GBA
Gemeinsamer
Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (GBA) on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Depemokimab (bronchial asthma, ≥ 12 years)

of 1 October 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 (GBA) 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 GBA 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 GBA 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 GBA 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 relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient depemokimab on 1 April 2026 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the GBA (VerfO). Pursuant to Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 of the Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the GBA on 30 March 2026.

The GBA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 July 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The GBA came to a resolution on whether an additional benefit of depemokimab compared with 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

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statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the GBA 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 depemokimab.

In the light of the above, and taking into account the statements received and the oral hearing, the GBA 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 Depemokimab (Exdensur) in accordance with the product information

Exdensur is indicated as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by blood eosinophil count in adults and adolescents 12 years and older who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller.

Therapeutic indication of the resolution (resolution of 01.10.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

a) Adolescents aged 12 to 17 years with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

   Appropriate comparator therapy for depemokimab as add-on therapy:

   - Individualised therapy with selection of
     - high dose ICS and LABA and LAMA
     - high dose ICS and LABA and, if applicable, LAMA and omalizumab or dupilumab
     - high dose ICS and LABA and, if applicable, LAMA and mepolizumab, provided that the criteria necessary for the administration of omalizumab and dupilumab are not met

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

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b) Adults with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

Appropriate comparator therapy for depemokimab as add-on therapy:

- Individualised therapy with selection of
  - high dose ICS and LABA and LAMA
  - high dose ICS and LABA and, if applicable, LAMA and omalizumab
  - high dose ICS and LABA, and, if applicable, LAMA and mepolizumab or reslizumab or benralizumab or dupilumab

Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the GBA 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 GBA 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 GBA 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

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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 supportive 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. In addition to depemokimab, active ingredients from various product classes are approved for the treatment of asthma:
- Selective beta-2 adrenergic receptor agonists: salbutamol, fenoterol, reproterol, salmeterol, formoterol, terbutaline, salbutamol, bambuterol and clenbuterol
- Inhaled muscarinic receptor antagonists: tiotropium bromide
- Inhaled corticosteroids: beclometasone, budesonide, ciclesonide, fluticasone and mometasone
- Oral corticosteroids: e.g.: prednisolone and prednisone
- Combination preparations: beclometasone/ formoterol, budesonide/ formoterol, formoterol/ fluticasone, salmeterol/ fluticasone, vilanterol/ fluticasone, ipratropium/ fenoterol, clenbuterol/ ambroxol, indacaterol/ glycopyrronium/ mometasone and beclometasone/ formoterol/ glycopyrronium
- Others: theophylline, montelukast, omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab

On 2. No non-medicinal measures are considered as the sole appropriate comparator therapy for the treatment of an inadequately controlled severe asthma.

On 3. The following resolutions on an amendment of the Pharmaceuticals Directive (AM-RL) are available:

Annex XII - Benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:
- Mepolizumab (resolution of 21 July 2016 and 22 March 2019)
- Reslizumab (resolution of 6 July 2017)
- Benralizumab (resolution of 2 August 2018)
- Dupilumab (resolution of 20 February 2020)
- Indacaterol/ glycopyrronium/ mometasone (resolution of 4 February 2021)
- Tezepelumab (resolution of 12 May 2023)

Annex IV - Therapeutic information:
- Omalizumab (resolution of 17 December 2015).

Annex XII / Annex IX: Definition of reference price groups
- Fluticasone furoate/ vilanterol

DMP guideline (DMP-RL): Asthma

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as reviews of clinical studies in the present indication and

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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 therapeutic indication according to Section 35a, paragraph 7 SGB V.

A joint written submission made by the German Society for Pneumology and Respiratory Medicine (DGP: Deutsche Gesellschaft für Pneumologie und Beatmungsmedizin e.V.) and the German Society for Allergology and Clinical Immunology (DGAKI: Deutsche Gesellschaft für Allergologie und Klinische Immunologie e.V.) is available. With regard to the relevant medicinal therapy steps for this therapeutic indication and the evidence supporting the corresponding recommendations, the two scientific-medical societies refer to the S2k guideline on the specialist diagnosis and treatment of asthma (2023) and to the National Asthma Health Care Guideline (2024).

