Gemeinsamer Bundesausschuss

Justification

of 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
Nemolizumab (atopic dermatitis, ≥ 12 years)

of 7 August 2025

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 decides 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 nemolizumab on 15 February 2025 in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure (VerfO) of the G-BA. The pharmaceutical company submitted the final dossier to the G-BA in accordance with 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 VerfO on 14 February 2025.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 May 2025 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 nemolizumab 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 nemolizumab.

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 Nemolizumab (Nemluvio) in accordance with the product information

Nemluvio is indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older who are candidates for systemic therapy.

Therapeutic indication of the resolution (resolution of 07.08.2025):

see the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults and adolescents 12 years and older with moderate-to-severe atopic dermatitis who are candidates for systemic therapy

Appropriate comparator therapy for nemolizumab:

- Dupilumab (in combination with TCS and/or TCI if required)

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 in accordance with the generally recognised state of medical knowledge (Section

[1] General Methods, version 7.0 from 19.09.2023. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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 it determines 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. Besides nemolizumab, medicinal products with the following active ingredients are approved for the present therapeutic indication:

- abrocitinib
- antihistamines
- baricitinib
- ciclosporin (severe atopic dermatitis)
- dupilumab
- lebrikizumab (from 40 kg body weight)
- pimecrolimus (moderate atopic eczema) and tacrolimus (moderate-to-severe atopic eczema)
- systemic glucocorticoids (severe eczema)
- topical glucocorticoids of classes 2 to 4
- tralokinumab
- upadacitinib

On 2. UV treatments (UVA/ NB-UVB/ balneophototherapy) are eligible as non-medicinal treatments for atopic dermatitis, but UVA1 is not eligible as it is not a reimbursable treatment.

On 3. In the therapeutic indication under consideration here, the following resolutions of the G-BA are available:

- Resolutions on the benefit assessment according to Section 35a SGB V for the active ingredient dupilumab dated 17 May 2018, 20 February 2020, 1 July 2021 and 21 September 2023
- Resolution on the amendment of the Directive of Prescription of Medicinal Products in SHI-accredited Medical Care (MVV-RL): "Balneophototherapy for atopic eczema," dated 20 March 2020
- Resolution on the benefit assessment according to Section 35a SGB V for the active ingredient baricitinib dated 6 May 2021 and 2 May 2024
- Resolutions on the benefit assessment according to Section 35a SGB V for the active ingredient tralokinumab dated 6 January 2022 and 12 May 2023
- Resolution on the benefit assessment according to Section 35a SGB V for the active ingredient upadacitinib dated 17 February 2022
- Resolutions on the benefit assessment according to Section 35a SGB V for the active ingredient abrocitinib dated 7 July 2022 and 17 October 2024
- Resolution on the benefit assessment according to Section 35a SGB V for the active ingredient lebrikizumab dated 6 June 2024

On 4. The generally recognised state of medical knowledge, on which the G-BA's decision is based, was illustrated by a systematic search for guidelines as well as reviews of clinical studies in the present indication and 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 indication according to Section 35a paragraph 7 SGB V (see “Information on Appropriate Comparator Therapy”).

The biologics dupilumab, lebrikizumab and tralokinumab as well as the JAK inhibitors abrocitinib, baricitinib and upadacitinib are approved for the present patient population of adults and adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.

Based on the benefit assessment resolution of 17 May 2018, an indication of a considerable additional benefit of dupilumab compared with the appropriate comparator therapy could be observed in adults. Furthermore, by resolution of 20 February 2020, a non-quantifiable additional benefit of dupilumab was identified for the patient population of adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis. In the overall assessment of the available evidence, dupilumab represents an adequate therapy option for both adults and adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for systemic therapy. Therefore, there is beneficial evidence for an active ingredient that has also proven itself in practical application.

In contrast, the G-BA identified no additional benefit of the active ingredients tralokinumab and lebrikizumab in adults and adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for systemic therapy, as no suitable data were available for a comparison with the appropriate comparator therapy. In addition, the active ingredients tralokinumab and lebrikizumab are comparatively newer therapy options whose significance cannot yet be conclusively assessed. Therefore, tralokinumab and lebrikizumab are not determined to be appropriate comparator therapy for the present patient group.

