Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on
an amendment to the Pharmaceuticals Directive (AM-RL), Annex XII - Benefit Assessment of Medicinal Products with New Active Ingredients in accordance with Section 35a SGB V: Baricitinib (new therapeutic indication: moderate to severe atopic dermatitis)

of 6 May 2021

At its meeting on 6 May 2021, 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 on DD. Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information is added after No 4 to the information on the benefit assessment of baricitinib in accordance with the decision of 21 September 2017:

Baricitinib

Resolution of: 6 May 2021
Entry into force on: 6 May 2021
BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 October 2020):

Olumiant is indicated for the treatment of moderate to severe atopic dermatitis in adult patients eligible for systemic therapy.

Therapeutic indication of the resolution (resolution of 6 May 2021):

see new therapeutic indication according to marketing authorisation

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

Adult patients with moderate to severe atopic dermatitis who are eligible for continuous systemic therapy

Appropriate comparator therapy:

Dupilumab (in combination with topical glucocorticoids (TCS) and/or topical calcineurin inhibitors (TCI) if required)

Extent and probability of the additional benefit of baricitinib compared to the appropriate comparator therapy:

An additional benefit is not proven.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n. a.	There are no suitable data.
Morbidity	n. a.	There are no suitable data.
Health-related quality of life	n. a.	There are no suitable data.
Side effects	n. a.	There are no suitable 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

2. Number of patients or demarcation of patient groups eligible for treatment

Adult patients with moderate to severe atopic dermatitis who are eligible for continuous systemic therapy

approx. 52,000 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) has published the contents of the product information (Summary of Product Characteristics, SmPC) for Olumiant (active ingredient: baricitinib) is freely available at the following link (last accessed: 14 April 2021):
https://www.ema.europa.eu/documents/product-information/olumiant-epar-product-information_de.pdf

In patients in whom no therapeutic benefit can be demonstrated after 8 weeks of treatment, discontinuation of treatment should be considered.

In accordance with the requirements for risk minimisation activities in the EPAR (European Public Assessment Report), the following information material on baricitinib must be provided by the pharmaceutical company:

- Training and information material for the doctor/medical staff
- Training and information material for the patient

4. Treatment costs

Annual treatment costs:

Adult patients with moderate to severe atopic dermatitis who are eligible for continuous systemic therapy

Name of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Baricitinib	€ 14,328.26
Additionally required SHI services:	€ 180.64
Appropriate comparator therapy:	
Dupilumab	€ 17,795.11

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 April 2021)

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 6 May 2021.

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

Berlin, 6 May 2021

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

Prof. Hecken