GBA
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: chronic spontaneous urticaria (CSU), ≥ 12 years)

of 5 November 2026

At their session on 5 November 2026, the Federal Joint Committee (GBA) 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 number 5 to the information on the benefit assessment of dupilumab in accordance with the resolution of 15 May 2025:**



Courtesy translation – only the German version is legally binding.

**Dupilumab**

Resolution of: 5 November 2026
Entry into force on: 5 November 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

**New therapeutic indication (according to the marketing authorisation of 6 November 2025):**

Dupixent is indicated for the treatment of moderate to severe chronic spontaneous urticaria in adults and adolescents (12 years and above) with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU.

**Therapeutic indication of the resolution (resolution of 5 November 2026):**

see new 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 above with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

**Appropriate comparator therapy:**

- Omalizumab, in combination with H1 antihistamines of the 2nd generation

**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:**[1]

Adults and adolescents 12 years and above with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

No data available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-50), unless otherwise indicated.



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**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | ∅ | No data available. |
| Morbidity | ∅ | No data available. |
| Health-related quality of life | ∅ | No data available. |
| Side effects | ∅ | No 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
∅: 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 above with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

Approximately 530 – 590 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 Dupixent (active ingredient: dupilumab) at the following publicly accessible link (last access: 21 September 2026):

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

Treatment with dupilumab must be initiated and monitored by specialists experienced in treating patients with chronic spontaneous urticaria (CSU).



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## 4. Treatment costs

### Annual treatment costs

Adults and adolescents 12 years and above with moderate to severe chronic spontaneous urticaria with inadequate response to H1 antihistamines and who are naive to anti-IgE therapy for CSU

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Dupilumab | € 15,759.96 |
| if applicable, in combination with: | |
| H1 antihistamines of the 2nd generation | € 62.01 - € 690.73 |
| Appropriate comparator therapy: | |
| Omalizumab | € 10,234.12 |
| in combination with: | |
| H1 antihistamines of the 2nd generation | € 62.01 - € 690.73 |

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 September 2026)

Costs for additionally required SHI services: not applicable

**II. The resolution will enter into force on the day of its publication on the GBA website on 5 November 2026.**

The justification for this resolution will be published on the GBA website at www.g-ba.de.

Berlin, 5 November 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk



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