Gemeinsamer Bundesausschuss

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
Remimazolam (procedural sedation)

From 18 June 2026

Contents

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,
7. number of study participants who participated in the clinical studies at study sites within the scope of SGB V, and total number of study participants.

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

In accordance with Section 35a, paragraph 1, sentence 3, as well as sentences 6 and 7 SGB V in conjunction with Section 3, paragraph 1, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1, sentences 1 and 2 of the Rules of Procedure of the G-BA (VerfO), the relevant date for the start of the benefit assessment procedure is, in principle, the first placing on the (German) market of a medicinal product with a new active ingredient. According to Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO, listing in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices is generally regarded as the relevant date for the first placing on the market. Notwithstanding this principle, the relevant date for the start of the benefit assessment procedure was determined in the present

procedure to be the granting of the import licence for the medicinal product Byfavo 20 mg pursuant to Section 11, paragraph 1 of the German Narcotics Act (BtMG) in conjunction with Section 1, paragraph 1 of the German Ordinance on the Foreign Trade of Narcotic (BtMAHV) on 14 January 2026. The medicinal product can be deemed to have actually been placed on the German market only after the import licence has been granted.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 April 2026 on the G-BA website (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 remimazolam 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 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 remimazolam.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have come to 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 Remimazolam (Byfavo) in accordance with the product information

Remimazolam is indicated in adults for procedural sedation.

Therapeutic indication of the resolution (resolution of 18.06.2026):

see the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults requiring procedural sedation

Appropriate comparator therapy for remimazolam:

Individualised therapy with selection of

- Propofol
- Midazolam
- Dexmedetomidine

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

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 in 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 in 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: In the therapeutic indication of procedural sedation, in addition to the active ingredient remimazolam to be assessed, the following active ingredients from the product class of benzodiazepines are approved: diazepam, lorazepam and midazolam. In addition, the active ingredients propofol, dexmedetomidine and etomidate are approved for procedural sedation.

On 2. A non-medicinal treatment cannot be considered as the appropriate comparator therapy for the indication to be assessed.

On 3. In the therapeutic indication to be considered here, there are no resolutions from the G-BA on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V.

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 therapeutic indication.

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.

The therapeutic indication covers "procedural sedation". Remimazolam can therefore be used for various diagnostic or surgical procedures in an inpatient or outpatient setting.

The available evidence for the "procedural sedation" indication is limited overall. There is a lack of significant, evidence-based guidelines covering the full range of treatments involving procedural sedation. As procedural sedation is most commonly used in endoscopy, reference is made below to the S3 guideline "Sedation in gastrointestinal endoscopy". According to the S3 guideline, propofol should be preferred to midazolam for sedation in gastrointestinal endoscopy, due to its shorter onset of action, better patient cooperation and faster recovery time. In cases where sedation with benzodiazepines is required, the guideline recommends midazolam due to its shorter half-life. Dexmedetomidine may be considered for endoscopic procedures in specific situations.

The scientific-medical societies involved pursuant to Section 35a, paragraph 7 SGB V mention propofol and benzodiazepines (in particular midazolam) as the active ingredients relevant to medical treatment practice within this therapeutic indication. According to the assessment of the scientific-medical societies, the use of dexmedetomidine may be considered in exceptional cases.

In everyday care, patient-individual factors such as pre-existing cardiovascular, respiratory or metabolic conditions, frailty, age, ASA classification and procedural risk factors are crucial in choosing the sedative.

In the overall assessment, the G-BA therefore consider it appropriate, in the present therapeutic indication, to determine individualised treatment with selection of propofol, midazolam and dexmedetomidine as the appropriate comparator therapy for remimazolam.

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, particular consideration must be given to the nature and duration of the diagnostic or surgical procedure, as well as to patients' comorbidities, taking into account the available evidence.

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 remimazolam is assessed as follows:

An additional benefit is not proven.

Justification:

The pharmaceutical company did not present any data for the assessment of the additional benefit of remimazolam compared to the appropriate comparator therapy.

In the present therapeutic indication, they identify the label-enabling CNS7056-003, CNS7056-004, CNS7056-006, CNS7056-008 and CNS7056-015 studies for comparing remimazolam with midazolam. The pharmaceutical company presented the CNS7056-006, CNS7056-008 and CNS7056-015 studies in the dossier, but did not process the results as part of the benefit assessment.

The pharmaceutical company considered the label-enabling studies identified by them to be unsuitable for the benefit assessment. They justify this on the grounds that only the active ingredient midazolam instead of an individualised therapy with selection of propofol, midazolam and dexmedetomidine was used in all approval studies. Subsequent to the studies, it was not possible to assess the extent to which the active ingredient midazolam was the most appropriate patient-individual option.

