

Justification

for the Resolution of the Federal Joint Committee (GBA) on an
Amendment of the Pharmaceuticals Directive:

Annex XII – Benefit Assessment of Medicinal Products with
New Active Ingredients according to Section 35a SGB V
Retifanlimab (new therapeutic indication: squamous cell
carcinoma of the anal canal; first-line)

of 1 October 2026

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1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (GBA) assess the benefit of all reimbursable medicinal products with new active ingredients.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V. Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy do not have to be submitted (Section 35a, paragraph 1, sentence 11, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V thus guarantees an additional benefit of an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, numbers 2 and 3 SGB V in conjunction with Chapter 5, Sections 5 et seqq. of the Rules of Procedure (VerfO) of the GBA has not been carried out. In accordance with Section 5, paragraph 8 AM-NutzenV, only the extent of the additional benefit is to be quantified indicating the significance of the evidence.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy sales prices and outside the scope of SHI-accredited medical care, including VAT exceeds € 30 million in the last 12 calendar months. In accordance with Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company shall provide evidence - within three months of being requested to do so by the GBA - in accordance with Chapter 5, Section 5, paragraphs 1 to 6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy specified by the GBA in accordance with Chapter 5, Section 6 VerfO, and in this evidence, demonstrate the additional benefit over the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the GBA decide whether to carry out the benefit assessment themselves or to commission the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the legal requirement in Section 35a, paragraph 1, sentence 11 SGB V that the additional benefit of an orphan drug is considered to be proven through the grant of the marketing authorisation, the GBA modified the procedure for the benefit assessment of orphan drugs at their session on 15 March 2012 to the effect that, for orphan drugs, the GBA initially no longer independently determine an appropriate comparator therapy as the basis for the solely legally permissible assessment of the extent of an additional benefit to be assumed by law. Rather, the extent of the additional benefit is assessed exclusively on the basis of the approval studies by the GBA indicating the significance of the evidence.

Accordingly, at their session on 15 March 2012, the GBA amended the mandate issued to the IQWiG by the resolution of 1 August 2011 for the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a, paragraph 2 SGB V such that, in the case of orphan drugs, the IQWiG is only commissioned to carry out a benefit assessment in the case of a previously defined comparator therapy when the sales volume of the medicinal product concerned has exceeded the turnover limit according to Section 35a, paragraph 1, sentence 12 SGB V and is therefore subject to an unrestricted benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment by the GBA 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 GBA 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 retifanlimab (Zynyz) was listed for the first time on 1 March 2026 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 5 March 2026, the active ingredient retifanlimab 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).

Retifanlimab for the first-line treatment of metastatic or unresectable locally recurrent squamous cell carcinoma of the anal canal (SCAC) is approved as a medicinal product for the treatment of a rare disease under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999.

In accordance with Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V, the additional benefit is considered to be proven through the grant of the marketing authorisation. The extent of the additional benefit and the significance of the evidence are assessed on the basis of the approval studies by the GBA.

On 31 March 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted a dossier in due time in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the GBA on the active ingredient retifanlimab with the new therapeutic indication

"Zynyz is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC).".

The GBA carried out the benefit assessment and commissioned the IQWiG to evaluate the information provided by the pharmaceutical company in Module 3 of the dossier on treatment costs and patient numbers. The benefit assessment was published along with the IQWiG assessment on 1 July 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The GBA have adopted their resolution on the basis of the dossier of the pharmaceutical company, the dossier assessment carried out by the GBA, the assessment of treatment costs and patient numbers (IQWiG G26-08) prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure as well as the amendment to the benefit assessment prepared by the GBA.

In order to determine the extent of the additional benefit, the GBA have assessed the studies relevant to the marketing authorisation on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7,

sentence 1, numbers 1 to 4 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods ¹ was not used in the benefit assessment of retifanlimab.

In the light of the above, and taking into account the statements received and the oral hearing, the GBA have made the following assessment:

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of Retifanlimab (Zynyz) in accordance with the product information

Zynyz is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC).