In particular, the recommendations of the National Asthma Health Care Guideline (NVL Asthma 2024, version 5.0) are consulted for the determination of the appropriate comparator therapy.

In view of the wording of the therapeutic indication, it is assumed that treatment with depemokimab is only indicated as an add-on to maintenance treatment with high dose inhaled corticosteroids (ICS) and at least one other medicinal product, and that patients are not adequately controlled with their current maintenance treatment. The stepped medicinal therapy regimen of the National Asthma Health Care Guideline (NVL Asthma 2024, version 5.0) for children and adolescents as well as for adults should be taken into account. It is assumed that in the therapeutic indication of depemokimab, patients in patient group a) are mapped to steps 5 to 6 of the stepped medicinal therapy regimen for children and adolescents and patients in patient group b) are mapped to steps 4 to 5 of the stepped medicinal therapy regimen for adults in accordance with the National Asthma Health Care Guideline 2024.

The guideline recommends therapy with a LAMA in addition to high dose ICS and LABA, both in step 5 for children and adolescents and in step 4 for adults. In step 6 for children and adolescents, an add-on biologic agent, preferably omalizumab or dupilumab and, as a second choice, mepolizumab, is recommended. Against this background, the active ingredient mepolizumab (in addition to high dose ICS and LABA, and, if applicable, LAMA) is designated as an appropriate therapy option only for adolescents (patient group a), provided that the criteria necessary for the administration of omalizumab and dupilumab are not met. In step 5 for adults, the National Asthma Health Care Guideline recommends additional treatment with omalizumab or with mepolizumab, reslizumab, benralizumab or dupilumab. In step 5 for adults and step 6 for children and adolescents, the National Asthma Health Care Guideline 2024 also recommends the additional administration of tezepelumab, whilst noting that "long-term data, particularly regarding safety, are still pending". The reliability of data of the identified evidence is assessed as low (adults) or very low (children and adolescents) overall. Tezepelumab is therefore not determined as an appropriate comparator therapy option.

For adolescents aged 12 to 17 years with severe asthma with type 2 inflammation (patient group a), the appropriate comparator therapy for depemokimab as an add-on maintenance treatment is therefore determined to be an individualised therapy with the selection of: high dose ICS and LABA and LAMA; high dose ICS and LABA and, if

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applicable, LAMA and omalizumab or dupilumab; high dose ICS and LABA, and, if applicable, LAMA and mepolizumab (provided that the criteria necessary for the administration of omalizumab and dupilumab are not met).

For adults with severe asthma with type 2 inflammation (patient group b), the appropriate comparator therapy is determined to be an individualised therapy with the selection of: high dose ICS and LABA and LAMA; high dose ICS and LABA and, if applicable, LAMA and omalizumab; high dose ICS and LABA and, if applicable, LAMA and mepolizumab or reslizumab or benralizumab or dupilumab.

Individualised therapy is based on the assumption that several treatment options, which allow an individualised medical treatment decision, are available. The treatment decision is made, in particular, taking into account previous therapy, the phenotype and comorbidities.

Long-term therapy with oral corticosteroids (OCS) is a second-line therapy option for the treatment of severe asthma in children, adolescents and adults. In justified cases, the administration of OCS for the treatment of severe asthma is also possible. These should only be used for a short time and in the lowest effective dose. When treating asthma with OCS, it must be made sure that the dosage of OCS does not exceed the Cushing's threshold permanently, if possible. Treatment of exacerbations must be distinguished from this.

Due to its narrow therapeutic range, the active ingredient theophylline is not the agent of first choice in asthma therapy and is therefore not determined as an appropriate comparator therapy. Nevertheless, patients who receive theophylline as a concomitant medication in the present therapeutic indication can be included in the relevant population for the benefit assessment.

