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
Ozanimod (new therapeutic indication: ulcerative colitis)

of 16 June 2022

At its session on 16 June 2022, 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. 4 to the information on the benefit assessment of Ozanimod in accordance with the resolution of 7 January 2021 last modified on 15 April 2021:

Ozanimod

Resolution of: 16 June 2022
Entry into force on: 16 June 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 18 November 2021):

Zeposia is indicated for the treatment of adult patients 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 biologic agent.

Therapeutic indication of the resolution (resolution of 16 June 2022):

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 with, lost response to, were intolerant to, or were contraindicated for conventional therapy.

Appropriate comparator therapy:

- A TNF-α antagonist (adalimumab or infliximab or golimumab) or vedolizumab or ustekinumab

Extent and probability of the additional benefit of ozanimod 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 with, lost response to, or were intolerant to either a biologic agent (TNF-α antagonist or integrin inhibitor or interleukin inhibitor) or a corresponding treatment.

Appropriate comparator therapy:

- A change of therapy to vedolizumab or tofacitinib or ustekinumab or a TNF-α antagonist (adalimumab or infliximab or golimumab), in each case taking into account the marketing authorisation and the previous therapy/ therapies

Extent and probability of the additional benefit of Ozanimod 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 with, lost response to, were intolerant to, or were contraindicated for conventional therapy.

No suitable data versus the appropriate comparator therapy

were presented.

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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

[1] Data from the dossier assessment of the IQWiG (A21-166 V2.0) unless otherwise indicated.

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

No suitable data versus the appropriate comparator therapy were presented.

Summary of results for relevant clinical endpoints

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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
∅: There are no usable data for the benefit assessment.
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 with, lost response to, were intolerant to, or contraindicated for conventional therapy.

approx. 3,500 – 16,500 patients

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

approx. 1,800 – 8,500 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 Zeposia (active ingredient: ozanimod) at the following publicly accessible link (last access: 30 May 2022):
https://www.ema.europa.eu/en/documents/product-information/zeposia-epar-product-information_en.pdf

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

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide a checklist for doctors, a guideline for patients and caregivers as well as a patient reminder card. The training and information material contains, in particular, instructions on how to deal with the side effects potentially occurring with ozanimod and on embryo-foetal toxicity.

4. Treatment costs

Annual treatment costs:

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Ozanimod	€ 23,496.32
Appropriate comparator therapy:	
Adalimumab	€ 11,435.41
Additionally required SHI services	€ 180.85
Total	€ 11,616.26
Golimumab	€ 10,383.71
Additionally required SHI services	€ 180.85
Total	€ 10,564.56
Infliximab	€ 16,685.14
Additionally required SHI services	€ 180.85
Total	€ 16,865.99
Ustekinumab	€ 21,432.83
Additionally required SHI services	€ 74.45
Total	€ 21,507.28
Vedolizumab	€ 15,468.08
Additionally required SHI services	€ 74.45
Total	€ 15,542.53

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 May 2022)

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
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Appropriate comparator therapy:	
Adalimumab	€ 11,435.41
Additionally required SHI services	€ 180.85
Total	€ 11,616.26
Golimumab	€ 10,383.71
Additionally required SHI services	€ 180.85
Total	€ 10,564.56
Infliximab	€ 16,685.14
Additionally required SHI services	€ 180.85
Total	€ 16,865.99
Tofacitinib	€ 12,566.75
Additionally required SHI services	€ 180.85
Total	€ 12,747.60
Ustekinumab	€ 21,432.83
Additionally required SHI services	€ 74.45
Total	€ 21,507.28
Vedolizumab	€ 15,468.08
Additionally required SHI services	€ 74.45
Total	€ 15,542.53

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 May 2022)

Other SHI services:

Designation of the therapy	Type of service	Unit cost	Number per patient per year	Costs per patient per year
Medicinal product to be assessed				
not applicable				
Appropriate comparator therapy for patient populations a) and b)				

Designation of the therapy	Type of service	Unit cost	Number per patient per year	Costs per patient per year
Infliximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	6.5	€ 461.50

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 June 2022.

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

Berlin, 16 June 2022

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

Prof. Hecken