

Justification

for the Resolution of the Federal Joint Committee (G-BA) 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

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1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient mepolizumab (Nucala) was listed for the first time on 1 February 2016 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 4 February 2026, mepolizumab received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 3 March 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted a dossier in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section

8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient mepolizumab with the new therapeutic indication "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)".

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 June 2026 on the G-BA website at (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of mepolizumab compared to the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG and the statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods ¹ was not used in the benefit assessment of mepolizumab.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have made the following assessment:

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

2.1.1 Approved therapeutic indication of Mepolizumab (Nucala) in accordance with the product information

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 03.09.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

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

Appropriate comparator therapy for mepolizumab as an add-on maintenance treatment:

¹ General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

Individualised therapy with selection of:

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

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the G-BA and Section 6, paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5, Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

- On 1. Depending on the therapeutic indication, various active ingredients from different product classes are available for the treatment of COPD:
- Selective beta2 agonist: formoterol, indacaterol, salbutamol, salmeterol, olodaterol, vilanterol, fenoterol
 - Anticholinergics: aclidinium bromide, glycopyrronium bromide, ipratropium bromide, tiotropium bromide, umeclidinium bromide
 - Corticosteroids: beclometasone, budesonide, fluticasone, methylprednisolone, prednisolone, prednisone, triamcinolone
 - Xanthines: aminophylline, theophylline
 - Phosphodiesterase inhibitors: roflumilast
 - Antibodies: dupilumab
- On 2. For the present therapeutic indication, a non-medicinal treatment is not considered as an appropriate comparator therapy.
- On 3. The following resolutions of the G-BA are available on an amendment of the Pharmaceuticals Directive: Annex XII – Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:
- fluticasone furoate/ vilanterol (resolution of 20 March 2014)
 - indacaterol/ glycopyrronium (resolution of 8 May 2014)
 - olodaterol (resolution of 17 July 2014)
 - tiotropium/ olodaterol (resolution of 4 February 2016)
 - umeclidinium/ vilanterol (resolution of 8 January 2015)
 - aclidinium bromide/ formoterol (resolution of 16 July 2015)
 - aclidinium bromide (new benefit assessment, resolution of 7 April 2016)
 - umeclidinium (resolution of 21 July 2016)
 - fluticasone furoate/ umeclidinium/ vilanterol (resolution of 16 August 2018; new therapeutic indication, resolution of 2 May 2019)
 - dupilumab (resolution of 6 February 2025)
- On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present indication according to Section 35a, paragraph 7 SGB V (see "Information on Appropriate Comparator Therapy").

The 2024 "Global Initiative for Chronic Obstructive Lung Disease (GOLD)" guideline was identified in this context. According to the GOLD guideline, the additional use of dupilumab (in the case of eosinophil counts ≥ 300 cells/ μ l and symptoms of chronic bronchitis) or the additional administration of roflumilast (in the case of a FEV1 level $< 50\%$ and symptoms of chronic bronchitis) may be considered for COPD patients, who continue to experience exacerbations despite treatment with a long-acting beta2-agonist (LABA), a long-acting muscarinic antagonist (LAMA) and an inhaled corticosteroid (ICS). The 2021 National Disease Management Guideline (NDMG) on COPD states that the administration of roflumilast to patients with COPD who continue to experience exacerbations despite treatment with LABA, LAMA and ICS, provided

they are classified as having the "chronic bronchitis" phenotype and have an FEV1 level < 50%. In their written submission, the AkdÄ also pointed out that the phosphodiesterase-4(PDE4) inhibitor roflumilast represents a further medicinal therapy option for patients in this therapeutic indication, who experience more frequent exacerbations despite optimised treatment, who can be classified as having the bronchitis phenotype, and who have an FEV1 level < 50%. Furthermore, dupilumab is approved as an add-on maintenance treatment for patients with COPD who have raised blood eosinophils.

For this therapeutic indication, an individualised therapy with the selection of LABA, LAMA, ICS and dupilumab, as well as LABA, LAMA, ICS and roflumilast, is therefore determined as the appropriate comparator therapy for mepolizumab as an add-on maintenance treatment. Individualised therapy is based on the assumption that several treatment options, which allow an individualised medical treatment decision, are available. When making the treatment decision, the eosinophil count and the FEV1 level in particular must be considered, taking into account the available evidence.

The unchanged continuation of an inadequate COPD therapy, if the option of therapy escalation still exists, does not correspond to the appropriate comparator therapy.

The marketing authorisations and product information of the medicinal products must be observed.