The active ingredient montelukast is only approved as an add-on therapy for mild to moderate persistent asthma. Nevertheless, patients with severe asthma who receive montelukast in the present therapeutic indication according to the recommendation of the National Asthma Health Care Guideline 2024 can be included in the relevant population for the benefit assessment.

The marketing authorisations and product information for the medicinal product of the appropriate comparator therapy must be observed.

Individualised therapy refers to the selection of product classes, not to the selection of individual active ingredients within a product class.

The unchanged continuation of an inadequate therapy of severe asthma, if the option of therapy escalation still exists, does not correspond to an appropriate comparator therapy in case of uncontrolled severe asthma.

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 GBA 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 depemokimab is assessed as follows:

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a) Adolescents aged 12 to 17 years with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

An additional benefit is not proven.

b) Adults with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

An additional benefit is not proven.

Justification:

No direct comparator data between depemokimab and the appropriate comparator therapy are available.

However, the pharmaceutical company additionally presented the results of the label-enabling SWIFT-1 and SWIFT-2 studies in the dossier. The two randomised, double-blind, multicentre studies compared depemokimab with placebo in adolescents aged 12 years and over and adults with uncontrolled asthma and elevated eosinophil count over a period of 52 weeks. These studies enrolled patients who had been diagnosed with asthma for at least 2 years and had experienced at least 2 confirmed asthma exacerbations requiring treatment with systemic corticosteroids (OCS) in the 12 months prior to screening despite taking medium or high dose ICS. Furthermore, study participants should have had an elevated peripheral blood eosinophil count of at least 300 cells/µl in the 12 months prior to screening, or of at least 150 cells/µl at the screening visit, and must have been receiving additional maintenance treatment with a LABA, LAMA, leukotriene receptor antagonist or theophylline, in addition to ICS therapy for at least 3 months. A total of 395 and 397 patients were enrolled in the SWIFT-1 and SWIFT-2 studies, respectively, and were randomised in a 2:1 ratio to receive depemokimab or placebo.

In the studies, patients should continue with their current maintenance treatment. Treatment with mepolizumab, reslizumab, benralizumab, omalizumab or dupilumab was prohibited both prior to enrolment in the study and during the study. The studies are unsuitable for deriving any additional benefit of depemokimab over the appropriate comparator therapy since the existing maintenance treatment was continued in both studies despite uncontrolled asthma, and there was no escalation to the appropriate therapy options in accordance with the appropriate comparator therapy.

In the overall assessment, an additional benefit of depemokimab over the appropriate comparator therapy was therefore not proven for both patient groups.

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2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product "Exdensur" with the active ingredient depemokimab. Depemokimab is indicated as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by blood eosinophil count in adults and adolescents 12 years and older who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller. In the therapeutic indication to be considered, two patient groups were distinguished:

a) Adolescents aged 12 to 17 years with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

b) Adults with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

The GBA have determined the following appropriate comparator therapy:

Patient group a)

- Individualised therapy with selection of
  - high dose ICS and LABA and LAMA
  - high dose ICS and LABA and, if applicable, LAMA and omalizumab or dupilumab
  - high dose ICS and LABA and, if applicable, LAMA and mepolizumab, provided that the criteria necessary for the administration of omalizumab and dupilumab are not met

Patient group b)

- Individualised therapy with selection of
  - high dose ICS and LABA and LAMA
  - high dose ICS and LABA and, if applicable, LAMA and omalizumab
  - high dose ICS and LABA, and, if applicable, LAMA and mepolizumab or reslizumab or benralizumab or dupilumab

The pharmaceutical company considered the patient groups of adolescents and adults together, and additionally submitted the randomised, double-blind, placebo-controlled SWIFT-1 and SWIFT-2 studies for the assessment of the additional benefit. The studies are unsuitable for deriving any additional benefit of depemokimab over the appropriate comparator therapy since the existing maintenance treatment was continued in both studies despite uncontrolled asthma, and there was no escalation to the appropriate therapy options in accordance with the appropriate comparator therapy.

