

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
Inebilizumab (new therapeutic indication: immunoglobulin
G4-related disease (IgG4-RD))

From 3 September 2026

Contents

1.	Legal basis.....	2
2.	Key points of the resolution.....	2
2.1	Additional benefit of the medicinal product in relation to the appropriate comparator therapy	3
2.1.1	Approved therapeutic indication of Inebilizumab (Uplizna) in accordance with the product information.....	3
2.1.2	Appropriate comparator therapy.....	3
2.1.3	Extent and probability of the additional benefit.....	6
2.1.4	Summary of the assessment	9
2.2	Number of patients or demarcation of patient groups eligible for treatment	10
2.3	Requirements for a quality-assured application	11
2.4	Treatment costs	11
3.	Bureaucratic costs calculation.....	16
4.	Process sequence	16

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.

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

The active ingredient inebilizumab (Uplizna) was listed for the first time on 1 August 2022 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 10 November 2025, inebilizumab received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 10 July 2025, the pharmaceutical company submitted an application to merge the assessment procedures of inebilizumab according to Section 35a, paragraph 5b SGB V. At their session on 4 September 2025, the G-BA approved the request for merger.

On 6 March 2026, the pharmaceutical company submitted a dossier in due time in accordance with Section 4, paragraph 3, number 3 Ordinance on the Benefit Assessment of

Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient inebilizumab.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 June 2026 on the G-BA website at (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 inebilizumab 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, the statements submitted in the written statement and oral hearing procedure, and the addendum to the benefit assessment prepared by IQWiG. 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 inebilizumab.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have made 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 Inebilizumab (Uplizna) in accordance with the product information

Uplizna is indicated for the treatment of adult patients with active IgG4-RD.

Therapeutic indication of the resolution (resolution of 03.09.2026):

See the approved therapeutic indication.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with active immunoglobulin G4-related disease (IgG4-RD)

Appropriate comparator therapy for inebilizumab:

An individualised therapy with the selection of:

- glucocorticoids
- best supportive care

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 for 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 for 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. No medicinal products other than inebilizumab are explicitly approved for adults with immunoglobulin G4-related disease (IgG4-RD).

- On 2. Non-medicinal therapy is not considered an appropriate comparator therapy for the present therapeutic indication.
- On 3. There are no G-BA resolutions relating to the therapeutic indication under assessment.
- 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 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").

A European guideline (Löhr JM et al., 2020) and a UK guideline (Chapman MH et al., 2019) were identified as part of the body of evidence. However, the available evidence in this therapeutic indication is limited overall.

There are no medicinal products explicitly approved for adults with immunoglobulin G4-related disease (IgG4-RD). Furthermore, it is not possible to derive a uniform and established therapy standard for long-term remission maintenance from the available guidelines.

Nor is there sufficient robust evidence to support the routine use of glucocorticoids for long-term remission maintenance. Rather, the guidelines recommend glucocorticoids primarily for remission induction with subsequent gradual dose tapering. Furthermore, despite high initial response rates, systemic glucocorticoids are not suitable for long-term treatment due to the toxicity associated with their long-term application. The available evidence is also limited regarding the use of glucocorticoid-sparing immunosuppressants.

Against this background, neither glucocorticoids as maintenance treatment nor glucocorticoid-sparing immunosuppressants are considered as the appropriate comparator therapy.

For patients for whom treatment with glucocorticoids alone is not (or no longer) indicated, there are therapy recommendations for the active ingredient rituximab^{3,4,5,6,7}. In their written submission, the scientific-medical societies also stated that the use of the active ingredient rituximab should be considered for these patients, both for remission maintenance and in cases of high risk of recurrence, particularly where multiple organs are affected. Despite these recommendations, based on the current body of evidence, the off-label use of rituximab cannot be regarded as part of the therapy standard for remission maintenance in this therapeutic indication. Consequently, the active ingredient rituximab is also not taken into account when determining the appropriate comparator therapy.

Given the limited body of evidence overall, and taking into account the German healthcare context, the G-BA have therefore determined an individualised therapy with the selection of glucocorticoids and best supportive care as the appropriate comparator therapy.