Therapeutic indication of the resolution (resolution of 1 October 2026):

See the approved therapeutic indication.

2.1.2 Extent of the additional benefit and significance of the evidence

Adults with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC); first-line treatment

In summary, the extent of the added benefit of retifanlimab in combination with carboplatin and paclitaxel is assessed as follows:

Hint of a minor additional benefit.

Justification:

The pharmaceutical company submitted data from the completed, pivotal, randomised, double-blind phase III POD1UM-303 study for the benefit assessment. This study compared retifanlimab in combination with carboplatin and paclitaxel with carboplatin in combination with paclitaxel.

Adult patients with unresectable, locally recurrent or metastatic SCAC were enrolled. Randomisation was stratified according to PD-L1 expression status ($< 1\%$ vs $\geq 1\%$), disease stage (locally relapsing vs metastatic) and geographical region (Australia, European Union, North America, United Kingdom vs rest of the world) in a 1:1 ratio to the study arms retifanlimab + carboplatin + paclitaxel (intervention arm, N = 154) and carboplatin + paclitaxel (control arm, N = 154). Both HIV-positive and HPV-positive patients were eligible for enrolment in the POD1UM-303 study. The proportion of HIV-positive patients was approximately 3%, whilst 97% of patients had a negative or unknown HIV status. With regard to HPV infection, approximately one-fifth of the patients tested positive for HPV according to local testing. There is no information on the HPV status of around four-fifths of the patients. Around 40% of patients tested positive for P16/INK4A according to local testing, whilst no such data is available for approximately 60% of them. Approximately half of the patients had a positive P16 status according to centralised testing. The other half showed negative and inconclusive results, as well as, for the most part, missing values.

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

Treatment with retifanlimab was in accordance with the requirements in the product information (6 cycles of retifanlimab in combination with carboplatin and paclitaxel, followed by retifanlimab as monotherapy in cycles 7–13). Patients in the control arm received 6 cycles of carboplatin in combination with paclitaxel.

Following disease progression, subjects in the control arm were able to receive retifanlimab monotherapy (treatment switch). To this end, the respective patients were unblinded regarding their treatment allocation at the time of disease progression.

The primary endpoint of the study was progression-free survival (PFS), additional endpoints on mortality, symptomatology, health-related quality of life and adverse events were assessed.

The pharmaceutical company reported a total of three data cut-offs for the study in the dossier: a primary data cut-off from 15 April 2024, a final data cut-off from 1 August 2025 and a safety data cut-off from 26 September 2025. Only the results on overall survival were reported in the dossier as of the data cut-off from 26 September 2025. With their written statement, the pharmaceutical company subsequently submitted data on adverse events for this data cut-off. This assessment is based on the data cut-off from 26 September 2025, with the exception of the results for the PFS endpoint, for which the results for the data cut-off from 1 August 2025 are used.

Mortality

In the POD1UM-303 study, overall survival was defined as the time from the date of randomisation to the date of death from any cause.

For this endpoint, there was a statistically significant difference to the advantage of retifanlimab in combination with carboplatin and paclitaxel; the extent of this difference is rated as a relevant, but no more than a minor improvement. It should be noted that the effect estimator is based on a wide confidence interval; consequently, uncertainty regarding the precision of the effect estimate is factored in when interpreting the results [HR = 0.73; 95% confidence interval: 0.54; 0.99].

In the POD1UM-303 study, patients were able to switch from the placebo arm to monotherapy with retifanlimab following disease progression (treatment switch). At the data cut-off date of 26 September 2025, 77 subjects (50.0%) in the control arm were receiving monotherapy with retifanlimab.

In the dossier, the pharmaceutical company provided analyses of the adjustment for the treatment switch using the Rank-Preserving Structural Failure Time Model (RPSFTM) and Inverse Probability of Censoring Weighting (IPCW).