In the overall assessment, an additional benefit of depemokimab over the appropriate comparator therapy was therefore not proven for both patient groups.

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

The patient numbers concern the statutory health insurance (SHI) target population.

The resolution is based on the information provided by the pharmaceutical company in the benefit assessment dossier. The method used to calculate patient numbers is the same as that

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set out in the 2023 dossier on tezepelumab[2]. In this case, the pharmaceutical company however used updated figures for the general population and SHI-insured subjects, and further restricted the patient population to patients with type 2 inflammation in accordance with the therapeutic indication. Overall, the information provided by the pharmaceutical company are largely plausible and are of a similar order of magnitude to those set out in the resolution on dupilumab[3] for the therapeutic indication of severe asthma with type 2 inflammation. The information is however subject to uncertainties. On the one hand, this is due to the uncertainties regarding the percentage of patients with type 2 inflammation and, on the other, to the uncertainties that have already been addressed in the dossier assessment for tezepelumab.

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 Exdensur (active ingredient: depemokimab) at the following publicly accessible link (last access: 15 September 2026):

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

Treatment with depemokimab should only be initiated and monitored by specialists experienced in treating patients with asthma.

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: 15 July 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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.

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.

In deriving the costs for the appropriate comparator therapy, the most cost-effective representative was presented for the inhaled corticosteroids (ICS), long-acting beta-2 adrenergic receptor agonists (LABA) and ICS + LABA fixed combinations.

[2] Benefit assessment procedure for the active ingredient tezepelumab (resolution of 12 May 2023) https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/904/#beschluesse
[3] Benefit assessment procedure for the active ingredient dupilumab (resolution of 20 February 2020) https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/487/#beschluesse

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For the calculation of omalizumab consumption based on dosages depending on body weight (BW), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population" were applied[4]. The average body weight is 48.7 kg for 12-year-old children, 67.9 kg for adolescents under the age of 18 years, and 78.3 kg for adults.

Treatment period:

a) Adolescents aged 12 to 17 years with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Depemokimab	Continuously, 1 x every 6 months	2.0	1	2.0
High dose inhaled corticosteroids (ICS)				
Mometasone furoate	Continuously, 2 x daily	365.0	1	365.0
Long-acting beta-2 adrenergic receptor agonist (LABA)				
Formoterol	Continuously, 2 x daily	365.0	1	365.0
Long-acting muscarinic receptor antagonists (LAMA)				
Tiotropium	Continuously, 1 x daily	365.0	1	365.0
High dose ICS + LABA fixed combination				
Fluticasone (ICS)/ formoterol (LABA)	Continuously, 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
High dose inhaled corticosteroids (ICS)				
Mometasone furoate	Continuously, 2 x daily	365.0	1	365.0
Long-acting beta-2 adrenergic receptor agonist (LABA)				
Formoterol	Continuously, 2 x daily	365.0	1	365.0
Long-acting muscarinic receptor antagonists (LAMA)				
Tiotropium	Continuously, 1 x daily	365.0	1	365.0

[4]Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
High dose ICS + LABA fixed combination				
Fluticasone (ICS)/ formoterol (LABA)	Continuously, 2 x daily	365.0	1	365.0
Monoclonal antibodies				
Dupilumab	Continuously, 1 x every 14 days	26.1	1	26.1
Mepolizumab	Continuously, 1 x every 28 days	13.0	1	13.0
Omalizumab	Continuously, every 28 days or 1 x every 14 days	13.0 – 26.1	1	13.0 – 26.1

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b) Adults with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Depemokimab	Continuously, 1 x every 6 months	2.0	1	2.0
High dose inhaled corticosteroid (ICS)				
Mometasone furoate	Continuously, 2 x daily	365.0	1	365.0
Long-acting beta-2 adrenergic receptor agonist (LABA)				
Formoterol	Continuously, 2 x daily	365.0	1	365.0
Long-acting muscarinic receptor antagonists (LAMA)				
Tiotropium	Continuously, 1 x daily	365.0	1	365.0
High dose ICS + LABA fixed combination				
Fluticasone (ICS)/ salmeterol (LABA)	Continuously, 2 x daily	365.0	1	365.0
High dose ICS + LABA + LAMA fixed combination				
Indacaterol (LABA)/ glycopyrronium (LAMA)/ mometasone furoate (ICS)	Continuously, 1 x daily	365.0	1	365.0
Appropriate comparator therapy				
High dose inhaled corticosteroid (ICS)				
Mometasone furoate	Continuously, 2 x daily	365.0	1	365.0
Long-acting beta-2 adrenergic receptor agonist (LABA)				
Formoterol	Continuously, 2 x daily	365.0	1	365.0
Long-acting muscarinic receptor antagonists (LAMA)				
Tiotropium	Continuously, 1 x daily	365.0	1	365.0
High dose ICS + LABA fixed combination				

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Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Fluticasone (ICS)/ salmeterol (LABA)	Continuously, 2 x daily	365.0	1	365.0
High dose ICS + LABA + LAMA fixed combination				
Indacaterol (LABA)/ glycopyrronium (LAMA)/ mometasone furoate (ICS)	Continuously, 1 x daily	365.0	1	365.0
Monoclonal antibodies				
Benralizumab	Continuously, 1 x every 56 days	6.5	1	6.5
Dupilumab	Continuously, 1 x every 14 days	26.1	1	26.1
Mepolizumab	Continuously, 1 x every 28 days	13.0	1	13.0
Omalizumab	Continuously, 1 x every 28 days or 1 x every 14 days	13.0 – 26.1	1	13.0 – 26.1
Reslizumab	Continuously, 1 x every 28 days	13.0	1	13.0

Consumption:

a) Adolescents aged 12 to 17 years with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

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					
Depemokimab	100 mg	100 mg	1 x 100 mg	2.0	2 x 100 mg
High dose inhaled corticosteroid (ICS)					
Mometasone furoate	400 µg	800 µg	2 puffs 400 µg each	365.0	730 puffs 400 µg each
Long-acting beta-2 adrenergic receptor agonist (LABA)					
Formoterol	12 µg – 24 µg	24 µg – 48 µg	2 x 12 µg – 4 x 12 µg	365.0	730 x 12 µg – 1,460 x 12 µg

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Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Long-acting muscarinic receptor antagonists (LAMA)					
Tiotropium	5 µg	5 µg	2 x 2.5 µg	365.0	730 x 2.5 µg
High dose ICS + LABA fixed combination					
Fluticasone (ICS)/ formoterol (LABA)	250 µg/ 10 µg	500 µg/ 20 µg	4 x 125 µg/ 5 µg	365.0	1,460 x 125 µg/ 5 µg
Appropriate comparator therapy					
High dose inhaled corticosteroid (ICS)					
Mometasone furoate	400 µg	800 µg	2 puffs 400 µg each	365.0	730 puffs 400 µg each
Long-acting beta-2 adrenergic receptor agonist (LABA)					
Formoterol	12 µg – 24 µg	24 µg – 48 µg	2 x 12 µg – 4 x 12 µg	365.0	730 x 12 µg – 1,460 x 12 µg
Long-acting muscarinic receptor antagonists (LAMA)					
Tiotropium	5 µg	5 µg	2 x 2.5 µg	365.0	730 x 2.5 µg
High dose ICS + LABA fixed combination					
Fluticasone (ICS) + formoterol (LABA)	250 µg/ 10 µg	500 µg/ 20 µg	4 x 125 µg/ 5 µg	365.0	1,460 x 125 µg/ 5 µg
Monoclonal antibodies					
Dupilumab	300 mg	300 mg	1 x 300 mg	26.1	26.1 x 300 mg
Mepolizumab	100 mg	100 mg	1 x 100 mg	13.0	13 x 100 mg
Omalizumab	150 mg – 600 mg	150 mg – 600 mg	1 x 150 mg – 4 x 150 mg	13.0 – 26.1	13 x 150 mg – 104.4 x 150 mg

