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 Depemokimab (bronchial asthma, ≥ 12 years)

of 1 October 2026

At their session on 1 October 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, information on the active ingredient Depemokimab shall be added in alphabetical order as follows:

Courtesy translation – only the German version is legally binding.

Depemokimab

Resolution of: 1 October 2026
Entry into force on: 1 October 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 12 February 2026):

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 1 October 2026):

See therapeutic indication according to marketing authorisation.

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

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:

- 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

Extent and probability of the additional benefit of depemokimab compared to the appropriate comparator therapy:

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

Appropriate comparator 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

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Extent and probability of the additional benefit of depemokimab compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

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

There are no assessable data for the benefit assessment.

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	∅	No data available.
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 ∅: No data available. n.a.: not assessable		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-36) unless otherwise indicated.

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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

There are no assessable data for the benefit assessment.

Summary of results for relevant clinical endpoints

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

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

Approximately 2,100 to 2,300 patients

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

Approximately 28,700 to 60,100 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 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.

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4. Treatment costs

Annual treatment costs:

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	Annual treatment costs/ patient
Medicinal product to be assessed:	
Depemokimab	€ 18,858.78
High dose inhaled corticosteroids (ICS)	
Mometasone furoate	€ 295.77
Long-acting beta-2 adrenergic receptor agonist (LABA)	
Formoterol	€ 325.96 - € 626.18
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 756.48
High dose ICS + LABA fixed combination	
Fluticasone (ICS)/ formoterol (LABA)	€ 264.50
Appropriate comparator therapy:	
High dose inhaled corticosteroids (ICS)	
Mometasone furoate	€ 311.22
Long-acting beta-2 adrenergic receptor agonist (LABA)	
Formoterol	€ 313.09 - € 626.18
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 756.48
High dose ICS + LABA fixed combination	
Fluticasone (ICS)/ formoterol (LABA)	€ 264.50
Monoclonal antibodies	
Dupilumab	€ 15,983.51
Mepolizumab	€ 16,167.36
Omalizumab	€ 5,117.06 - € 41,093.93

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 July 2026)

Costs for additionally required SHI services: not applicable

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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	Annual treatment costs/ patient
Medicinal product to be assessed:	
Depemokimab	€ 18,858.78
High dose inhaled corticosteroids (ICS)	
Mometasone furoate	€ 295.77
Long-acting beta-2 adrenergic receptor agonist (LABA)	
Formoterol	€ 325.96 - € 626.18
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 756.48
High dose ICS + LABA fixed combination	
Fluticasone (ICS)/ salmeterol (LABA)	€ 342.69
High dose ICS + LABA + LAMA fixed combination	
Indacaterol (LABA)/ glycopyrronium (LAMA)/ mometasone furoate (ICS)	€ 1,086.65
Appropriate comparator therapy:	
High dose inhaled corticosteroids (ICS)	
Mometasone furoate	€ 311.22
Long-acting beta-2 adrenergic receptor agonist (LABA)	
Formoterol	€ 313.09 - € 626.18
Long-acting muscarinic receptor antagonists (LAMA)	
Tiotropium	€ 756.48
High dose ICS + LABA fixed combination	
Fluticasone (ICS)/ salmeterol (LABA)	€ 342.69
High dose ICS + LABA + LAMA fixed combination	
Indacaterol (LABA)/ glycopyrronium (LAMA)/ mometasone furoate (ICS)	€ 1,086.65
Monoclonal antibodies	
Benralizumab	€ 15,988.18
Dupilumab	€ 15,983.51
Mepolizumab	€ 16,167.36
Omalizumab	€ 5,117.06 - € 41,093.93
Reslizumab	€ 16,361.22

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 July 2026)

Costs for additionally required SHI services: not applicable

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Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Reslizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13.0	€ 1,300

II. The resolution will enter into force on the day of its publication on the GBA website on 1 October 2026.

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

Berlin, 1 October 2026

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

Dr Optendrenk

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