survey at the start of the study and an RB (rectal bleeding) score of 0 ("no blood visible in the stool") at week 38. The SF score and the RB score are calculated using a patient diary for the last 7 days before the visit. At week 38, a total of 58 (81.7%) vs 48 (66.7%) of the patients had an SF score of 0 or 1 and 56 (78.9%) vs 45 (62.5%) of the patients had an RB score of 0.
d. An increase in the score by ≥ 15% of the scale range (total score: ≥ 28.8 points; bowel symptoms: ≥ 9 points; systemic symptoms or social functioning: ≥ 4.5 points or emotional functioning: ≥ 10.8 points) compared to the start of the study is considered as clinically relevant improvement (range of the scales: 32 to 224 [total score], 10 to 70 [bowel symptoms], 5 to 35 [systemic symptoms and social functioning] and 12 to 84 [emotional functioning]).
e. A decrease in score by ≥ 8.07 points compared to the start of the study is considered as clinically relevant improvement (scale range: 29.4 to 83.2).

f. Defined as any improvement in symptom severity compared to the start of the study ("very much improved", "much improved", or "slightly improved").
g. An increase in the score by ≥ 15% of the scale range (physical functioning: ≥ 5.1 points; participation in social roles and activities: ≥ 5.51 points) compared to the start of the study is considered as clinically relevant improvement (range of the scales: 22.9 to 56.9 [physical functioning]; 27.5 to 64.2 [participation in social roles and activities]).
h. A decrease in the score by ≥ 15% of the scale range (anxiety: ≥ 6.2 points; depressiveness: ≥ 5.76 points; exhaustion: ≥ 6.32 points; sleep impairment: ≥ 6.2 points; impairment due to pain: ≥ 5.1 points, pain severity: ≥ 5 points) compared to the start of the study is considered as clinically relevant improvement (range of the scales: 40.3 to 81.6 [anxiety]; 41.0 to 79.4 [depressiveness]; 33.7 to 75.8 [exhaustion]; 32.0 to 73.3 [sleep impairment]; 41.6 to 75.6 [impairment due to pain]; 0 to 10 [pain severity]).
i. Overall rate without disease-related events.
j. Operationalised as infections and infestations (SOC, AEs).

Abbreviations used:
IBDQ: Inflammatory Bowel Disease Questionnaire; n.d.: no data available; CI: confidence interval; n: number of patients with (at least 1) event; N: number of patients evaluated; NRI: non-response imputation; MHS: Mental Health Summary Score; PGIC: Patient Global Impression of Change; PHS: Physical Health Summary Score; PROMIS: Patient-Reported Outcome Measurement Information System; RCT: randomised controlled trial; RR: relative risk; SF 7a: Short Form 7a; SOC: system organ class; SAE: serious adverse event; AE: adverse event

b) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to a biologic agent (TNF-α antagonist or integrin inhibitor or interleukin inhibitor)

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

a) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to conventional therapy

Approx. 19,200 patients

b) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to a biologic agent (TNF-α antagonist or integrin inhibitor or interleukin inhibitor)

Approx. 9,900 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Tremfya (active ingredient: guselkumab) at the following publicly accessible link (last access: 26 September 2025):

https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf

Treatment with guselkumab should only be initiated and monitored by specialists experienced in treating ulcerative colitis.

4. Treatment costs

Annual treatment costs:

a) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to conventional therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Guselkumab Additionally required SHI services: Total:	€ 17,290.10 € 71.45 € 17,361.55
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services: Total:	€ 12,193.92 € 81.94 € 12,275.86
Golimumab Additionally required SHI services: Total:	€ 11,037.30 € 81.94 € 11,119.24
Infliximab Additionally required SHI services: Total:	€ 16,898.75 € 81.94 € 16,980.69
Mirikizumab	€ 11,720.58
Ozanimod	€ 19,245.52
Ustekinumab Additionally required SHI services: Total:	€ 11,798.81 € 71.45 € 11,870.26
Vedolizumab Additionally required SHI services: Total:	€ 14,783.13 € 71.45 € 14,854.58

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 September 2025)

b) Adults with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a biologic agent (TNF-α antagonist or integrin inhibitor or interleukin inhibitor)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Guselkumab Additionally required SHI services: Total:	€ 17,290.10 € 71.45 € 17,361.55
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services: Total:	€ 12,193.92 € 81.94 € 12,275.86
Filgotinib Additionally required SHI services: Total:	€ 11,662.20 € 81.94 € 11,744.14
Golimumab Additionally required SHI services: Total:	€ 11,037.30 € 81.94 € 11,119.24
Infliximab Additionally required SHI services: Total:	€ 16,898.75 € 81.94 € 16,980.69
Mirikizumab	€ 11,720.58
Ozanimod	€ 19,245.52
Tofacitinib Additionally required SHI services: Total:	€ 11,721.15 € 81.94 € 11,803.09
Upadacitinib Additionally required SHI services: Total:	€ 14,166.34 - € 18,079.83 € 81.94 € 14,248.28 - € 18,161.77
Ustekinumab Additionally required SHI services: Total:	€ 11,798.81 € 71.45 € 11,870.26
Vedolizumab Additionally required SHI services: Total:	€ 14,783.13 € 71.45 € 14,854.58

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 September 2025)

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

a) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to conventional therapy

- No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to a biologic agent (TNF-α antagonist or integrin inhibitor or interleukin inhibitor)

- No medicinal product with new active ingredients that can be used in a combination therapy, for which the requirements of Section 35a, paragraph 3, sentence 4 SGB V are fulfilled.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 November 2025.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 20 November 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken