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)
Abrocitinib (new therapeutic indication: atopic dermatitis, ≥ 12 to ≤ 17 years)

of 17 October 2024

At its session on 17 October 2024, 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 Abrocitinib in accordance with the resolution of 7 July 2022:

Abrocitinib

Resolution of: 17 October 2024
Entry into force on: 17 October 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 21 March 2024):

Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

Therapeutic indication of the resolution (resolution of 17 October 2024):

Cibinqo is indicated for the treatment of moderate-to-severe atopic dermatitis in adolescents ≥ 12 to ≤ 17 years of age who are candidates for systemic therapy.

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

Adolescents 12 to ≤ 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

Appropriate comparator therapy:

- Dupilumab (in combination with TCS and/or TCI if required)

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adolescents 12 to ≤ 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

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 ∅: No data available. n.a.: not assessable		

No suitable data submitted.

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

Adolescents 12 to ≤ 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

Approx. 5,300 – 10,600 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 Cibinqo (active ingredient: abrocitinib) at the following publicly accessible link (last access: 5 September 2024):

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-25) unless otherwise indicated.

Treatment with abrocitinib should only be initiated and monitored by doctors experienced in treating atopic dermatitis.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card).

In particular, the training material contains information and warnings on the risk of serious and opportunistic infections including tuberculosis and herpes zoster. It also points out the need for an effective contraceptive method.

4. Treatment costs

Annual treatment costs:

Adolescents 12 to ≤ 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Abrocitinib	€ 16,236.92- € 18,976.43
Additionally required SHI costs	€ 181.82
Total	€ 16,418.74- € 19,158.25
Appropriate comparator therapy:	
Dupilumab	€ 16,036.14

Costs after deduction of statutory rebates ((LAUER-TAXE®) as last revised: 15 September 2024)

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adolescents 12 to ≤ 17 years of age with moderate to severe atopic dermatitis who are candidates for systemic therapy

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 17 October 2024.

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

Berlin, 17 October 2024

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

Prof. Hecken