Furthermore, measures that affect the symptom of frequent exacerbations, such as acetylcysteine administration and saline inhalations, must be implemented.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of mepolizumab as an add-on maintenance treatment is assessed as follows:

The additional benefit compared with the appropriate comparator therapy is not proven for adults with uncontrolled COPD characterised by raised blood eosinophils on a combination of ICS, LABA, and LAMA.

Justification:

No direct comparator studies on mepolizumab versus the appropriate comparator therapy are available for adult patients with uncontrolled COPD characterised by raised blood eosinophils despite a combination therapy of ICS, LABA, and LAMA.

In the dossier, the pharmaceutical company only additionally presented analyses of the METREX, METREO and MATINEE approval studies relating to those patients who, in accordance with the approved therapeutic indication, had an elevated blood eosinophil count (≥ 300 cells/ μ l) at the time of screening. The three studies are double-blind, randomised controlled trials comparing mepolizumab as an add-on maintenance treatment with placebo in adult patients with COPD whose condition was inadequately controlled despite a combination therapy comprising an ICS, a LABA and a LAMA. Treatment with a placebo as an

add-on maintenance treatment in the respective comparator arm of the three RCTs does not constitute an appropriate comparator therapy.

In addition, the pharmaceutical company stated in the dossier that they intend to additionally present an indirect comparison of mepolizumab with dupilumab based on data from the METREX, METREO and MATINEE studies, as well as published data from the BOREAS and NOTUS studies, using the bridge comparator placebo + LAMA + LABA + ICS. However, as the pharmaceutical company did not present this indirect comparison in Module 4 of the dossier, no assessment is made of its suitability for the benefit assessment.

In the overall assessment, there are therefore no suitable data for the benefit assessment that would allow a comparison of mepolizumab with the appropriate comparator therapy. The additional benefit of mepolizumab compared to the appropriate comparator therapy is therefore not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient mepolizumab. The therapeutic indication assessed here is as follows: 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). The G-BA determined an individualised therapy with the selection of LABA + LAMA + ICS + dupilumab and LABA + LAMA + ICS + roflumilast as the appropriate comparator therapy.

The METREX, METREO and MATINEE approval studies are double-blind, randomised controlled trials comparing mepolizumab as an add-on maintenance treatment with placebo in adult patients with COPD whose condition was inadequately controlled despite a combination therapy comprising an ICS, a LABA and a LAMA. Treatment with a placebo as an add-on maintenance treatment in the respective comparator arm of the three approval studies does not constitute an appropriate comparator therapy.

For the assessment of the additional benefit, the pharmaceutical company did not present or use an indirect comparison of mepolizumab with dupilumab they carried out on the basis of data from the METREX, METREO and MATINEE studies, as well as published data from the BOREAS and NOTUS studies, using the bridge comparator placebo + LAMA + LABA + ICS.

In the overall assessment, there are therefore no suitable data for the benefit assessment that would allow a comparison of mepolizumab with the appropriate comparator therapy. The additional benefit of mepolizumab compared to the appropriate comparator therapy is therefore not proven.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI). The resolution is based on the information from the dossier of the pharmaceutical company.

The number of patients estimated by the pharmaceutical company is subject to uncertainty overall and tends to be underestimated. The reasons for this are, in particular, the underestimated percentages of patients with a higher severity grading and of those with an

elevated blood eosinophil count within the population of patients experiencing exacerbations despite triple therapy.

2.3 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.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 1 July 2026).

The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

In general, initial induction regimens are not taken into account for the cost representation, since the present indication is a chronic disease with a continuous need for therapy and, as a rule, no new titration or dose adjustment is required after initial titration.

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

Since the inhaled corticosteroid (ICS) and the long-acting beta2 agonist (LABA) are assigned to a reference price group, one representative of each product class is shown as an example when deriving the costs. A representative of the fixed combinations and the long-acting muscarinic antagonist (LAMA) is also presented as an example.

