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: Tralokinumab (atopic dermatitis)

of 6 January 2022

At its session on 6 January 2022, 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 Tralokinumab as follows:**

**Tralokinumab**

Resolution of: 6 January 2022
Entry into force on: 6 January 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

**Therapeutic indication (according to the marketing authorisation of 17 June 2021):**

Adtralza is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.

**Therapeutic indication of the resolution (resolution of 6 January 2022):**

see 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 Tralokinumab compared to Dupilumab:**

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. | No suitable data available. |
| Morbidity | n.a. | No suitable data available. |
| Health-related quality of life | n.a. | No suitable data available. |
| Side effects | n.a. | No suitable data 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 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) provides the contents of the product information (summary of product characteristics, SmPC) for Adtralza (active ingredient: tralokinumab) at the following publicly accessible link (last access: 14 December 2021):

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

Discontinuation of treatment should be considered for patients who do not show a response after 16 weeks of treatment. Some patients with an initial partial response may continue to benefit from fortnightly treatment continued beyond 16 weeks.

## 4. Treatment costs

**Annual treatment costs:**

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

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Tralokinumab | € 8,863.47 - € 17,795.11 |
| Appropriate comparator therapy: | |
| Dupilumab | € 17,795.11 |

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 December 2021)

Costs for additionally required SHI services: not applicable

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 6 January 2022.**

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

Berlin, 6 January 2022

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

Prof. Hecken