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
Remimazolam (procedural sedation)

From 18 June 2026

At their session on 18 June 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, information on the active ingredient Remimazolam shall be added in alphabetical order as follows:

Remimazolam

Resolution of: 18 June 2026
Entry into force on: 18 June 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 26 March 2021):

Remimazolam is indicated in adults for procedural sedation.

Therapeutic indication of the resolution (resolution of 18 June 2026):

see therapeutic indication according to marketing authorisation.

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

Adults requiring procedural sedation

Appropriate comparator therapy:

Individualised therapy with selection of

- Propofol
- Midazolam
- Dexmedetomidine

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults requiring procedural sedation

There are no suitable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-161), unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	n.a.	The data are not assessable.
Health-related quality of life	∅	No data available.
Side effects	n.a.	The data are not assessable.
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 requiring procedural sedation

Approx. 2,620,000 to 2,730,000 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 Byfavo (active ingredient: remimazolam) at the following publicly accessible link (last access: 30 March 2026):

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

Treatment with remimazolam should only be initiated and monitored by specialists experienced in administering sedation to patients.

4. Treatment costs

Treatment costs:

Adults requiring procedural sedation

The costs represented relate to a single treatment.

Name of the therapy	Treatment costs per treatment/ patient[2]
Medicinal product to be assessed:	
Remimazolam	€ 24.99
Appropriate comparator therapy:	
Propofol	€ 3.39
Midazolam	€ 1.19 - € 2.38
Dexmedetomidine	€ 17.85

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

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adults requiring procedural sedation

- No medicinal product with new active ingredients for use in combination therapy in compliance with the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

[2] The costs of the medicinal products and the additionally required SHI services are reimbursed via the respectively applicable inpatient case flat fees or the Uniform Value Scale, or via defined service items.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Byfavo is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is ≥ 5% of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore conducted to a relevant extent within the scope of SGB V.

II. The resolution entered into force on the day of its publication on the G-BA website on 18 June 2026.

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

Berlin, 18 June 2026

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

Prof. Hecken