Glucocorticoids should be used for remission induction in this context. "Best supportive care" is defined as the therapy that provides the best possible, patient-individually optimised, supportive treatment to alleviate symptoms and improve quality of life.

Individualised therapy is based on the assumption that several treatment options, which allow an individualised medical treatment decision, are available.

Changes in the appropriate comparator therapy

The originally determined appropriate comparator therapy was an individualised therapy with the selection of glucocorticoids (as maintenance treatment) and rituximab (only for patients who are no longer eligible for glucocorticoid therapy alone) for adults with active IgG4-RD.

However, taking into account the written statement procedure and the available body of evidence, it is not possible to derive a uniform and established therapy standard for long-term remission maintenance.

For this reason, the G-BA consider it appropriate to change the appropriate comparator therapy at the present time.

Consequently, an individualised therapy with the selection of glucocorticoids and best supportive care is determined as the appropriate comparator therapy.

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 inebilizumab is assessed as follows:

Adults with active immunoglobulin G4-related disease (IgG4-RD)

Hint of non-quantifiable additional benefit.

Justification:

The pharmaceutical company presented the MITIGATE study for the assessment of the additional benefit of inebilizumab compared with the appropriate comparator therapy.

The study is a double-blind, randomised controlled trial comparing treatment with inebilizumab to placebo in adults with active IgG4-RD over a period of 52 weeks.

Patients with a current or recent IgG4-RD flare received induction therapy with high-dose glucocorticoids for three to a maximum of eight weeks prior to randomisation; this was then tapered off within eight weeks following randomisation.

Flares that occurred during the study could be treated on a patient-individual basis with glucocorticoids up to a glucocorticoid dose of 40 mg/day prednisone equivalent at the principal investigator's discretion. However, exceeding a glucocorticoid dose of 40 mg/day prednisone equivalent led to discontinuation of the study treatment, although these patients were also monitored until the end of the study. Overall, it can therefore be concluded that a glucocorticoid flare treatment as part of the study was, in principle, possible at the doctor's discretion and in accordance with the individual disease progression.

In addition, at the principal investigator's discretion, patients were able to receive necessary medicinal products and treatments as part of best supportive care, provided that these did not include biological or non-biological immunosuppressants.

In the overall analysis, it is therefore assumed that the determined appropriate comparator therapy in the MITIGATE study was adequately implemented in the form of an individualised therapy with the selection of glucocorticoids and best supportive care.

Extent and probability of the additional benefit

Mortality

Overall mortality

There were no deaths in either treatment arms of the MITIGATE study.

Morbidity

IgG4-RD flares

For the endpoint of IgG4-RD flares, the pharmaceutical company provided analyses of the time to first treated IgG4-RD flare, as confirmed by an independent, blinded Adjudication Committee (AC).

In addition, the pharmaceutical company submitted predefined analyses of the annual relapse rate of both treated and untreated IgG4-RD flares, as confirmed by the Adjudication Committee. The identification and initiation of diagnostic investigations (e.g. imaging) as well as treatment of any flares were at the principal investigator's discretion. Each flare had to be confirmed by an independent, blinded Adjudication Committee on the basis of the collected data and using the same organ- or tissue-specific criteria.

In the flares observed in the MITIGATE study, at least two organs were affected in around 60% of the patients involved. The organs most commonly affected included the bile ducts, the pancreas, the lymph nodes and the lacrimal glands.

For the endpoint of IgG4-RD flares, there was a statistically significant advantage of inebilizumab over placebo overall. However, it remains unclear whether, and to what extent, the observed effects of inebilizumab in preventing flares lead to an improvement in long-term disease progression and to the prevention of secondary complications, compared with the treatment of occurred flares with glucocorticoids in the control arm.

Remission

The pharmaceutical company submitted a total of three analyses of the composite endpoint of flare-free and corticosteroid-free or treatment-free complete remission at week 52 for the purpose of the benefit assessment.

Remission was defined as the absence of any flare - confirmed by the independent Adjudication Committee - during the 52-week treatment phase, the absence of any need for additional therapy to control flares or the disease, and the absence of disease activity at week 52, as assessed by the principal investigator (absence of disease activity was defined as an IgG4-RD Responder Index = 0 or, according to the principal investigator's assessment, the absence of disease activity based on physical or pathological findings, laboratory results or other indications). According to the operationalisation of the endpoint, patients were classified as responders only if all three endpoint components were met.

