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) Etrasimod (ulcerative colitis, pretreated, ≥ 16 years)

of 2 October 2024

At its session on 2 October 2024, 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. Annex XII shall be amended in alphabetical order to include the active ingredient Etrasimod as follows:

Etrasimod

Resolution of: 2 October 2024
Entry into force on: 2 October 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 16 February 2024):

Velsipity is indicated for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

Therapeutic indication of the resolution (resolution of 2 October 2024):

See therapeutic indication according to marketing authorisation.

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

a) Adults and adolescents 16 years of age and older 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 etrasimod compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults and adolescents 16 years of age and older 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 etrasimod compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

a) Adults and adolescents 16 years of age and older 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		

b) Adults and adolescents 16 years of age and older 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 and adolescents 16 years of age and older 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 and adolescents 16 years of age and older 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 Velsipity (active ingredient: etrasimod) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 15 April 2024):

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

Treatment with etrasimod should only be initiated and monitored by doctors experienced in treating ulcerative colitis.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (including pregnancy-specific patient pass). The training material contains, in particular, instructions on how to deal with the side effects potentially occurring with etrasimod and on embryo-foetal toxicity.

Prior to treatment with etrasimod, all patients should take an electrocardiogram (ECG) to detect any pre-existing cardiac abnormalities.

4. Treatment costs

Annual treatment costs:

a) Adults and adolescents 16 years of age and older 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:	

Designation of the therapy	Annual treatment costs/ patient
Etrasimod	€ 14,696.50
Appropriate comparator therapy:	
Adalimumab Additionally required SHI services: Total:	€ 12,192.92 - € 24,385.84 € 86.82 € 12,279.74 - € 24,472.66
Golimumab Additionally required SHI services: Total:	€ 11,036.31 € 86.82 € 11,123.13
Infliximab Additionally required SHI services: Total:	€ 12,605.00 - € 16,897.75 € 86.82 € 12,691.82 - € 16,984.57
Vedolizumab Additionally required SHI services: Total:	€ 14,903.93 € 86.82 € 14,990.75
Ustekinumab Additionally required SHI services: Total:	€ 14,155.51 € 86.62 € 14,242.33
Ozanimod	€ 19,211.37

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2024)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Infliximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.5	€ 650

b) Adults and adolescents 16 years of age and older 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:	
Etrasimod	€ 14,696.50
Appropriate comparator therapy:	
Vedolizumab	€ 14,903.93

Designation of the therapy	Annual treatment costs/ patient
Additionally required SHI services: Total:	€ 86.82 € 14,990.75
Tofacitinib Additionally required SHI services: Total:	€ 11,720.23 € 86.82 € 11,807.05
Ustekinumab Additionally required SHI services: Total:	€ 14,155.51 € 86.62 € 14,242.33
Filgotinib Additionally required SHI services: Total:	€ 11,661.26 € 86.82 € 11,748.08
Ozanimod	€ 19,211.37
Adalimumab Additionally required SHI services: Total:	€ 12,192.92 - € 24,385.84 € 86.82 € 12,279.74 - € 24,472.66
Golimumab Additionally required SHI services: Total:	€ 11,036.31 € 86.82 € 11,123.13
Infliximab Additionally required SHI services: Total:	€ 12,605.00 - € 16,897.75 € 86.82 € 12,691.82 - € 16,984.57

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2024)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Appropriate comparator therapy					
Infliximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6.5	€ 650

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 and adolescents 16 years of age and older 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 and adolescents 16 years of age and older 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 2 October 2024.

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

Berlin, 2 October 2024

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

Prof. Hecken