However, the active ingredient midazolam is a recognised option within the context of individualised therapy. The approval studies could therefore allow statements to be made on the patients for whom midazolam would be a suitable therapy. However, the pharmaceutical company did not present any processed data for this sub-population, either in the dossier or during the written statement procedure. Overall, it can be concluded that the label-enabling studies contain data that are potentially suitable for the benefit assessment of remimazolam compared with midazolam.

In addition, the IQWiG identify further studies relevant to the benefit assessment which contain potentially suitable data on remimazolam compared with midazolam or propofol. The pharmaceutical company did not provide these study results either.

In the overall assessment, an additional benefit of remimazolam for procedural sedation of adults is not proven.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Byfavo with the active ingredient remimazolam.

The therapeutic indication assessed here is as follows: "Remimazolam is indicated in adults for procedural sedation".

The G-BA determined the appropriate comparator therapy to be an individualised therapy with selection of propofol, midazolam and dexmedetomidine.

The pharmaceutical company deem the label-enabling studies for comparing remimazolam with midazolam, and the further studies identified by the IQWiG for comparing remimazolam with midazolam or propofol to be unsuitable for the benefit assessment, as in each case only the active ingredient midazolam or propofol was used in the comparator arm, rather than an individualised therapy with selection of propofol, midazolam and dexmedetomidine. However, the studies would have contained potentially suitable data for the benefit assessment of remimazolam compared with midazolam or propofol.

An additional benefit of remimazolam for procedural sedation of adults 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 G-BA take into account the patient numbers stated in the pharmaceutical company's dossier; however, these figures are fraught with uncertainties overall due to the limited target population (only considering procedural sedation as part of tracheobronchoscopy and colonoscopy).

Overall, an underestimation of the patient numbers can be assumed.

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 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.

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 April 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.

Remimazolam, as well as the active ingredients of the appropriate comparator therapy – propofol, midazolam and dexmedetomidine – are used in diagnostic or surgical procedures in both outpatient and inpatient settings. As the nature, complexity and duration of the procedures in question may be different from patient to patient, the cost calculation is based on a single administration with an average treatment duration of 13.52 minutes. The information used for this purpose is taken from Module 3A of the pharmaceutical company's documentation. This module took into account data from controlled phase III clinical studies on procedural sedation with remimazolam. As only gastroenterological endoscopies were carried out in these studies, transferability of the average duration of sedation to other diagnostic or surgical procedures is unclear.

Adults requiring procedural sedation

Treatment period:

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Remimazolam	Single use	1	1	1
Appropriate comparator therapy				
Propofol	Single use	1	1	1
Midazolam	Single use	1	1	1
Dexmedetomidine	Single use	1	1	1

Consumption:

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "2021 Microcensus – body measurements of the population" were used as a basis (average body weight: 77.7 kg)[2].

Name 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					
Remimazolam (< 65 years)	Induction:			1	1 x 7.5 mg – 1 x 19.5 mg
	5[3] mg – 7[4] mg	5[3] mg – 7[4] mg	1 x 5 mg – 1 x 7 mg		
	Maintenance/ titration:				
	2.5 mg	2.5 mg – 12.5 mg	1 x 2.5 mg – 5[5] x 2.5 mg		
Remimazolam (≥ 65 years; < 50 kg)	Induction:			1	1 x 3.75 mg – 1 x 17.5 mg
	2.5 mg – 5 mg	2.5 mg – 5 mg	1 x 2.5 mg – 1 x 5 mg		
	Maintenance/ titration:				
	1.25 mg – 2.5 mg	1.25 mg – 12.5 mg	1 x 1.25 mg – 5[5] x 2.5 mg		
Appropriate comparator therapy					
Propofol	Induction:			1	1 x 55.4 mg – 1 x 150.7 mg
	0.5 mg/kg – 1.0 mg/kg = 38.85 mg – 77.7 mg	38.85 mg – 77.7 mg	1 x 38.85 mg – 1 x 77.7 mg		
	Maintenance:				
	1.5 mg/kg BW/h – 4.5 mg/kg BW/h = 16.55 mg – 72.90 mg	16.55 mg – 72.96 mg	1 x 16.55 mg – 1 x 72.96 mg		

[2] Federal Health Reporting. Average body measurements of the population (2021, both sexes, 15 years and older), www.gbe-bund.de

[3] Starting dose for procedural sedation with an opioid

[4] Starting dose for procedural sedation without an opioid

[5] According to the product information, an additional sedative should be considered if the desired level of sedation has not been achieved after 5 bolus doses.