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b) Adults with severe asthma with type 2 inflammation characterised by elevated blood eosinophil count who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller

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					
Depemokimab	100 mg	100 mg	1 x 100 mg	2.0	2 x 100 mg
High dose inhaled corticosteroid (ICS)					
Mometasone furoate	400 µg	800 µg	2 puffs each 400 µg	365.0	730 puffs each 400 µg
Long-acting beta-2 adrenergic receptor agonist (LABA)					
Formoterol	12 µg – 24 µg	24 µg – 48 µg	2 x 12 µg – 4 x 12 µg	365.0	730 x 12 µg – 1,460 x 12 µg
Long-acting muscarinic receptor antagonists (LAMA)					
Tiotropium	5 µg	5 µg	2 x 2.5 µg	365.0	730 x 2.5 µg
High dose ICS + LABA fixed combination					
Fluticasone (ICS)/ salmeterol (LABA)	500 µg/ 50 µg	1,000 µg/ 100 µg	2 x 500 µg/ 50 µg	365.0	730 x 500 µg/ 50 µg
High dose ICS + LABA + LAMA fixed combination					
Indacaterol (LABA)/ glycopyrronium (LAMA)/ mometasone furoate (ICS)	114 µg/ 46 µg/ 136 µg	114 µg/ 46 µg/ 136 µg	1 × 114 µg/ 46 µg/ 136 µg	365.0	365 x 114 µg/ 46 µg/ 136 µg
Appropriate comparator therapy					
High dose inhaled corticosteroid (ICS)					
Mometasone furoate	400 µg	800 µg	2 puffs, each 400 µg	365.0	730 puffs, each 400 µg
Long-acting beta-2 adrenergic receptor agonist (LABA)					
Formoterol	12 µg – 24 µg	24 µg – 48 µg	2 x 12 µg – 4 x 12 µg	365.0	730 x 12 µg – 1,460 x 12 µg
Long-acting muscarinic receptor antagonists (LAMA)					
Tiotropium	5 µg	5 µg	2 x 2.5 µg	365.0	730 x 2.5 µg
High dose ICS + LABA fixed combination					
Fluticasone (ICS)/ salmeterol (LABA)	500 µg/ 50 µg	1,000 µg/ 100 µg	2 x 500 µg/ 50 µg	365.0	730 x 500 µg/ 50 µg

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Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
High dose ICS + LABA + LAMA fixed combination					
Indacaterol (LABA)/ glycopyrronium (LAMA)/ mometasone furoate (ICS)	114 µg/ 46 µg/ 136 µg	114 µg/ 46 µg/ 136 µg	1 × 114 µg/ 46 µg/ 136 µg	365.0	365 x 114 µg/ 46 µg/ 136 µg
Monoclonal antibodies					
Benralizumab	30 mg	30 mg	1 x 30 mg	6.5	6.5 x 30 mg
Dupilumab	300 mg	300 mg	1 x 300 mg	26.1	26.1 x 300 mg
Mepolizumab	100 mg	100 mg	1 x 100 mg	13.0	13 x 100 mg
Omalizumab	150 mg – 600 mg	150 mg – 600 mg	1 x 150 mg – 4 x 150 mg	13.0 – 26.1	13 x 150 mg – 104.4 x 150 mg
Reslizumab	225 mg	225 mg	2 x 100 mg + 1 x 25 mg	13.0	26 x 100 mg + 13 x 25 mg

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.

