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 (chronic rhinosinusitis with nasal polyps)

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, the following information shall be added after number 4 to the information on the benefit assessment of Depemokimab in accordance with the resolution of 1 October 2026 (bronchial asthma, ≥ 12 years):

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):

Chronic rhinosinusitis with nasal polyps (CRSwNP)

EXDENSUR is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

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

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

Appropriate comparator therapy for depemokimab as an add-on therapy to intranasal corticosteroids:

- Dupilumab or mepolizumab or omalizumab, each in combination with intranasal corticosteroids (budesonide or mometasone furoate)

Extent and probability of the additional benefit of depemokimab in combination with intranasal corticosteroids compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

There are no assessable data for the benefit assessment.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-37) unless otherwise indicated.

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

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

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

Approximately 23,500 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: 16 July 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 CRSwNP.

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4. Treatment costs

Annual treatment costs:

Adults with severe chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids, and/or surgery do not provide adequate disease control

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Depemokimab	€ 18,858.78
Intranasal corticosteroids	€ 62.96 - € 251.85
Total	€ 18,921.74 - € 19,110.63
Appropriate comparator therapy:	
Dupilumab	€ 15,983.51
Intranasal corticosteroids	€ 62.96 - € 251.85
Total	€ 16,046.47 - € 16,235.36
Mepolizumab	€ 16,167.36
Intranasal corticosteroids	€ 62.96 - € 251.85
Total	€ 16,230.32 - € 16,419.21
Omalizumab	€ 5,117.06 - € 41,093.93
Intranasal corticosteroids	€ 62.96 - € 251.85
Total	€ 5,180.02 - € 41,345.78

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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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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