Gemeinsamer Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Vimseltinib (symptomatic tenosynovial giant cell tumours)

of 16 April 2026

Contents

1. Legal basis

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

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, Nos. 2 and 3 SGB V in conjunction with Chapter 5 Sections 5 et seqq. of the Rules of Procedure (VerfO) of the G-BA 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 G-BA - 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 G-BA 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 G-BA decide whether to carry out the benefit assessment itself 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 G-BA 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 G-BA 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 G-BA indicating the significance of the evidence.

Accordingly, at their session on 15 March 2012, the G-BA 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 to that effect 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 G-BA 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 relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient vimseltinib on 1 November 2025 in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO). Pursuant to Section 4, paragraph 3, No. 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, No. 1 Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the G-BA on 30 October 2025.

Vimseltinib for the treatment of symptomatic tenosynovial giant cell tumours is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No 141/2000 of the European Parliament and 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 by the G-BA on the basis of the approval studies.

The G-BA 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 on 2 February 2026 together with the IQWiG assessment 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 adopted their resolution on the basis of the pharmaceutical company's dossier, the dossier assessment carried out by the G-BA, the IQWiG assessment of treatment costs and patient numbers (IQWiG G25-03) and the statements made in the written statement and oral hearing procedure, as well of the amendment drawn up by the G-BA on the benefit assessment.

In order to determine the extent of the additional benefit, the G-BA 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 vimseltinib.

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

2.1 Additional benefit of the medicinal product

2.1.1 Approved therapeutic indication of Vimseltinib (Romvimza) in accordance with the product information

Romvimza is indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability.

Therapeutic indication of the resolution (resolution of 16 April 2026):

See the approved therapeutic indication

2.1.2 Extent of the additional benefit and significance of the evidence

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

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

Indication of a considerable additional benefit

Justification:

For the assessment of the extent of the additional benefit of vimseltinib in the therapeutic indication of tenosynovial giant cell tumours (TGCT), the pharmaceutical company submitted data from the multicentre, randomised, placebo-controlled, multi-part phase III MOTION study, which has been conducted at 30 study sites in North America, Europe and Asia from October 2021.

The ongoing MOTION study compares vimseltinib (+ best supportive care, BSC) with placebo (+ BSC) in adults with symptomatic TGCT in whom, based on an assessment during a surgical consultation or by a multidisciplinary tumour board, surgical resection is likely to result in physical functional deterioration or severe morbidity. A total of 123 adults were enrolled in a 2:1 ratio (intervention arm N = 83; control arm N = 40) and stratified according to tumour localisation (lower limbs vs all others) and region (USA vs rest of the world).

Part 1 of the study is the 24-week double-blind, randomised part of the study, which was completed in August 2023. Patients in the intervention arm will continue to be treated with vimseltinib after week 24. Patients in the placebo arm may also receive vimseltinib from week 25 onwards.

The primary endpoint of the study was objective response rate according to IRR based on RECIST. Additional endpoints were assessed in the categories of morbidity and side effects, with deaths recorded as part of the safety assessment; data on health-related quality of life were not collected.

The comparative results from the double-blind part 1 of the study, which was completed in August 2023, were considered relevant for the benefit assessment, and were used.

Mortality

In the Motion study, deaths were recorded as AEs that resulted in death as part of the safety assessment. No deaths occurred.

Morbidity

Tumour response

In the MOTION study, tumour response or the "objective response rate" (ORR), is defined as the percentage of study participants with a complete response (CR) or partial response (PR) at week 25, where CR and PR are defined as follows:

- CR: Disappearance of all target lesions. All pathological lymph nodes must be less than 10 mm in their shortest axis. Non-nodular target lesions must have disappeared.
- PR: At least 30% reduction in the sum of the diameters of the target lesions, with the sum of the baseline diameters acting as a reference.

For the assessment of the response, magnetic resonance imaging (MRI) of the affected joint was performed at week 13 and week 25. There was a statistically significant difference in favour of vimseltinib.

Tumour response was assessed by means of independent radiological review (IRR) in accordance with the Response Evaluation Criteria in Solid Tumours (RECIST) criteria version 1.1; thus, the assessment was not based on symptoms but was primarily based on imaging procedures. For this reason, this endpoint is classified as not patient-relevant.

The "objective response rate" by means of IRR in accordance with RECIST at week 25 is presented additionally as the primary endpoint of the study.

Physical functioning using PROMIS-PF and PGIC-PF/ PGIS-PF

Physical functioning was assessed in the MOTION study using 15 questions from the standardised item bank of the "Patient-Reported Outcomes Measurement Information System Physical Function" (PROMIS-PF) and using the self-reported PGIC-PF and PGIS-PF questionnaires.

