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
Dupilumab (new therapeutic indication: eosinophilic esophagitis, ≥ 1 year to < 12 years)

of 15 May 2025

At their session on 15 May 2025, 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. 5 to the information on the benefit assessment of Dupilumab in accordance with the resolution of 6 February 2025:

Dupilumab

Resolution of: 15 May 2025
Entry into force on: 15 May 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 4 November 2024):

Dupixent is indicated for the treatment of eosinophilic esophagitis in children 1 to 11 years old, weighing at least 15 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy.

Therapeutic indication of the resolution (resolution of 15 May 2025):

See new therapeutic indication according to marketing authorisation.

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

Children 1 to 11 years old with eosinophilic esophagitis (EoE), who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy

Appropriate comparator therapy:

An individualised therapy with a selection of budesonide and proton pump inhibitors (PPI)

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

An additional benefit is not proven.

Study results according to endpoints:

There are no assessable data.

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

Children 1 to 11 years old with eosinophilic esophagitis (EoE), who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy

Approx. 530 to 590 children.

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 Dupixent (active ingredient: dupilumab) at the following publicly accessible link (last access: 7 April 2025):

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

Treatment with dupilumab should only be initiated and monitored by doctors experienced in treating patients with EoE.

4. Treatment costs

Annual treatment costs:

Children 1 to 11 years old with eosinophilic esophagitis (EoE), who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy

Designation of the therapy	Annual treatment costs/ child
Medicinal product to be assessed:	
Dupilumab	€ 16,037.15 – € 32,012.85
Appropriate comparator therapy:	
Budesonide	€ 2,797.58
Esomeprazole[1]	€ 69.92 – € 1,286.63
Esomeprazole ECG ≥ 1 year (min. 15 kg) to < 6 years	€ 1,286.63
Esomeprazole ECT < 6 years	€ 69.92
Esomeprazole ECT ≥ 6 years to < 12 years	€ 85.37
Omeprazole[1]	€ 71.50 – € 5,722.34
Omeprazole POS 1 year (min. 15 kg) < 6 years	€ 4,126.69 – € 5,722.34
Omeprazole ECT < 6 years	€ 71.50
Omeprazole ECT ≥ 6 years to < 12 years	€ 71.50 – € 85.78
Abbreviations: ECG = enteric coated granules POS = powder for oral suspension ECT = enteric coated tablets	

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2025)

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:

Children 1 to 11 years old with eosinophilic esophagitis (EoE), who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal 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

[1] Esomeprazole and omeprazole are shown as examples of the product class of proton pump inhibitors.

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 15 May 2025.

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

Berlin, 15 May 2025

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

Prof. Hecken