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
Risankizumab (new therapeutic indication: ulcerative colitis, pretreated)

of 20 February 2025

At its session on 20 February 2025, the Federal Joint Committee (G-BA) resolved 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. 5 to the information on the benefit assessment of Risankizumab in accordance with the resolution of 15 June 2023 last modified on 21 December 2023:

Risankizumab

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

New therapeutic indication (according to the marketing authorisation of 24 July 2024):

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

Therapeutic indication of the resolution (resolution of 20 February 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 ozanimod or ustekinumab or vedolizumab

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

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 ozanimod or tofacitinib or ustekinumab or vedolizumab

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

An additional benefit is not proven.

Study results according to endpoints:[1]

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

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		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-84) unless otherwise indicated.

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 Skyrizi (active ingredient: risankizumab) at the following publicly accessible link (last access: 15 October 2024):

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

Treatment with risankizumab should only be initiated and monitored by doctors 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:	
Risankizumab Additionally required SHI services: Total:	€ 19,116.44 € 81.94 € 19,198.38
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services: Total:	€ 12,193.92 € 81.94 € 12,275.86
Golimumab Additionally required SHI services:	€ 11,037.30 € 81.94

Designation of the therapy	Annual treatment costs/ patient
Total:	€ 11,119.24
Infliximab Additionally required SHI services: Total:	€ 16,898.75 € 81.94 € 16,980.69
Ozanimod	€ 19,212.22
Ustekinumab Additionally required SHI services: Total:	€ 23,597.63 € 81.94 € 23,679.57
Vedolizumab Additionally required SHI services: Total:	€ 14,904.93 € 81.94 € 14,986.87

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2025)

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)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Risankizumab Additionally required SHI services: Total:	€ 19,116.44 € 81.94 € 19,198.38
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
Filgotinib Additionally required SHI services: Total:	€ 11,662.20 € 81.94 € 11,744.14
Infliximab Additionally required SHI services: Total:	€ 16,898.75 € 81.94 € 16,980.69
Ozanimod	€ 19,212.22
Tofacitinib Additionally required SHI services: Total:	€ 11,721.15 € 81.94 € 11,803.09

Designation of the therapy	Annual treatment costs/ patient
Ustekinumab Additionally required SHI services: Total:	€ 23,597.63 € 81.94 € 23,679.57
Vedolizumab Additionally required SHI services: Total:	€ 14,904.93 € 81.94 € 14,986.87

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 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 and 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 that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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 February 2025.**

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

Berlin, 20 February 2025

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

Prof. Hecken