It is not clear which findings/ criteria (laboratory results, imaging findings, symptoms) led the principal investigator to make the respective assessment of disease activity. It is therefore unclear whether this operationalisation is suitable for identifying all patients in remission.

The remission endpoint is therefore not used for the present assessment. The results are presented additionally in the resolution.

Symptomatology (patient global assessment of disease activity (PGA))

The PGA consists of a single question which asks patients to rate their IgG4-RD perception on a 10 cm visual analogue scale ranging from 0 (very good) to 10 (very poor).

For the endpoint of symptomatology, assessed using the PGA, there was no statistically significant difference between the treatment arms.

Fatigue (FACIT-Fatigue)

The "Functional Assessment of Chronic Illness Therapy – Fatigue Scale" (FACIT-Fatigue) is a fatigue-specific module of the "Functional Assessment of Chronic Illness Therapy Measurement System" (FACIT).

For the fatigue endpoint, assessed using the FACIT-Fatigue, there was no statistically significant difference between the treatment arms.

Health-related quality of life

Health-related quality of life was assessed using the SF-36v2. For the SF-36, the physical component summary (PCS) score and the mental component summary (MCS) score are considered individually.

For health-related quality of life, assessed using the SF-36v2, there was no statistically significant difference between the treatment arms.

Side effects

SAEs, severe AEs and discontinuation due to AEs

For the endpoints of SAEs, severe AEs and discontinuation due to AEs, there was no statistically significant difference between the treatment arms in each case.

Specific AEs – infections and infestations (SAEs) and blood and lymphatic system disorders (severe AEs)

Detailed analysis of the endpoints of infections and infestations (SAEs) and blood and lymphatic system disorders (severe AEs) showed a statistically significant disadvantage of inebilizumab compared with placebo in each case.

Overall assessment

The pharmaceutical company presented the MITIGATE study for the assessment of the additional benefit of inebilizumab in adults with immunoglobulin G4-related disease (IgG4-RD).

The MITIGATE study is a double-blind, randomised controlled trial comparing treatment with inebilizumab to placebo in adult patients with active IgG4-RD over a period of 52 weeks.

Patients with a current or recent IgG4-RD flare received glucocorticoids for three to a maximum of eight weeks prior to randomisation, which were subsequently tapered off over a period of eight weeks.

Adequate implementation of the determined appropriate comparator therapy in the MITIGATE study was generally assumed since flare treatment with glucocorticoids as part of the study was permitted at the doctor's discretion and depending on individual disease activity. Furthermore, necessary concomitant treatments could be administered as part of best supportive care.

There were no deaths in the MITIGATE study.

For the endpoint of IgG4-RD flares in the endpoint category of morbidity, there was a statistically significant advantage of inebilizumab over placebo. However, its relevance to long-term disease progression and its impact on secondary complications, compared with flare therapy with glucocorticoids, remains unclear.

For the endpoints of symptomatology, assessed using the PGA, and fatigue, assessed using the FACIT-Fatigue, there was no statistically significant difference between the treatment arms in either case.

For the physical component summary (PCS) and the mental component summary (MCS) scores in the endpoint category of health-related quality of life, the SF-36v2 did not show any statistically significant difference between the treatment arms.

For the endpoints of SAEs, severe AEs and discontinuation due to AEs in the endpoint category of side effects, there was no statistically significant difference between the treatment arms in each case. Detailed analysis of the specific AEs of infections and infestations (SAEs) and blood and lymphatic system disorders (severe AEs) showed a statistically significant disadvantage of inebilizumab compared with placebo in each case.

For the endpoint of IgG4-RD flares, the overall assessment showed an advantage of inebilizumab over placebo. However, the extent of the advantage shown is not conclusively quantifiable as it remains unclear how the prevention of flares with inebilizumab - compared to flare treatment with glucocorticoids - impacts long-term disease progression and secondary complications. Furthermore, no advantages were observed in the endpoint of health-related quality of life and other morbidity endpoints used for the benefit assessment.

Overall, an additional benefit of inebilizumab was therefore identified for adults with active IgG4-RD; however, the extent of this benefit cannot be quantified on the basis of the available data.