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

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed:				
Mepolizumab	Continuously, 1 x every 28 days	13.0	1	13.0
<i>Long-acting muscarinic antagonist (LAMA)</i>				
Tiotropium	Continuously, 1 x daily	365.0	1	365.0
<i>Long-acting beta2 agonist (LABA)</i>				
Formoterol	Continuously, 2 x daily	365.0	1	365.0
<i>Inhaled corticosteroid (ICS)</i>				
Fluticasone	Continuously, 2 x daily	365.0	1	365.0
<i>LAMA + LABA fixed combination</i>				
Umeclidinium I Vilanterol	Continuously, 1 x daily	365.0	1	365.0
<i>LAMA + LABA + ICS fixed combination</i>				
Beclometasone I Formoterol I Glycopyrronium	Continuously, 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
LABA and LAMA and ICS and dupilumab				
Dupilumab	Continuously, 1 x every 14 days	26.1	1	26.1
<i>Long-acting muscarinic antagonist (LAMA)</i>				
Tiotropium	Continuously, 1 x daily	365.0	1	365.0
<i>Long-acting beta2 agonist (LABA)</i>				
Formoterol	Continuously, 2 x daily	365.0	1	365.0
<i>Inhaled corticosteroid (ICS)</i>				
Fluticasone	Continuously, 2 x daily	365.0	1	365.0

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
<i>LAMA + LABA fixed combination</i>				
Umeclidinium I Vilanterol	Continuously, 1 x daily	365.0	1	365.0
<i>LAMA + LABA + ICS fixed combination</i>				
Beclometasone I Formoterol I Glycopyrronium	Continuously, 2 x daily	365.0	1	365.0
<i>LABA and LAMA and ICS and roflumilast</i>				
Roflumilast	Continuously, 2 x daily	365.0	1	365.0
<i>Long-acting muscarinic antagonist (LAMA)</i>				
Tiotropium	Continuously, 1 x daily	365.0	1	365.0
<i>Long-acting beta2 agonist (LABA)</i>				
Formoterol	Continuously, 2 x daily	365.0	1	365.0
<i>Inhaled corticosteroid (ICS)</i>				
Fluticasone	Continuously, 2 x daily	365.0	1	365.0
<i>LAMA + LABA fixed combination</i>				
Umeclidinium I Vilanterol	Continuously, 1 x daily	365.0	1	365.0
<i>LAMA + LABA + ICS fixed combination</i>				
Beclometasone I Formoterol I Glycopyrronium	Continuously, 2 x daily	365.0	1	365.0

Consumption:

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed:					
Mepolizumab	100 mg	100 mg	1 x 100 mg	13.0	13 x 100 mg
<i>Long-acting muscarinic antagonist (LAMA)</i>					
Tiotropium	2.5 µg	5 µg	2 x 2.5 µg	365.0	730.0 x 2.5 µg
<i>Long-acting beta2 agonist (LABA)</i>					
Formoterol	12 µg	24 µg	2 x 12 µg	365.0	730.0 x 12 µg
<i>Inhaled corticosteroid (ICS)</i>					
Fluticasone	500 µg	1,000 µg	2 x 500 µg	365.0	730.0 x 500 µg
<i>LAMA + LABA fixed combination</i>					
Umeclidinium I Vilanterol	65 µg/ 22 µg	65 µg/ 22 µg	1 x 65 µg/ 22 µg	365.0	365.0 x 65 µg/ 22 µg
<i>LAMA + LABA + ICS fixed combination</i>					
Beclometasone I Formoterol I Glycopyrronium	88 µg/ 5 µg/ 9 µg	176 µg/ 10 µg/ 18 µg	2 x 88 µg/ 5 µg/ 9 µg	365.0	730.0 x 88 µg/ 5 µg/ 9 µg
Appropriate comparator therapy					
LABA and LAMA and ICS and dupilumab					
Dupilumab	300 mg	300 mg	1 x 300 mg	26.1	26.1 x 300 mg
<i>Long-acting muscarinic antagonist (LAMA)</i>					
Tiotropium	2.5 µg	5 µg	2 x 2.5 µg	365.0	730.0 x 2.5 µg
<i>Long-acting beta2 agonist (LABA)</i>					
Formoterol	12 µg	24 µg	2 x 12 µg	365.0	730.0 x 12 µg
<i>Inhaled corticosteroid (ICS)</i>					
Fluticasone	500 µg	1,000 µg	2 x 500 µg	365.0	730.0 x 500 µg
<i>LAMA + LABA fixed combination</i>					
Umeclidinium/ vilanterol	55 µg/ 22 µg	55 µg/ 22 µg	1 x 55 µg/ 22 µg	365.0	365.0 x 55 µg/ 22 µg
<i>LAMA + LABA + ICS fixed combination</i>					
Beclometasone/ formoterol/ glycopyrronium	88 µg/ 5 µg/ 9 µg	176 µg/ 10 µg/ 18 µg	2 x 88 µg/ 5 µg/ 9 µg	365.0	730.0 x 88 µg/ 5 µg/ 9 µg