The items in the PROMIS-PF were selected on the basis of literature reviews, clinical expertise and patient interviews, with separate scales being developed for the upper and lower limbs. Physical functioning using PROMIS-PF is considered patient-relevant. A T-score was calculated using the "API scoring manual" for evaluation of the PROMIS-PF. In this regard, the pharmaceutical company established a post-hoc response threshold of at least 8.025 points compared with the baseline value. Given that no conversion tables could be identified for the PROMIS scale used, it is unclear whether the score of 8.025 defined post hoc corresponds to a response threshold of 15% of the scale range. Therefore, only continuous evaluations are used for the benefit assessment.

In the PGIC, patients were assessed on a seven-point scale ("very much improved", "much improved", "minimally improved", "no change", "minimally worse", "much worse", "very much worse"), with patients showing an improvement in the respective item ("minimally improved", "much improved" or "very much improved") compared to baseline being classified as responders.

In the PGIS, patients were assessed on a five-point scale ("no symptoms", "mild", "moderate", "severe", "very severe"), with patients showing a reduction by at least 1 point in the relevant item compared to baseline being classified as responders.

For the endpoint of physical functioning using PROMIS-PF, there was a statistically significant and clinically relevant difference in favour of vimseltinib at week 25. A statistically significant improvement was also observed for vimseltinib in the PGIC-PF/ PGIS-PF.

In view of the present results of the PGIC-PF/ PGIS-PF, there may have been double counting with regard to the "physical functioning" endpoint. Overall, the results of the PGIC-PF/ PGIS-PF are therefore regarded as a confirmation of the results of the PROMIS-PF.

Limitations in range of motion using NRS-stiffness and PGIC-ROM/ PGIS-ROM

In the MOTION study, limitations in range of motion were assessed using NRS-stiffness and PGIC-ROM/ PGIS-ROM.

In this study, patient-reported stiffness of the affected joint was collected every other day using a single question (Numerical Rating Scale, NRS) to rate the most severe stiffness experienced over the past 24 hours on a scale from 0 ("no stiffness") to 10 ("the most severe stiffness imaginable"). Joint stiffness is considered to be patient-relevant.

The response threshold defined a priori for an improvement by 2 points corresponds to a change by at least 15% of the NRS scale range and is taken into account in the benefit assessment.

With regard to the PGIC-ROM and PGIS-ROM, please refer to the above explanations for the "physical functioning" endpoint concerning the operationalisation.

For the stiffness endpoint using the NRS, there was a statistically significant advantage of vimseltinib at week 25. A statistically significant improvement was also observed for vimseltinib in the PGIC-ROM.

In view of the present results of the PGIC-ROM, there may also have been double counting with regard to the "limitations in range of motion" endpoint. Overall, the results of the PGIC-ROM are therefore regarded as a confirmation of the results of the NRS-stiffness.

Active range of motion (ROM)

For the endpoint of active range of motion (ROM), the range of motion of the affected joint was collected and assessed by adequately trained, blinded study staff using goniometry.

The measured value (in degrees) for the affected joint was used to derive a relative range of motion, which was calculated by normalising the measurement against a reference standard value provided by the American Medical Association (AMA) for each movement.

At week 25, there was a statistically significant difference to the advantage of vimseltinib compared to baseline.

According to statements made by the clinical experts at the oral hearing, improvement in active motion, that is, independent, unassisted movement by study participants, is a relevant parameter in everyday clinical practice.

The immediate effects of the changes in range of motion, as measured in this study using goniometry, on activities of daily living were already assessed in the MOTION study using the patient-relevant endpoints of NRS-stiffness and PGIC/ PGIS.

Active range of motion is not considered to be directly patient-relevant and is only presented additionally.

Pain using BPI-SF

In the MOTION study, the patient-reported "pain" endpoint was collected using two individual items of the BPI-SF ("worst pain" and "moderate pain") on a scale from 0 ("no pain") to 10 ("worst pain imaginable").

The response threshold of 30% defined a priori compared to baseline does not refer to the scale range, but to the individual baseline value, thus not in every case corresponding to a

response threshold of 15% of the scale range. Therefore, only continuous evaluations are used for the benefit assessment.

On both the "pain" and "moderate pain" scales, there was a statistically significant and clinically relevant advantage of vimseltinib at week 25.

Health status using EQ-5D VAS

The health status was assessed in the MOTION study using the visual analogue scale (VAS) of the EQ-5D questionnaire. For the benefit assessment, responder analyses showing an improvement by ≥ 15% of the scale range at week 25 were used.

