

**Ozanimod** (new therapeutic indication: ulcerative colitis)

Resolution of: 16 June 2022

valid until: unlimited

Entry into force on: 16 June 2022

Federal Gazette, BAnz AT 08 08 2022 B3

**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- $\alpha$  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- $\alpha$  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- $\alpha$  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:<sup>1</sup>**

- 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		

<sup>1</sup> 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- $\alpha$  antagonist or integrin inhibitor or interleukin inhibitor) or a corresponding treatment.

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## 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- $\alpha$  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](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- $\alpha$  antagonist or integrin inhibitor or interleukin inhibitor) or a corresponding treatment.

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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
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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