

Lebrikizumab (atopic dermatitis, ≥ 12 years)

Resolution of: 6 June 2024
Entry into force on: 6 June 2024
Federal Gazette, BAnz AT 04 07 2024 B6

Valid until: unlimited

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: ↑: 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		

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.