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Costs of the medicinal products:

Patient groups a) and b)

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					
Depemokimab 100 mg	1 SFI	€ 9,998.86	€ 1.77	€ 567.70	€ 9,429.39
Formoterol 12 µg[5]	180 SD	€ 84.78	€ 1.77	€ 5.81	€ 77.20
Fluticasone 125 µg/ Formoterol 5 µg[6]	360 SD	€ 71.77	€ 1.77	€ 4.78	€ 65.22
Fluticasone 50 µg/ Salmeterol 500 µg[6]	180 SD	€ 92.71	€ 1.77	€ 6.44	€ 84.50
Indacaterol 136 µg/ glycopyrronium 46 µg/ mometasone furoate 114 µg	90 SD	€ 269.71	€ 1.77	€ 0.00	€ 267.94
Mometasone furoate 400 µg[6]	60 SD	€ 27.35	€ 1.77	€ 0.00	€ 25.58
Tiotropium 2.5 µg	180 SD	€ 198.63	€ 1.77	€ 10.33	€ 186.53
Appropriate comparator therapy					
Benralizumab 30 mg	1 PEN	€ 2,607.04	€ 1.77	€ 145.55	€ 2,459.72
Formoterol 12 µg[6]	180 SD	€ 84.78	€ 1.77	€ 5.81	€ 77.20
Dupilumab 300 mg	6 SFI	€ 3,895.26	€ 1.77	€ 219.12	€ 3,674.37
Fluticasone 125 µg/ Formoterol 5 µg[6]	360 SD	€ 71.77	€ 1.77	€ 4.78	€ 65.22
Fluticasone 50 µg/ Salmeterol 500 µg[6]	180 SD	€ 92.71	€ 1.77	€ 6.44	€ 84.50
Indacaterol 136 µg/ glycopyrronium 46 µg/ mometasone furoate 114 µg	90 SD	€ 269.71	€ 1.77	€ 0.00	€ 267.94
Mepolizumab 100 mg	3 SFI	€ 3,732.70	€ 1.77	€ 0.00	€ 3,730.93
Omalizumab 150 mg	10 SFI	€ 4,172.95	€ 1.77	€ 234.98	€ 3,936.20
Reslizumab 100 mg	2 CIS	€ 1,181.80	€ 1.77	€ 64.76	€ 1,115.27
Reslizumab 50 mg	2 CIS	€ 304.53	€ 1.77	€ 16.19	€ 286.57
Mometasone furoate 400 µg[6]	60 SD	€ 27.35	€ 1.77	€ 0.00	€ 25.58
Tiotropium 2.5 µg	180 SD	€ 198.63	€ 1.77	€ 10.33	€ 186.53

[5]Fixed reimbursement rate

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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
Abbreviations: SD = single doses; CIS = concentrate for the preparation of an infusion solution; SFI = solution for injection; PEN = solution for injection in a pre-filled pen; TAB = tablets					

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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 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.

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 01.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131, paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic agents a maximum amount of € 100 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 100 per ready-to-apply unit are to be payable. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

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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 25 February 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 30 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of depemokimab to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 1 April 2026 in conjunction with the resolution of the GBA 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 GBA commissioned the IQWiG to assess the dossier concerning the active ingredient depemokimab.

The dossier assessment by the IQWiG was submitted to the GBA on 26 June 2026, and the written statement procedure was initiated with publication on the GBA website on 1 July 2026. The deadline for submitting written statements was 22 July 2026.

The oral hearing was held on 10 August 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 22 September 2026, and deliberation of the draft resolution was concluded.

At their session on 1 October 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

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Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	25 February 2025	Determination of the appropriate comparator therapy
Working group Section 35a	5 August 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	10 August 2026	Conduct of the oral hearing
Working group Section 35a	19 August 2026 2 September 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	22 September 2026	Concluding discussion of the draft resolution
Plenum	1 October 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 1 October 2026

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

Dr Optendrenk

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