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Midazolam [6] (< 60 years)	3.5 mg – 7.5 mg	3.5 mg – 7.5 mg	1 x 3.5 mg – 1 x 7.5 mg	1	1 x 3.5 mg – 1 x 7.5 mg
Midazolam (≥ 60 years)	1.0 mg – 3.5 mg	1.0 mg – 3.5 mg	1 x 1.0 mg – 1 x 3.5 mg	1	1 x 1.0 mg – 1 x 3.5 mg
Dexmedetomidine	Induction:			1	1 x 78.62 µg – 1 x 82.26 µg –
	1.0 µg/kg = 77.7 µg	77.7 µg	1 x 77.7 µg		
	Maintenance:				
	0.2 - 1.0 µg/kg/h	0.92 µg – 4.56 µg	1 x 0.92 µg – 1 x 4.56 µg		

Costs:

The therapeutic indication of remimazolam and the active ingredients of the appropriate comparator therapy covers procedures carried out in both the inpatient and outpatient sectors. The inpatient sector is exempt from the provisions of the Pharmaceutical Price Ordinance, meaning that no rebates under Sections 130 and 130a SGB V apply there. Furthermore, no additional charges are applied for remimazolam and the active ingredients of the appropriate comparator therapy.

As the costs of medicinal products are reimbursed in the inpatient sector via the flat-rate inpatient remuneration system (Diagnosis Related Groups, DRG system) and in the outpatient sector via the Uniform Value Scale (UVS) or via defined service items, the calculation is based on an approximation of the sales price of the pharmaceutical company (SPC) plus 19% VAT. The actual hospital costs may vary from hospital to hospital.

[6] According to the product information, the total dose of midazolam resulting from induction and maintenance is specified as a consumption range.

Costs of the medicinal products:

Name of the therapy	Packaging size	Cost (manufacturer sales price)	Value added tax (19%)	Costs of the medicinal product[7]
Medicinal product to be assessed				
Remimazolam 20 mg	10 PSI	€ 210.00	€ 39.90	€ 249.90
Appropriate comparator therapy				
Propofol 200 mg (10 mg/ml)	5 EMU	€ 14.24	€ 2.71	€ 16.95
Midazolam 5 mg/5 ml	5 SFI	€ 4.99	€ 0.95	€ 5.94
Dexmedetomidine 100 µg/ml	5 CIS	€ 75.00	€ 14.25	€ 89.25
Abbreviations: EMU = emulsion; CIS = concentrate for the preparation of an infusion solution; SFI = solution for injection; PSI = powder for solution for injection				

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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.

[7] The costs of medicinal products are reimbursed via the applicable DRG case flat fees or via the UVS.

2.5 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

According to Section 35a, paragraph 3, sentence 4, the G-BA designate all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

A designation is also not considered if the G-BA have decided on an exemption as a reserve antibiotic for the assessed medicinal product in accordance with Section 35a, paragraph 1c, sentence 1 SGB V. The additional benefit is deemed to be proven if the G-BA have decided on an exemption for a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V; the extent of the additional benefit and its therapeutic significance are not to be assessed by the G-BA. Due to the lack of an assessment mandate by the G-BA following the resolution on an exemption according to Section 35a, paragraph 1c, sentence 1 SGB V with regard to the extent of the additional benefit and the therapeutic significance of the reserve antibiotic to be assessed, there is a limitation due to the procedural privileging of the pharmaceutical companies to the effect that neither the proof of an existing nor an expected at least considerable additional benefit is possible for exempted reserve antibiotics in the procedures according to Section 35a, paragraph 1 or 6 SGB V and Section 35a, paragraph 1d SGB V. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V must therefore also be taken into account at the level of designation according to Section 35a, paragraph 3, sentence 4 SGB V in order to avoid valuation contradictions.

With regard to the further examination steps, a differentiation is made between a "determined" or "undetermined" combination, which may also be the basis for a designation.

A "determined combination" exists if one or more individual active ingredients which can be used in combination with the assessed medicinal product in the assessed therapeutic indication are specifically named.

An "undetermined combination" exists if there is information on a combination therapy, but no specific active ingredients are named. An undetermined combination may be present if the information on a combination therapy:

- names a product class or group from which some active ingredients not specified in detail can be used in combination therapy with the assessed medicinal product, or

- does not name any active ingredients, product classes or groups, but the assessed medicinal product is used in addition to a therapeutic indication described in more detail in the relevant product information, which, however, does not include data from the product information on active ingredients within the scope of this therapeutic indication.

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2, paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

Based on an "undetermined combination", the concomitant active ingredient must be attributable to the information on the product class or group or the therapeutic indication according to the product information of the assessed medicinal product in the assessed therapeutic indication, whereby the definition of a product class or group is based on the corresponding requirements in the product information of the assessed medicinal product.

In addition, there must be no reasons for exclusion of the concomitant active ingredient from a combination therapy with the assessed medicinal product, in particular no exclusive marketing authorisation as monotherapy.

In addition, all sections of the currently valid product information of the eligible concomitant active ingredient are checked to see whether there is any information that excludes its use in combination therapy with the assessed medicinal product in the assessed therapeutic indication under marketing authorisation regulations. Corresponding information can be, for example, dosage information or warnings. In the event that the medicinal product is used as part of a determined or undetermined combination which does not include the assessed medicinal product, a combination with the assessed medicinal product shall be excluded.