Reliability of data (probability of the additional benefit)

This assessment is based on the results of the double-blind, randomised controlled MITIGATE study.

The risk of bias across endpoints in the MITIGATE study is assessed as low overall. However, there are uncertainties regarding the reliability of the results for the endpoint of IgG4-RD flares. These results can only be interpreted to a limited extent in terms of their long-term relevance to patients.

Furthermore, uncertainties arise because the duration of the glucocorticoid taper over eight weeks was significantly shorter than the three to six months recommended in the guidelines.

This reduces the reliability of data regarding the additional benefit overall.

Against this background, the reliability of data is classified under the "hint" category.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient inebilizumab.

The therapeutic indication assessed here is as follows: Uplizna is indicated for the treatment of adult patients with active IgG4-RD.

The G-BA determined an individualised therapy with the selection of glucocorticoids and best supportive care as the appropriate comparator therapy.

The pharmaceutical company presented the MITIGATE study for the assessment of the additional benefit of inebilizumab in adults with immunoglobulin G4-related disease (IgG4-RD). The MITIGATE study is a double-blind RCT comparing inebilizumab with placebo in adult patients with active IgG4-RD over a period of 52 weeks. Induction therapy with high-dose glucocorticoids was followed by an eight-week dose tapering.

Adequate implementation of the determined appropriate comparator therapy in the MITIGATE study was generally assumed since flare treatment with glucocorticoids as part of the study was permitted at the doctor's discretion and depending on individual disease activity. Furthermore, necessary concomitant treatments could be administered as part of best supportive care.

There were no deaths in the MITIGATE study.

For the endpoint of IgG4-RD flares in the endpoint category of morbidity, there was a statistically significant advantage of inebilizumab over placebo. For the endpoints of symptomatology and fatigue, as well as for the health-related quality of life, there were no statistically significant differences between the treatment arms.

For the endpoints of SAEs, severe AEs and discontinuation due to AEs in the endpoint category of side effects, there was no statistically significant difference between the treatment arms in each case. Detailed analysis of the specific AEs of infections and infestations (SAEs) and blood and lymphatic system disorders (severe AEs) showed a statistically significant disadvantage of inebilizumab in each case.

For the endpoint of IgG4-RD flares, the overall assessment showed a statistically significant advantage of inebilizumab over placebo. However, the extent of the advantage shown is not conclusively quantifiable as it remains unclear how the prevention of flares with inebilizumab - compared to flare treatment with glucocorticoids - impacts long-term disease progression and secondary complications.

The significance of the evidence is classified in the hint category. Despite the overall low risk of bias across endpoints, there are uncertainties regarding the interpretability of the results for the endpoint of IgG4-RD flares. The fact that the glucocorticoid tapering phase was shorter than that recommended in the guidelines adds to this uncertainty.

Overall, a hint of non-quantifiable additional benefit of inebilizumab was found in adults with active IgG4-RD.

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, which are, however, subject to uncertainties overall due to several aspects.

The lack of a specific ICD-10-GM code means that the identification of patients with active IgG4-RD (lower limit) in the German healthcare context is fraught with major uncertainties. At the same time, both the incomplete diagnostic data in the cited study and the exclusive focus of the cited consensus paper on autoimmune pancreatitis make it difficult to derive a reliable upper limit and to extrapolate to the entire clinical picture of IgG4-RD.

Overall, there are therefore uncertainties regarding the number of patients in the SHI target population as stated by the pharmaceutical company.

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 Uplizna (active ingredient: inebilizumab) at the following publicly accessible link (last access: 18 June 2026):

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

Treatment with inebilizumab should only be initiated and monitored by specialists experienced in treating patients with IgG4-RD.

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: 1 July 2026).

The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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 is different 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.

Treatment period:

Adults with active immunoglobulin G4-related disease (IgG4-RD)

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed:				
Inebilizumab	Continuously, 1 x every 6 months	2.0	1	2.0
Best supportive care	Different from patient to patient			
Appropriate comparator therapy				
An individualised therapy with the selection of:				
Glucocorticoids	Different from patient to patient			
Best supportive care	Different from patient to patient			

Consumption:

Adults with active immunoglobulin G4-related disease (IgG4-RD)

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:					
Inebilizumab	300 mg	300 mg	3 x 100 mg	2	6 x 100 mg
Best supportive care	Different from patient to patient				
Appropriate comparator therapy					
An individualised therapy with the selection of:					
Glucocorticoids	Different from patient to patient				
Best supportive care	Different from patient to patient				

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.