In addition, the JAK inhibitors abrocitinib, baricitinib and upadacitinib were assessed by the G-BA as part of the early benefit assessment. For the active ingredient upadacitinib, the G-BA identified an indication of a considerable additional benefit in adults with moderate-to-severe atopic dermatitis who are candidates for a continuous systemic therapy and for whom 30 mg upadacitinib is the appropriate dose. For the active ingredient upadacitinib, no additional benefit could be identified by the G-BA in adolescents and adults with moderate-to-severe atopic dermatitis who are candidates for a continuous systemic therapy and for whom 15 mg upadacitinib is the appropriate dose, as no suitable data were available for this patient population. The G-BA did not determine an additional benefit of baricitinib because no suitable data were available for a comparison with the appropriate comparator therapy. For the active ingredient abrocitinib, the G-BA identified a hint for a considerable additional benefit in adults with moderate-to-severe atopic dermatitis who are candidates for a continuous systemic therapy. For adolescents aged 12 to 17 years with moderate to severe atopic dermatitis who are eligible for systemic therapy, no additional benefit could be established for abrocitinib, as no suitable data were available for this patient population.

The German S3 guideline[2] "Atopic dermatitis" mentions the active ingredients dupilumab, tralokinumab and the JAK inhibitors with the same level of recommendation. As explained above, tralokinumab could show no additional benefit on the one hand. On the other, it is not yet possible to conclusively assess the significance of this active ingredient in healthcare. Compared to the JAK inhibitors,

[2] S3 guideline "Atopic dermatitis" (AWMF register no. 013-027) (2023)

dupilumab continues to be of primary importance in the German healthcare context due to its longer market availability and good efficacy/ safety profile. In addition, there are limitations in the safety profile of JAK inhibitors for sub-populations. Therefore, upadacitinib, baricitinib and abrocitinib are currently not found to be appropriate comparator therapy for the present patient group.

Even with permanent or continuous systemic therapy of atopic dermatitis, topical glucocorticoids (TCS) in classes 2, 3 or 4 and the calcineurin inhibitor (TCI) tacrolimus and pimecrolimus may also be indicated as topical therapy options for individual lesions or in a limited period of time according to the guidelines.

In adults and adolescents 12 to 17 years of age with moderate-to-severe atopic dermatitis who are candidates for a continuous systemic therapy, dupilumab (possibly in combination with TCS and/or TCI) is the appropriate comparator therapy.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5 Section 6, paragraph 3 Rules of Procedure.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of nemolizumab is assessed as follows:

For adults and adolescents 12 years and older with moderate-to-severe atopic dermatitis who are candidates for systemic therapy, the additional benefit is not proven.

Justification:

No relevant study was identified for the assessment of the additional benefit of nemolizumab compared to the appropriate comparator therapy.

In the label-enabling ARCADIA 1 and ARCADIA 2 studies, which were planned and conducted in the same way, a randomised comparison of nemolizumab versus placebo was conducted over 16 weeks. Patients in both treatment arms could also receive low to medium potent TCS or low potent TCI. Treatment with dupilumab was prohibited up to 10 weeks prior to enrolment in the study as well as during the study. The therapy in the comparator arm of the ARCADIA 1 and ARCADIA 2 studies does not correspond to the appropriate comparator therapy. This is why no data are available comparing nemolizumab with the determined appropriate comparator therapy.

In the overall assessment, an additional benefit of nemolizumab over the appropriate comparator therapy is therefore not proven for adults and adolescents aged 12 years and older with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Nemluvio with the active ingredient nemolizumab.

Nemolizumab is indicated for the treatment of moderate-to-severe atopic dermatitis in adult and adolescent patients 12 years and older who are candidates for systemic therapy.

The G-BA determined a therapy with dupilumab (in combination with TCS and/or TCI if required) as the appropriate comparator therapy.

