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

of 12 May 2023

At its session on 12 May 2023, 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 Tralokinumab in accordance with the resolution of 6 January 2022:

Benefit assessment procedure comprises several resolutions.
Please note the current version of the Pharmaceuticals Directive/Annex XII.

Courtesy translation – only the German version is legally binding.

Tralokinumab

Resolution of: 12 May 2023
Entry into force on: 12 May 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 14 October 2022):

Adtralza is indicated for the treatment of moderate-to-severe atopic dermatitis in adult and adolescent patients 12 years and older who are candidates for systemic therapy.

Therapeutic indication of the resolution (resolution of 12 May 2023):

Treatment of moderate-to-severe atopic dermatitis in adolescents 12 to 17 years of age who are eligible for systemic therapy.

Please note the current version of the Pharmaceuticals Directive/Annex XII.
Brief assessment procedure comprises several resolutions.

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 continuous systemic therapy

Appropriate comparator therapy:

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

Extent and probability of the additional benefit of tralokinumab 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

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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 continuous systemic therapy

Approx. 5,300 to 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 Adtralza (active ingredient: tralokinumab) at the following publicly accessible link (last access: 8 May 2023):

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:

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

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tralokinumab	€ 8,234.46 -€ 16,532.26
Appropriate comparator therapy:	
Appropriate comparator therapy:	
Dupilumab	€ 17,035.73

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2023)

Costs for additionally required SHI services: not applicable

Please note: The benefit assessment procedure comprises several resolutions. Only the German version of the Pharmaceuticals Directive/Annex XII.

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5. 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 Tralokinumab

Medicinal products with the new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with tralokinumab for the treatment of moderate to severe atopic dermatitis in adolescents between 12 and 17 years of age on the basis of the marketing authorisation granted under Medicinal Products Act:

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

A designation of the concomitant active ingredients shall be made in a further resolution. The adoption of the resolution will be preceded by a written and oral written statement procedure pursuant to Chapter 5, Section 19 of the Regulation, in the course of which the pharmaceutical companies concerned will be given the opportunity to comment on the planned designation.

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 12 May 2023.

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

Berlin, 12 May 2023

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

Prof. Hecken

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