The RPSFT and IPCW models are not statistical methods that allow a sufficiently reliable assessment of a treatment effect in relation to the endpoint of overall survival in studies involving a treatment switch. This is primarily because the central assumptions of these models (common treatment effect and no unmeasured confounders) cannot be verified using empirical data.

Irrespective of this, the models were not adequately documented by the pharmaceutical company, and the relevant model assumptions were inadequately discussed.

Although the European Medicines Agency (EMA) list the results on overall survival using the RPSFT and IPCW models in the European Assessment Report², they classify them as

² Assessment Report – ZYNYZ, 29 January 2026, EMA/VR/0000247788

exploratory and supportive and did not include them in their assessment of the benefit-risk ratio.

In the overall assessment, the analysis of overall survival using the RPSFT and IPCW models is not taken into account in this benefit assessment.

Morbidity

Progression-free survival (PFS)

PFS was the primary endpoint of the POD1UM-303 study and was operationalised as the time from the date of randomisation to disease progression according to RECIST 1.1 criteria (based on assessment by a blinded independent central review (BICR)) committee or death.

PFS was statistically significantly prolonged with retifanlimab in combination with carboplatin and paclitaxel.

The PFS endpoint is a composite endpoint comprising endpoints of the mortality and morbidity categories. The endpoint component "mortality" is already assessed via the endpoint "overall survival" as an independent endpoint. The morbidity component of disease progression was not assessed in a symptom-related manner but exclusively by means of imaging procedures (disease progression assessed by radiology according to the RECIST 1.1 criteria).

Taking into account the aspects mentioned above, there are different opinions within the GBA regarding the patient relevance of the PFS endpoint. The overall statement on the extent of the additional benefit remains unaffected.

Symptomatology (EORTC QLQ-C30) and health status (EQ-5D-VAS)

Data on patient-reported symptomatology and health status were collected in the POD1UM-303 study using the EORTC QLQ-C30 symptom scales and the EQ-5D visual analogue scale, respectively.

However, the data are unsuitable for making statements on the extent of the additional benefit due to the low return rates [the percentage of missing values already at baseline (approx. 20%) and in the early stages of the study (mostly > 30% from cycle 2 onwards)].

Quality of life

EORTC QLQ-C30 and EORTC QLQ-ANL27

In line with the above comments on symptomatology, no suitable data are also available on health-related quality of life that would allow statements to be made on the extent of the additional benefit.

Side effects

Total adverse events (AEs)

AEs occurred in all patients in the POD1UM-303 study. The results were only presented additionally.

Serious AEs (SAEs), severe AEs (CTCAE grade ≥ 3)

For the endpoints of serious AEs (SAEs) and severe AEs (CTCAE grade ≥ 3), there were no statistically significant differences between the treatment arms.

Therapy discontinuation due to AEs

For the endpoint of therapy discontinuation due to AEs, there was a statistically significant difference to the disadvantage of retifanlimab in combination with carboplatin and paclitaxel.

Specific AEs

Detailed analysis of the results on SAEs and severe AEs (CTCAE grade ≥ 3), which occurred with an incidence $\geq 5\%$ in one study arm, showed no statistically significant differences.

In the overall analysis, the higher rate of therapy discontinuations due to AEs in the endpoint category of side effects leads to a disadvantage of retifanlimab in combination with carboplatin and paclitaxel.

Overall assessment

The results of the randomised, controlled POD1UM-303 study, which compared retifanlimab in combination with carboplatin and paclitaxel against carboplatin and paclitaxel are available for the benefit assessment of retifanlimab in combination with carboplatin and paclitaxel for the first-line treatment of metastatic or unresectable locally recurrent squamous cell carcinoma of the anal canal (SCAC).

For this endpoint, there was a statistically significant difference to the advantage of retifanlimab in combination with carboplatin and paclitaxel; the extent of this difference is rated as a relevant, but no more than a minor improvement. This takes into account the fact that the effect estimator is based on a wide confidence interval; consequently, uncertainty regarding the precision of the effect estimate is factored in when interpreting the results.