In the dossier, the pharmaceutical company presented the data from the label-enabling ARCADIA 1 and ARCADIA 2 studies, comparing nemolizumab with placebo. Due to the lack of comparison with the appropriate comparator therapy, the data presented are therefore unsuitable for deriving an additional benefit.

In the overall assessment, an additional benefit of nemolizumab over the appropriate comparator therapy is therefore not proven for adults and adolescents aged 12 years and older with moderate-to-severe atopic dermatitis who are candidates for systemic therapy.

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 information is based on the data from the resolutions of the G-BA on dupilumab in the therapeutic indication of moderate-to-severe atopic dermatitis in adults[3] and adolescents[4] who are candidates for systemic therapy. The specified range for the SHI target population is basically plausible, but is subject to uncertainty due to the older sources used.

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 Nemluvio (active ingredient: nemolizumab) at the following publicly accessible link (last access: 21 May 2025):

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

Treatment with nemolizumab should only be initiated and monitored by specialists experienced in treating atopic dermatitis.

[3] Resolution of the G-BA on the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a SGB V of
17 May 2018

[4] Resolution of the G-BA on the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a SGB V of 20 February 2020.

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 2025).

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 varies 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.

Nemolizumab is indicated for the treatment of adults and adolescents aged 12 years and older with moderate-to-severe atopic dermatitis and may be used in combination with topical corticosteroids and/or topical calcineurin inhibitors. Thus, if applicable, the corresponding costs for the combination medicinal products are incurred both for the medicinal product under assessment and for the appropriate comparator therapy and are not listed separately.

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Nemolizumab	Continuously, 1x every 56 days	6.5	1	6.5
Appropriate comparator therapy				
Dupilumab	Continuously, 1x every 14 days	26.1	1	26.1

Consumption:

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					
Nemolizumab	30 mg	30 mg	1 x 30 mg	6.5	6.5 x 30 mg
Appropriate comparator therapy					
Dupilumab	Adolescents 12 to 17 years of age < 60 kg				
	200 mg	200 mg	1 x 200 mg	26.1	26.1 x 200 mg
	Adolescents 12 to 17 years of age ≥ 60 kg and adults				
	300 mg	300 mg	1 x 300 mg	26.1	26.1 x 300 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.

Costs of the medicinal products:

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					
Nemolizumab	1 PSI	€ 2,483.32	€ 1.77	€ 138.53	€ 2,343.02
Appropriate comparator therapy					
Dupilumab 200 mg	6 SFI	€ 3,886.33	€ 1.77	€ 218.66	€ 3,665.90
Dupilumab 300 mg	6 SFI	€ 3,886.33	€ 1.77	€ 218.66	€ 3,665.90
Abbreviations: SFI = solution for injection; PSI = powder and solvent for solution for injection					

LAUER-TAXE® last revised: 15 July 2025

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.

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 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 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:

No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

References:
Product information for nemolizumab (Nemluvio); Nemluvio 30 mg powder and solvent for solution for injection; last revised: February 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 nemolizumab 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 the authorisation dossier for the assessment of the clinical efficacy and safety of the medicinal product in the therapeutic indication to be assessed.

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 per cent (12.8%) of the total number of study participants.

As part of the written statement procedure, the pharmaceutical company updated the information on the number of study participants in authorisation-relevant studies on which the calculation is based. The calculation is considered plausible despite remaining uncertainties. 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 27 February 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 14 February 2025, the pharmaceutical company submitted a dossier for the benefit assessment of nemolizumab to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 17 February 2025 in conjunction with the resolution of the G-BA 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 G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient nemolizumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 13 May 2025, and the written statement procedure was initiated with publication on the G-BA website on 15 May 2025. The deadline for submitting statements was 5 June 2025.

The oral hearing was held on 23 June 2025.

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 was discussed at the session of the Subcommittee on 29 July 2025, and the proposed draft resolution was approved.

At their session on 7 August 2025, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	27 February 2024	Determination of the appropriate comparator therapy
Working group Section 35a	18 June 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	23 June 2025	Conduct of the oral hearing
Working group Section 35a	1 July 2025 15 July 2025	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	29 July 2025	Concluding discussion of the draft resolution
Plenum	7 August 2025	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 7 August 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken