Filgotinib (new therapeutic indication: ulcerative colitis)

Resolution of: 19 May 2022 valid until: unlimited
Entry into force on: 19 May 2022
Federal Gazette, BAnz AT 13 06 2022 B4

New therapeutic indication (according to the marketing authorisation of 12 November 2021):

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

Therapeutic indication of the resolution (resolution of 19 May 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 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 Filgotinib 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 therapies

Extent and probability of the additional benefit of Filgotinib 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 (A21-155 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.

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↓↓: 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 were 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 Jyseleca (active ingredient: filgotinib) at the following publicly accessible link (last access: 5 May 2022):

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

Treatment with filgotinib 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 training material and a patient identification card. The training material for medical professionals includes instructions on how to manage the potential side effects associated with filgotinib, particularly severe and opportunistic infections including tuberculosis and herpes zoster and the risk for impaired spermatogenesis. The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. The reversibility of these potential effects is not known. The potential risk of decreased fertility or infertility should be discussed with male patients prior to initiation of treatment.

Furthermore, against the background of the ongoing Pharmacovigilance Risk Assessment Committee (PRAC) procedure of the EMA, the safety profile of the JAK inhibitors, such as filgotinib, cannot be conclusively assessed at present.

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 were contraindicated for conventional therapy.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Filgotinib	€ 11,662.07
Additionally required SHI services	€ 106.40
Total	€ 11,768.47
Appropriate comparator therapy:	
Adalimumab	€ 11,435.41
Additionally required SHI services	€ 106.40
Total	€ 11,541.81

Designation of the therapy	Annual treatment costs/ patient
Golimumab	€ 10,383.71
Additionally required SHI services	€ 106.40
Total	€ 10,490.11
Infliximab	€ 16,685.14
Additionally required SHI services	€ 106.40
Total	€ 16,791.54
Ustekinumab	€ 21,432.83
Vedolizumab	€ 15,468.08

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 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:	
Filgotinib	€ 11,662.07
Additionally required SHI services	€ 106.40
Total	€ 11,768.47
Appropriate comparator therapy:	
Adalimumab	€ 11,435.41
Additionally required SHI services	€ 106.40
Total	€ 11,541.81
Golimumab	€ 10,383.71
Additionally required SHI services	€ 106.40
Total	€ 10,490.11
Infliximab	€ 16,685.14
Additionally required SHI services	€ 106.40
Total	€ 16,791.54
Tofacitinib	€ 12,566.75
Additionally required SHI services	€ 106.40
Total	€ 12,673.15
Ustekinumab	€ 21,432.83
Vedolizumab	€ 15,468.08

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 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)				
Infliximab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	6.5	€ 461.50