Glucocorticoids are classified into several reference price groups. For example, prednisolone is cited as a representative from the product class of oral glucocorticoids.

Costs of the medicinal products:

Adults with active immunoglobulin G4-related disease (IgG4-RD)

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:					
Inebilizumab 100 mg	3 CIS	€ 54,517.59	€ 1.77	€ 3,110.17	€ 51,405.65
Best supportive care	Different from patient to patient				
Appropriate comparator therapy					

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
Prednisolone 20 mg ²	100 TAB	€ 22.40	€ 1.77	€ 0.82	€ 19.81
Prednisolone 10 mg ⁹	100 TAB	€ 18.59	€ 1.77	€ 0.51	€ 16.31
Prednisolone 5 mg ⁹	100 TAB	€ 16.21	€ 1.77	€ 0.33	€ 14.11
Prednisone 20 mg ⁹	100 TAB	€ 30.06	€ 1.77	€ 1.42	€ 26.87
Prednisone 10 mg ⁹	100 TAB	€ 22.00	€ 1.77	€ 0.00	€ 20.23
Prednisone 5 mg ⁹	100 TAB	€ 17.52	€ 1.77	€ 0.43	€ 15.32
Best supportive care	Different from patient to patient				
Abbreviations: CIS = concentrate for the preparation of an infusion solution; TAB = tablets					

LAUER-TAXE® last revised: 1 July 2026

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.

Premedication

According to the product information, premedication with a glucocorticoid e.g. methylprednisolone 80-125 mg IV or equivalent is necessary approx. 30 min before the application of inebilizumab. Therefore, the costs for methylprednisolone with the dosage for premedication given in the product information are presented as an example. The costs may vary depending on the glucocorticoid used and the dosage form.

Designation of the therapy	Packaging size	Cost (pharmacy discount price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Inebilizumab							
<i>Premedication</i>							
Methylprednisolone 80 mg - 125 mg, IV	3 PII x 32 mg	€ 26.48	€ 1.77	€ 6.88	€ 17.83	2.0	€ 35.66
	3 PII x 32 mg	€ 26.48	€ 1.77	€ 6.88	€ 17.83	2.0	€ 47.55
Dimetindene IV 1 mg/ 10 kg	5 x 4 mg SFI	€ 26.24	€ 1.77	€ 6.92	€ 17.55	2.0	€ 14.04

² Fixed reimbursement rate

Designation of the therapy	Packaging size	Cost (pharmacy discount price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Paracetamol ^{3,4} 500 mg	10 TAB x 500 mg	€ 2.96	€ 0.15	€ 0.13	€ 2.68	2.0	€ 0.54
- 1,000 mg, oral	10 TAB x 1,000 mg	€ 3.32	€ 0.17	€ 0.14	€ 3.01	2.0	€ 0.60
Abbreviations: TAB = tablets; SFI = solution for injection; PII = powder and solvent for solution for injection or infusion							

Diagnosis of tuberculosis

For the medicinal product under assessment, inebilizumab, costs are regularly incurred for examining for both active and inactive ("latent") tuberculosis infections. The costs presented are a blood test (quantitative determination of an in vitro interferon-gamma release after ex vivo stimulation with antigens specific for Mycobacterium tuberculosis-complex (except BCG)). In addition, a chest radiograph is usually required to detect pulmonary tuberculosis. The tuberculin skin test is not presented due to lack of sensitivity and specificity as well as the possibility of "sensitisation". These examinations are not required when using the appropriate comparator therapy.

