

# Resolution



## **of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL):**

### **Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Apremilast (New Therapeutic Indication: Behçet’s Disease)**

of 5 November 2020

On 5 November 2020, the Federal Joint Committee (G-BA) resolved by written statement to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 on DD 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 apremilast in accordance with the resolution of 17 August 2015:**

## **Apremilast**

Resolution of: 5 November 2020

Entry into force on: 5 November 2020

Federal Gazette, BAnz AT DD MM YYYY Bx

### **New therapeutic indication (according to the marketing authorisation of 8 April 2020):**

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet's disease (BD) who are candidates for systemic therapy.

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

Adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy.

#### **Appropriate comparator therapy:**

- Therapy according to the doctor's instructions

#### **Extent and probability of the additional benefit of apremilast compared with the appropriate comparator therapy:**

An additional benefit is not proven.

#### **Study results according to endpoints:<sup>1</sup>**

Adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy.

No suitable data were submitted for the benefit assessment.

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<sup>1</sup> Data from the dossier assessment of the IQWiG (A20-44) unless otherwise indicated.

## Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n.a.	No relevant data are available.
Morbidity	n.a.	No relevant data are available.
Health-related quality of life	n.a.	No relevant data are available.
Side effects	n.a.	No relevant data are available.
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

Adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy.

approx. 750–2,200 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 Otezla® (active ingredient: apremilast) at the following publicly accessible link (last access: 3 September 2020):

[https://www.ema.europa.eu/documents/product-information/otezla-epar-product-information\\_en.pdf](https://www.ema.europa.eu/documents/product-information/otezla-epar-product-information_en.pdf)

Treatment with apremilast should only be initiated and monitored by specialists who are experienced in the treatment of patients with Behçet's disease.

#### 4. Treatment costs

##### Annual treatment costs:

Adult patients with oral ulcers associated with Behçet's disease who are candidates for systemic therapy.

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Apremilast	€ 13,867.61
Appropriate comparator therapy:	
Therapy according to the doctor's instructions	
- Azathioprine <sup>a</sup>	€ 93.18–464.17
<sup>a</sup> Costs are only shown for the active ingredient azathioprine. In addition to azathioprine, the medicinal products cyclosporine, colchicine, interferon-alpha, thalidomide and TNF alpha inhibitors also represent suitable comparators for the present benefit assessment in the context of a therapy according to the doctor's instructions. However, these medicinal products are not approved in the present therapeutic indication and therefore no costs are shown for them.	

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2020

Costs for additionally required SHI services: not applicable

**II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 5 November 2020.**

The justification to this resolution will be published on the website of the G-BA at [www.g-ba.de](http://www.g-ba.de).

Berlin, 5 November 2020

Federal Joint Committee  
in accordance with Section 91 SGB V  
The Chair

Prof. Hecken