For the endpoint of health status assessed using the EQ-5D VAS, there was a statistically significant advantage in favour of vimseltinib at week 25.

General disease symptomatology using PGIC

Patient-reported general disease symptomatology at the tumour site was collected using the PGIC disease symptomatology questionnaire. With regard to operationalisation, please refer to the above explanations on the PGIC-PF (physical functioning).

For the PGIC disease symptomatology, there was a statistically significant improvement for vimseltinib.

The overall analysis of the morbidity endpoint category showed consistent and clear advantages of vimseltinib across almost all endpoints.

Quality of life

No data on health-related quality of life were collected in the MOTION study.

Side effects

Adverse events (AEs) in total

In the MOTION study, AEs occurred in almost all patients in both study arms. The results are only presented additionally.

Serious adverse events (SAEs) and therapy discontinuation due to AEs

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

Severe AEs (CTCAE grade 3 or 4)

For the endpoint of severe AEs, there was a statistically significant disadvantage of vimseltinib + BSC compared with placebo + BSC.

In summary, in terms of side effects, there were disadvantages of vimseltinib due to an increase in severe AEs.

Overall assessment

Results on mortality, morbidity and side effects from the randomised, multicentre, placebo-controlled phase III MOTION study, which compared vimseltinib + best supportive care (BSC) with placebo + BSC, are available for the assessment of the extent of the additional benefit. The comparative results from the double-blind part 1 of the study, which was completed in August 2023, were considered relevant for the benefit assessment, and were used.

There were no deaths in the MOTION study.

For the endpoint category of morbidity, there was a clear overall advantage of vimseltinib for treatment with vimseltinib, taking into account the endpoints "physical functioning" (using PROMIS-PF and PGIC-PF/ PGIS-PF), "worst pain" and "moderate pain" (using BPI-SF in each case), "limitations in range of motion" (using NRS-stiffness and PGIC-ROM), "health status" using EQ-5D VAS, and PGIC disease symptomatology.

No data on the endpoint category of health-related quality of life were collected in the MOTION study.

In the endpoint category of side effects, there was a disadvantage of vimseltinib due to a significant increase in severe AEs; there were no differences in the endpoints of serious AEs and therapy discontinuation due to AEs.

In the overall analysis, the consistently positive effects in the endpoint category of morbidity (physical functioning, pain, limitations in range of motion and health status) are offset by a negative effect in the endpoint category of side effects (severe AEs). The negative effect is assessed as not calling into question the extent of the additional benefit resulting from the significant improvement in morbidity.

Overall, a considerable additional benefit of vimseltinib + BSC compared with placebo + BSC can therefore be identified in adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability.

Significance of the evidence

The present benefit assessment is based on the results of the double-blind, randomised, placebo-controlled phase III MOTION study.

The risk of bias is considered to be low at study level and for the endpoint of side effects.

Although potential unblinding cannot be ruled out due to substance-specific side effects of vimseltinib, the reliability of data is not considered to be reduced in the endpoint category of morbidity, given the consistency and extent of the effects.

Overall, the G-BA derive an indication of the identified additional benefit with regard to the significance of the evidence.

2.1.3 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Romvimza with the active ingredient vimseltinib.

Vimseltinib has been approved for treatment of adult patients with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability.

The results from the randomised, multicentre, placebo-controlled phase III MOTION study comparing vimseltinib + best supportive care (BSC) with placebo + BSC are available for the benefit assessment; the comparative results from the double-blind part 1 of the study, which was completed in August 2023, were considered relevant and used.

There were no deaths in the MOTION study.

For the endpoint category of morbidity, there was a clear overall advantage of vimseltinib for treatment with vimseltinib, taking into account the endpoints "physical functioning" (using

PROMIS-PF and PGIC-PF/ PGIS-PF), "worst pain" and "moderate pain" (using BPI-SF in each case), "limitations in range of motion" (using NRS-stiffness and PGIC-ROM), "health status" using EQ-5D VAS, and PGIC disease symptomatology.

No data on the endpoint category of health-related quality of life were collected in the MOTION study.

In the endpoint category of side effects, there was a disadvantage of vimseltinib in terms of severe AEs; there were no statistically significant differences in the endpoints of serious AEs and therapy discontinuation due to AEs.

The overall assessment showed consistently positive effects across almost all endpoints in the endpoint category of morbidity. In contrast, there was a disadvantage in terms of side effects due to the increase in severe AEs; however, this does not call into question the consistent advantages in the endpoint category of morbidity.