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
LABA and LAMA and ICS and roflumilast					
Roflumilast	500 µg	500 µg	1 x 500 µg	365.0	365 x 500 µg
<i>Long-acting muscarinic antagonist (LAMA)</i>					
Tiotropium	2.5 µg	5 µg	2 x 2.5 µg	365.0	730.0 x 2.5 µg
<i>Long-acting beta2 agonist (LABA)</i>					
Formoterol	12 µg	24 µg	2 x 12 µg	365.0	730.0 x 12 µg
<i>Inhaled corticosteroid (ICS)</i>					
Fluticasone	500 µg	1,000 µg	2 x 500 µg	365.0	730.0 x 500 µg
<i>LAMA + LABA fixed combination</i>					
Umeclidinium/ vilanterol	55 µg/ 22 µg	55 µg/ 22 µg	1 x 55 µg/ 22 µg	365.0	365.0 x 65 µg/ 22 µg
<i>LAMA + LABA + ICS fixed combination</i>					
Beclometasone/ formoterol/ glycopyrronium	88 µg/ 5 µg/ 9 µg	176 µg/ 10 µg/ 18 µg	2 x 88 µg/ 5 µg/ 9 µg	365.0	730.0 x 88 µg/ 5 µg/ 9 µg

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed:					
Mepolizumab 100 mg	3 SFI	€ 3,732.70	€ 1.77	€ 0.00	€ 3,730.93
<i>Long-acting muscarinic antagonist (LAMA)</i>					
Tiotropium 2.5 µg	180 SD	€ 198.63	€ 1.77	€ 10.33	€ 186.53
<i>Long-acting beta2 agonist (LABA)</i>					
Formoterol 12 µg ²	180 SD	€ 84.78	€ 1.77	€ 5.81	€ 77.20
<i>Inhaled corticosteroid (ICS)</i>					
Fluticasone 500 µg ²	120 SD	€ 46.33	€ 1.77	€ 2.77	€ 41.79
<i>LAMA + LABA fixed combination</i>					
Umeclidinium 55 µg/ vilanterol 22 µg	90 SD	€ 156.18	€ 1.77	€ 7.98	€ 146.43
<i>LAMA + LABA + ICS fixed combination</i>					
Beclometasone 88 µg/ formoterol 5 µg/ glycopyrronium 9 µg	360 SD	€ 309.67	€ 1.77	€ 16.48	€ 291.42
Appropriate comparator therapy					
Dupilumab 300 mg	6 SFI	€ 3,895.26	€ 1.77	€ 219.12	€ 3,674.37
Roflumilast 500 µg ²	90 FCT	€ 129.03	€ 1.77	€ 9.31	€ 117.95
<i>Long-acting muscarinic antagonist (LAMA)</i>					
Tiotropium 2.5 µg	180 SD	€ 198.63	€ 1.77	€ 10.33	€ 186.53
<i>Long-acting beta2 agonist (LABA)</i>					
Formoterol 12 µg ²	180 SD	€ 84.78	€ 1.77	€ 5.81	€ 77.20
<i>Inhaled corticosteroid (ICS)</i>					
Fluticasone 500 µg ²	120 SD	€ 46.33	€ 1.77	€ 2.77	€ 41.79
<i>LAMA + LABA fixed combination</i>					
Umeclidinium 55 µg/ vilanterol 22 µg	90 SD	€ 156.18	€ 1.77	€ 7.98	€ 146.43
<i>LAMA + LABA + ICS fixed combination</i>					
Beclometasone 88 µg/ formoterol 5 µg/ glycopyrronium 9 µg	360 SD	€ 309.67	€ 1.77	€ 16.48	€ 291.42

LAUER-TAXE® last revised: 1 July 2026

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of

²Fixed reimbursement rate

other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Because there are no regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, no costs for additionally required SHI services had to be taken into account.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 11 March 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 3 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of mepolizumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

By letter dated 9 March 2026 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient mepolizumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 10 June 2026, and the written statement procedure was initiated with publication on the G-BA website on 15 June 2026. The deadline for submitting written statements was 6 July 2026.

The oral hearing was held on 27 July 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 25 August 2026, and deliberation of the draft resolution was concluded.

At their session on 3 September 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	11 March 2025	Determination of the appropriate comparator therapy
Working group Section 35a	15 July 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	27 July 2026	Conduct of the oral hearing
Working group Section 35a	5 August 2026 19 August 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	25 August 2026	Concluding discussion of the draft resolution
Plenum	3 September 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 3 September 2026

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

Dr Optendrenk