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)
Lebrikizumab (atopic dermatitis, ≥ 12 years)

of 6 June 2024

At its session on 6 June 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. Annex XII shall be amended in alphabetical order to include the active ingredient Lebrikizumab as follows:**

**Lebrikizumab**

Resolution of: 6 June 2024
Entry into force on: 6 June 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

**Therapeutic indication (according to the marketing authorisation of 16 November 2023):**

Ebglyss is indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older with a body weight of at least 40 kg who are candidates for systemic therapy.

**Therapeutic indication of the resolution (resolution of 6 June 2024):**

Therapeutic indication according to marketing authorisation.

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

Adults and adolescents 12 years and older 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 lebrikizumab 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 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:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

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

Adults and adolescents 12 years and older with moderate-to-severe atopic dermatitis who are candidates for systemic therapy

Approx. 57,300 to 62,600 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 Ebglyss (active ingredient: lebrikizumab) at the following publicly accessible link (last access: 24 April 2024):

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

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

## 4. Treatment costs

**Annual treatment costs:**

Adults and adolescents 12 years and older 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: | |
| Lebrikizumab | € 13,537.51 |
| Appropriate comparator therapy: | |
| Dupilumab | € 16,183.04 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2024)

Costs for additionally required SHI services: not applicable

**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:

Adults and adolescents 12 years and older 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 6 June 2024.**

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

Berlin, 6 June 2024

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

Prof. Hecken