A considerable additional benefit of vimseltinib is identified overall. The significance of the evidence for the additional benefit identified is classified in the "indication" category overall.

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 base their resolution on the information from the dossier of the pharmaceutical company; however, the sources cited by the pharmaceutical company are subject to the following significant limitations and uncertainty.

Firstly, the prevalence figure cited by the pharmaceutical company on the basis of a routine data analysis should be regarded as a lower limit, especially due to the absence of a specific ICD-10-GM diagnostic code for identifying TGCT patients, meaning that certain segments of the TGCT patient population have not been assessed.

Furthermore, with regard to the other sources cited by the pharmaceutical company, the transferability of the percentages used is particularly questionable, or these values are likewise subject to uncertainty, as these sources examined, in particular, partly selected patient populations (such as therapy naïve patients) and the percentages from these differently selected patient populations were applied to one another in the pharmaceutical company's calculations.

The lower limit indicated by the pharmaceutical company is therefore subject to uncertainty overall, and the upper limit tends to be underestimated despite the uncertainty.

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 Romvimza (active ingredient: vimseltinib) at the following publicly accessible link (last access: 8 April 2026):

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

Therapy with vimseltinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, who are experienced in the treatment of patients with tenosynovial giant cell tumours as well as specialists in orthopaedics and trauma surgery, and other doctors from other specialist groups participating in the Oncology Agreement.

2.4 Treatment costs

The treatment costs are based on the requirements in the product information and the information listed in the LAUER-TAXE® (last revised: 15 February 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 the maximum treatment duration, if specified in the product information.

The annual treatment costs shown refer to the first year of treatment.

Treatment period:

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Vimseltinib	2 x per week	104.3	1	104.3

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.

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

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					
Vimseltinib	30 mg	30 mg	1 x 30 mg	104.3	104.3 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.

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					
Vimseltinib 30 mg	8 HC	€ 27,329.48	€ 1.77	€ 1,557.50	€ 25,770.21
Abbreviations: HC = hard capsules					

LAUER-TAXE® last revised: 15 February 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.

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

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

Basic principles of the assessed medicinal product

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

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

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

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

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

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

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

Concomitant active ingredient

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

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

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

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

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

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

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

Designation

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

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

Exception to the designation

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

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

Legal effects of the designation

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

The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

Justification for the findings on designation in the present resolution:

Adults with symptomatic tenosynovial giant cell tumour (TGCT) associated with clinically relevant physical function deterioration and in whom surgical options have been exhausted or would induce unacceptable morbidity or disability

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

References:
Product information for vimseltinib (Romvimza); last revised: March 2026

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 vimseltinib is a medicinal product placed on the market from 1 January 2025. In accordance with Section 35a, paragraph 3, sentence 5 SGB V, the G-BA must determine whether a relevant percentage of the clinical studies on the medicinal product were conducted within the scope of SGB V. This is the case if the percentage of study participants who have participated in the clinical studies on the medicinal product to be assessed in the therapeutic indication to be assessed at study sites within the scope of SGB V is at least five per cent of the total number of study participants.

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

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

The pharmaceutical company state that the percentage of study participants at study sites within the scope of SGB V is 3.1% for all relevant studies (DCC-3014-01-001 and DCC-3014-03-001 [MOTION]). This information is comprehensible.

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 (3.1%) of the total number of study participants according to the information provided by the pharmaceutical company.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant percentage 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

On 30 October 2025, the pharmaceutical company submitted a dossier for the benefit assessment of vimseltinib to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 1, sentence 2 VerfO.

The benefit assessment of the G-BA was published on 2 February 2026 together with the IQWiG assessment of treatment costs and patient numbers on the G-BA website (www.g-ba.de), thus initiating the written statement procedure. The deadline for submitting written statements was 23 February 2026.

The oral hearing took place on 9 March 2026.

An amendment to the benefit assessment with a supplementary assessment was submitted on 26 March 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 conclusively discussed at the Subcommittee's session on 8 April 2026, and the draft resolution was approved.

At its session on 16 April 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	27 January 2026	Information of the benefit assessment of the G-BA
Working group Section 35a	4 March 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	9 March 2026	Conduct of the oral hearing
Working group Section 35a	18 March 2026 1 April 2026	Consultation on the dossier assessment by the G-BA, the assessment of treatment costs and patient numbers by the IQWiG, and the

		evaluation of the written statement procedure
Subcommittee on Medicinal Products	8 April 2026	Concluding discussion of the draft resolution
Plenum	16 April 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 16 April 2026

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

Prof. Hecken