Furthermore, the product information of the assessed medicinal product must not contain any specific information that excludes its use in combination therapy with the eligible concomitant active ingredient in the assessed therapeutic indication under marketing authorisation regulations.

Medicinal products with new active ingredients for which the G-BA have decided on an exemption as a reserve antibiotic in accordance with Section 35a, paragraph 1c, sentence 1 SGB V are ineligible as concomitant active ingredients. The procedural privileging of the reserve antibiotics exempted according to Section 35a, paragraph 1c, sentence 1 SGB V also applies accordingly to the medicinal product eligible as a concomitant active ingredient.

Designation

The medicinal products which have been determined as concomitant active ingredients in accordance with the above points of examination are named by indicating the relevant active ingredient and the invented name. The designation may include several active ingredients, provided that several medicinal products with new active ingredients may be used in the same combination therapy with the assessed medicinal product or different combinations with different medicinal products with new active ingredients form the basis of the designation.

If the present resolution on the assessed medicinal product in the assessed therapeutic indication contains several patient groups, the designation of concomitant active ingredients shall be made separately for each of the patient groups.

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a considerable or major additional benefit has been determined by resolution according to Section 35a, paragraph 3, sentence 1 SGB V or it has been determined according to Section 35a, paragraph 1d, sentence 1 SGB V that at least considerable additional benefit of the combination can be expected. In this context, the combination therapy that is excluded from the designation must, as a rule, be identical to the combination therapy on which the preceding findings were based.

In the case of designations based on undetermined combinations, only those concomitant active ingredients - based on a resolution according to Section 35a, paragraph 3, sentence 1 SGB V on the assessed medicinal product in which a considerable or major additional benefit had been determined - which were approved at the time of this resolution are excluded from the designation.

Legal effects of the designation

The designation of combinations is carried out in accordance with the legal requirements according to Section 35a, paragraph 3, sentence 4 and is used exclusively to implement the combination discount according to Section 130e SGB V between statutory health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

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.

Justification for the findings on designation in the present resolution:

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.

References:
Product information for remimazolam (Byfavo); Byfavo 20 mg powder for solution for injection; last revised: 28.11.2025

2.6 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. In accordance with Section 35a, paragraph 3, sentence 5 SGB V, the G-BA must determine whether a relevant percentage of the clinical studies on the medicinal product were conducted within the scope of SGB V. This is the case if the percentage of study participants who have participated in the clinical studies on the medicinal product to be assessed in the therapeutic indication to be assessed at study sites within the scope of SGB V is at least five per cent of the total number of study participants.

The calculation is based on all studies that were submitted as part of the benefit assessment dossier in the therapeutic indication to be assessed in accordance with Section 35a, paragraph 1, sentence 3 SGB V in conjunction with Section 4, paragraph 6 AM-NutzenV.

Approval studies include all studies submitted to the regulatory authority in section 2.7.3 (Summary of Clinical Efficacy) and 2.7.4 (Summary of Clinical Safety) of the authorisation dossier in the therapeutic indication for which marketing authorisation has been applied for. In addition, studies, which were conducted in whole or in part within the therapeutic indication described in this document, and in which the company was a sponsor or is otherwise financially involved, must also be indicated.

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% (5.3%) of the total number of study participants according to the information provided by the pharmaceutical company.

The pharmaceutical company provided information on 16 studies and stated the percentage of study participants at study sites within the scope of SGB V as 5.3% across all relevant studies. In comparison with the Common Technical Document, a further study, which was submitted to the regulatory authority for the assessment of the clinical efficacy and safety of the medicinal product in the therapeutic indication to be assessed, was identified; however, this study was conducted in the USA. Even taking into account this additional study identified by comparing with the CTD, the percentage of study participants at study sites within the scope of SGB V remains above 5%.

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.

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 10 February 2026, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 23 December 2025, the pharmaceutical company submitted a dossier for the benefit assessment of remimazolam to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 23 December 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits 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 remimazolam.

The dossier assessment by the IQWiG was submitted to the G-BA on 30 March 2026, and the written statement procedure was initiated with publication on the G-BA website on 1 April 2026. The deadline for submitting written statements was 22 April 2026.

The oral hearing was held on 11 May 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 9 June 2026, and the draft resolution was conclusively discussed.

At their session on 18 June 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	10 February 2026	Determination of the appropriate comparator therapy
Working group Section 35a	5 May 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	11 May 2026	Conduct of the oral hearing
Working group Section 35a	19 May 2026 2 June 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	9 June 2026	Concluding discussion of the draft resolution
Plenum	18 June 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 18 June 2026

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

Prof. Hecken