

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
Mepolizumab (new therapeutic indication: COPD)

From 3 September 2026

At their session on 3 September 2026, 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 number 4 (new therapeutic indication: hypereosinophilic syndrome) to the information on the benefit assessment of Mepolizumab in accordance with the resolution of 19 May 2022:**

Mepolizumab

Resolution of: 3 September 2026

Entry into force on: 3 September 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 4 February 2026):

Nucala is indicated in adults as an add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA).

Therapeutic indication of the resolution (resolution of 3 September 2026):

See new therapeutic indication according to marketing authorisation.

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

Adults with uncontrolled COPD characterised by raised blood eosinophils on a combination of ICS, LABA, and LAMA

Appropriate comparator therapy:

Individualised therapy with selection of:

- LABA and LAMA and ICS and dupilumab
- LABA and LAMA and ICS and roflumilast

Extent and probability of the additional benefit of mepolizumab as an add-on maintenance treatment compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:¹

Adults with uncontrolled COPD characterised by raised blood eosinophils on a combination of ICS, LABA, and LAMA

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 Ø: no data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

Adults with uncontrolled COPD characterised by raised blood eosinophils on a combination of ICS, LABA, and LAMA

Approximately 8,870 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 Nucala (active ingredient: mepolizumab) at the following publicly accessible link (last access: 6 July 2026):

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

Treatment with mepolizumab should only be initiated and monitored by specialists experienced in treating patients with COPD.

¹ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-25), unless otherwise indicated.

4. Treatment costs

Annual treatment costs:

Adults with uncontrolled COPD characterised by raised blood eosinophils on a combination of ICS, LABA, and LAMA

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Mepolizumab	€ 16,167.36
<i>Long-acting muscarinic antagonist (LAMA)</i>	
Tiotropium	€ 756.48
<i>Long-acting beta2 agonist (LABA)</i>	
Formoterol	€ 313.09
<i>Inhaled corticosteroid (ICS)</i>	
Fluticasone	€ 254.22
<i>LAMA + LABA fixed combination</i>	
Umeclidinium/ vilanterol	€ 593.86
<i>LAMA + LABA + ICS fixed combination</i>	
Beclometasone/ formoterol/ glycopyrronium	€ 590.94
Appropriate comparator therapy:	
LABA and LAMA and ICS and dupilumab	
Dupilumab	€ 15,983.51
<i>Long-acting muscarinic antagonist (LAMA)</i>	
Tiotropium	€ 756.48
<i>Long-acting beta2 agonist (LABA)</i>	
Formoterol	€ 313.09
<i>Inhaled corticosteroid (ICS)</i>	
Fluticasone	€ 254.22
<i>LAMA + LABA fixed combination</i>	
Umeclidinium/ vilanterol	€ 593.86
<i>LAMA + LABA + ICS fixed combination</i>	
Beclometasone/ formoterol/ glycopyrronium	€ 590.94
LABA and LAMA and ICS and roflumilast	
Roflumilast	€ 478.35
<i>Long-acting muscarinic antagonist (LAMA)</i>	

Designation of the therapy	Annual treatment costs/ patient
Tiotropium	€ 756.48
<i>Long-acting beta2 agonist (LABA)</i>	
Formoterol	€ 313.09
<i>Inhaled corticosteroid (ICS)</i>	
Fluticasone	€ 254.22
<i>LAMA + LABA fixed combination</i>	
Umeclidinium/ vilanterol	€ 593.86
<i>LAMA + LABA + ICS fixed combination</i>	
Beclometasone/ formoterol/ glycopyrronium	€ 590.94

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

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the G-BA website on 3 September 2026.

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

Berlin, 3 September 2026

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

Dr Optendrenk