For the patient-reported endpoints on symptomatology and health status in the endpoint category of morbidity, no suitable data are available for making statements on the extent of the additional benefit due to insufficient return rates.

Due to the insufficient return rates, no suitable data are also available on health-related quality of life for making statements on the extent of the additional benefit.

The results on side effects showed a disadvantage of retifanlimab in combination with carboplatin and paclitaxel due to a significantly higher rate of therapy discontinuations due to AEs.

In the overall assessment, therefore, the advantage in terms of overall survival is offset by the disadvantage in terms of therapy discontinuation due to AEs. This disadvantage does not call into question the extent of the improvement in overall survival. Overall, the extent of the additional benefit is therefore rated as low.

Significance of the evidence

The present benefit assessment is based on the results of the randomised, double-blind phase III POD1UM-303 study.

The risk of bias at the study level is considered low.

At the endpoint level, the risk of bias in terms of overall survival is considered high, particularly due to the high percentage of patients in the control arm who switch to retifanlimab monotherapy upon disease progression.

It should also be conditionally noted that the POD1UM-303 study did not provide any usable data on patient-reported morbidity and health-related quality of life. In view of the fact that high significance is attributed to statements on quality of life especially in the advanced palliative situation, there is uncertainty regarding the significance of the evidence.

In the overall assessment, this results in the classification of the significance of the evidence in the "hint" category.

2.1.3 Summary of the assessment

The present assessment concerns the benefit assessment of a new therapeutic indication for the medicinal product Zynyz with the active ingredient retifanlimab. Zynyz was approved as an orphan drug in the following, new therapeutic indication:

"Zynyz is indicated in combination with carboplatin and paclitaxel for the first-line treatment of adult patients with metastatic or with inoperable locally recurrent squamous cell carcinoma of the anal canal (SCAC).".

For the benefit assessment, the pharmaceutical company submitted data from the randomised, double-blind phase III POD1UM-303 study, which compared retifanlimab in combination with carboplatin and paclitaxel against carboplatin in combination with paclitaxel.

For the endpoint on overall survival, there was a statistically significant difference to the advantage of retifanlimab in combination with carboplatin and paclitaxel; the extent of this difference is rated as a relevant, but no more than a minor improvement. This takes into account the fact that the effect estimator is based on a wide confidence interval; consequently, uncertainty regarding the precision of the effect estimate is factored in when interpreting the results.

For the patient-reported endpoints on symptomatology and health status in the endpoint category of morbidity, as well as in the endpoint category of health-related quality of life, no usable data are available for making statements on the extent of the additional benefit due to insufficient return rates.

For the endpoint of therapy discontinuation due to AEs in the endpoint category of side effects, there was a disadvantage of retifanlimab in combination with carboplatin and paclitaxel.

In the overall assessment, the advantage in terms of overall survival is offset by the disadvantage in terms of therapy discontinuation due to AEs. This disadvantage does not call into question the extent of the improvement in overall survival. Overall, the extent of the additional benefit is therefore rated as low. Particularly in view of the high risk of bias for the endpoint on overall survival and the lack of suitable data on the patient-reported endpoints on symptomatology and quality of life, a hint of the identified extent of the additional benefit results with regard to the significance of the evidence.

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 GBA base their resolution on the patient numbers indicated by the pharmaceutical company in the dossier. The pharmaceutical company's approach to deriving the patient numbers is mathematically plausible.

Overall, the information on the number of patients in the SHI target population tend to be underestimated. Despite numerous uncertainties and conflicting effects, this is attributable in

particular to a very low applied incidence of anal cancer, which stems from the use of age-standardised incidence rates.

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 Zynyz (active ingredient: retifanlimab) at the following publicly accessible link (last access: 12 August 2026):

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

Therapy with retifanlimab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with anal carcinoma, as well as specialists in internal medicine and gastroenterology and other specialists from other specialist groups participating in the Oncology Agreement.

