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: bronchial asthma, 6 to 11 years)

of 6 October 2022

At its session on 6 October 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. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of dupilumab in accordance with the resolution of 1 July 2021:**

**Dupilumab**

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

**New therapeutic indication (according to the marketing authorisation of 4 April 2022):**

Dupixent is indicated in children 6 to 11 years old as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), see section 5.1, who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

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

See new therapeutic indication according to marketing authorisation

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

Children 6 to 11 years old with severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO) who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment

**Appropriate comparator therapy:**

a patient-individual therapy escalation taking into account the previous therapy with selection of:

- high-dose ICS and LABA and, if necessary, LAMA

or

- high-dose ICS and LABA and, if necessary, LAMA and omalizumab, provided that the criteria necessary for the administration of omalizumab are met

**Extent and probability of the additional benefit of dupilumab 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
∅: 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

Children 6 to 11 years old with severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO) who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment

approx. 150 – 860 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: 22 July 2022):

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

## 4. Treatment costs

**Annual treatment costs:**

Children 6 to 11 years old with severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO) who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Dupilumab | € 8,863.99 - € 17,796.15 |
| *Inhaled corticosteroids (ICS, medium dose)* | |
| Budesonide | € 75.08 |
| *Inhaled corticosteroids (ICS, high dose)* | |
| Budesonide | € 140.89 |
| *Long-acting beta-2 receptor agonists (LABA)* | |
| Formoterol | € 310.05 |
| *Long-acting muscarinic receptor antagonists (LAMA)* | |
| Tiotropium | € 753.24 |
| Appropriate comparator therapy: | |
| high-dose ICS and LABA and, if necessary, LAMA or high-dose ICS and LABA and, if necessary, LAMA and omalizumab | |
| *Inhaled corticosteroids (ICS, high dose)* | |
| Budesonide | € 140.89 |
| *Long-acting beta-2 receptor agonists (LABA)* | |
| Formoterol | € 310.05 |
| *Long-acting muscarinic receptor antagonists (LAMA)* | |
| Tiotropium | € 753.24 |
| *Anti-IgE antibodies* | |
| Omalizumab | € 3,442.53 - € 50,938.22 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2022)

Costs for additionally required SHI services: not applicable

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

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

Berlin, 6 October 2022

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

Prof. Hecken