Hepatitis B and hepatitis C diagnostics

Diagnostics to rule out chronic hepatitis B requires sensibly coordinated steps. A step-by-step serological diagnosis initially consists of the examination of HBs antigen and anti-HBc antibodies. If both are negative, a past HBV infection can be excluded. In certain case constellations, further steps may be necessary in accordance with current guideline recommendations.⁵

Diagnostics to rule out hepatitis C requires sensibly coordinated steps. HCV screening is based on the determination of anti-HCV antibodies. In certain case constellations, it may be necessary to verify the positive anti-HCV antibody findings in parallel or subsequently by HCV-RNA detection to confirm the diagnosis of an HCV infection.⁶

³ The dosage of 650 mg paracetamol in premedication stated in the product information cannot be achieved by tablets. Because of this, a dosage of 500 – 1,000 mg is used.

⁴ Fixed reimbursement rate Non-prescription medicinal products that are reimbursable at the expense of the statutory health insurance according to Section 12, paragraph 7, of the AM-RL (information as concomitant medication in the product information of the prescription medicinal product) are not subject to the current medicinal products price regulation. Instead, in accordance with Section 129, paragraph 5a SGB V, when a non-prescription medicinal product is dispensed invoiced according Section 300, a medicinal product sale price applies to the insured person in the amount of the sale price of the pharmaceutical company plus the surcharges according to Sections 2 and 3 of the Pharmaceutical Price Ordinance in the valid version of 31 December 2003.

⁵ S3 guideline on prevention, diagnosis and therapy of hepatitis B virus infection; AWMF registry no.: 021/011 https://register.awmf.org/assets/guidelines/021-011l_S3_Prophylaxe-Diagnostik-Therapie-der-Hepatitis-B-Virusinfektion_2021-07.pdf

⁶ S3 guideline on prevention, diagnosis and therapy of hepatitis C virus (HCV) infection; AWMF registry no.: 021/012 https://register.awmf.org/assets/guidelines/021-012l_S3_Hepatitis-C-Virus_HCV-Infektion_2018-07.pdf.

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	Treatment days/year	Costs/patient/year
Inebilizumab							
<i>Tuberculosis diagnostics</i>							
Quantitative determination of in vitro interferon-gamma release following ex vivo stimulation with antigens (except BCG) (FSI 32670)	-	-	-	-	€ 53.36	1.0	€ 53.36
Chest radiograph (FSI 34241)	-	-	-	-	€ 18.09	1.0	€ 18.09
<i>HBV screening</i>							
HBV test Hepatitis B surface antigen status (FSI 32781)	-	-	-	-	€ 5.06	1.0	€ 5.06
Anti-HBc antibody (FSI 32614)	-	-	-	-	€ 5.43	1.0	€ 5.43
<i>HCV screening</i>							
Hepatitis C HCV antibody status (FSI 32618)	-	-	-	-	€ 9.02	1.0	€ 9.02

The calculation of the additionally required SHI services is based on packs in distribution with the LAUER-TAXE® last revised on 15 September 2025 and fee structure items (FSI) - last revised in the 3rd quarter of 2025 of the uniform value scale (UVS 2025/Q3).

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 01.10.2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131, paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic agents a maximum amount of € 100 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 100 per ready-to-apply unit are to be payable. These additional other costs are not added to the pharmacy sales price but rather follow the rules for calculating in the Hilfstaxe. The cost representation is based on the pharmacy retail price and the maximum surcharge for the preparation and is only an approximation of the treatment costs. This presentation does not take into account, for example, the rebates on the pharmacy purchase price of the active ingredient, the invoicing of discards, the calculation of application containers, and carrier solutions in accordance with the regulations in Annex 3 of the Hilfstaxe.

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

The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 23 July 2024.

On 6 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of inebilizumab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 2 VerfO.

By letter dated 12 March 2026 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 inebilizumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 11 June 2026, and the written statement procedure was initiated with publication on the G-BA website on 15 June 2026. The deadline for submitting written statements was 6 July 2026.

The oral hearing was held on 27 July 2026.

By letter dated 28 July 2026, the IQWiG was commissioned with a supplementary assessment. The addendum prepared by the IQWiG was submitted to the G-BA on 18 August 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 25 August 2026, and deliberation of the draft resolution was concluded.

At their session on 3 September 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	23 July 2024	Determination of the appropriate comparator therapy
Working group Section 35a	15 July 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	27 July 2026	Conduct of the oral hearing, commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	5 August 2026 19 August 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	25 August 2026	Concluding discussion of the draft resolution
Plenum	3 September 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 3 September 2026

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

Dr Optendrenk