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 2026).

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

According to the product information for retifanlimab, treatment should be continued for up to 1 year.

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				
Retifanlimab in combination with carboplatin and paclitaxel				
Retifanlimab	1 x per 28-day cycle	13	1	13
Carboplatin	1 x per 28-day cycle	6	1	6
Paclitaxel	Day 1, 8 and 15 of a 28-day cycle	6	3	18

Consumption:

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.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population" were applied (average body height: 1.73 m; average body weight: 78.3 kg). This results in a body surface area of 1.92 m² (calculated according to Du Bois 1916)³.

The carboplatin dosage according to the target AUC is calculated using the Calvert formula and the estimation of renal function with the Cockcroft-Gault equation using the average height (women: 166 cm, men: 179 cm), average weight (women 69.7 kg, men 86.5 kg) and the average age of women and men in Germany in 2024 (women: 46.2 years, men: 43.5 years)⁴ and the mean standard serum creatinine concentration (women: 0.75 mg/dl, men: 0.9 mg/dl).⁵

The mean value (AUC 5 = 704.4 mg) formed from these doses for women (AUC 5 = 639.6 mg) and men (AUC 5 = 769.1 mg) was used as the basis for calculating the cost of carboplatin.

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					
Retifanlimab in combination with carboplatin and paclitaxel					
Retifanlimab	500 mg	500 mg	1 x 500 mg	13	13 x 500 mg
Carboplatin	AUC 5 = 704.4 mg	704.4 mg	1 x 600 mg + 1 x 150 mg	6	6 x 600 mg + 6 x 150 mg
Paclitaxel	80 mg/m ² = 153.6 mg	153.6 mg	1 x 100 mg + 2 x 30 mg	18	18 x 100 mg + 36 x 30 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.

³ Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

⁴ Federal Institute for Population Research, average age of the population in Germany (1871-2021) <https://www.bib.bund.de/DE/Fakten/Fakt/B19-Durchschnittsalter-Bevoelkerung-ab-1871.html>

⁵ DocCheck Flexikon – Serum creatinine, URL: <https://flexikon.doccheck.com/de/Serumkreatinin> [last access on: 15.07.2026]

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					
Retifanlimab	1 CIS	€ 13,541.13	€ 1.77	€ 770.00	€ 12,769.36
Carboplatin 600 mg	1 CIS	€ 301.62	€ 1.77	€ 13.74	€ 286.11
Carboplatin 150 mg	1 CIS	€ 83.81	€ 1.77	€ 3.40	€ 78.64
Paclitaxel 100 mg	1 CIS	€ 290.13	€ 1.77	€ 13.19	€ 275.17
Paclitaxel 30 mg	1 CIS	€ 94.93	€ 1.77	€ 3.93	€ 89.23
Abbreviations: CIS = concentrate for the preparation of an infusion solution					

LAUER-TAXE® last revised: 15 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.

No additional SHI services required are taken into account for the cost representation.

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

On 31 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of retifanlimab to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 2 VerfO.

The benefit assessment of the GBA was published on 1 July 2026 together with the IQWiG assessment of treatment costs and patient numbers on the GBA website (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 22 July 2026.

The oral hearing was held on 10 August 2026.

An amendment to the benefit assessment with a supplementary assessment of data submitted in the written statement procedure was submitted on 11 September 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 22 September 2026, and deliberation of the draft resolution was concluded.

At their session on 1 October 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 June 2026	Information of the benefit assessment of the GBA
Working group Section 35a	4 August 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	10 August 2026	Conduct of the oral hearing
Working group Section 35a	18 August 2026 15 September 2026	Consultation on the dossier assessment by the GBA, the assessment of treatment costs and patient numbers by the IQWiG, and the evaluation of the written statement procedure
Subcommittee on Medicinal Products	22 September 2026	Concluding discussion of the draft resolution
Plenum	1 October 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 1 October 2026

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

Dr Optendrenk