Gemeinsamer Bundesausschuss

Justification

to 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
Tislelizumab (new therapeutic indication: non-small cell lung cancer, high risk of recurrence, neoadjuvant and adjuvant treatment, monotherapy or combination with platinum-based chemotherapy)

From 19 March 2026

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application,

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 tislelizumab (Tevimbra) was listed for the first time on 1 September 2024 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 21 August 2025, tislelizumab 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 17 September 2025, 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 G-BA on the active ingredient tislelizumab with the new therapeutic indication

"Tislelizumab, in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of adult patients with resectable NSCLC at high risk of recurrence"

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The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 2 January 2026 on the G-BA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of tislelizumab compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of tislelizumab.

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 Tislelizumab (Tevimbra) in accordance with the product information

Tevimbra, in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of adult patients with resectable NSCLC at high risk of recurrence.

Therapeutic indication of the resolution (resolution of 19 March 2026):

See the approved therapeutic indication

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

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

Appropriate comparator therapy for tislelizumab in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment:

- Neoadjuvant treatment with nivolumab in combination with platinum-based therapy followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression ≥ 1%)

or

- Neoadjuvant treatment with pembrolizumab in combination with platinum-based therapy followed by adjuvant treatment with pembrolizumab

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5 Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment

according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved in the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved in the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

On 1. In addition to tislelizumab, the active ingredients atezolizumab, nivolumab, pembrolizumab, durvalumab and vinorelbine are approved in the present therapeutic indication.

On 2. Pre-operative (neoadjuvant) radiotherapy and post-operative (adjuvant) radiotherapy (stage III) are generally considered as non-medicinal treatment in the present therapeutic indication.

On 3. Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:

- Durvalumab: resolution of 22.01.2026
- Nivolumab: resolutions of 04.12.2025 and 01.02.2024
- Atezolizumab: resolution of 20.03.2025
- Pembrolizumab: two resolutions from 17.10.2024

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 therapeutic indication according to Section 35a, paragraph 7 SGB V. A joint written statement by the German Society for Haematology and Medical Oncology (DGHO), the German Society for Pneumology and Respiratory Medicine (DGP), the Working Group for Thoracic Oncology in the Working Group for

Internal Oncology of the German Cancer Society (AIO) and the Working Group for Pneumological Oncology of the German Cancer Society (POA) is available.

Among the approved active ingredients listed under 1., only certain active ingredients named below will be included in the appropriate comparator therapy, taking into account the evidence on therapeutic benefit, the guideline recommendations and the reality of care.

Patients at high risk of recurrence in tumour stages IIA to IIIB according to the 8th edition of the Union for International Cancer Control (UICC) were enrolled in the present therapeutic indication.

With regard to systemic pre- and/or postoperative therapy for resectable NSCLC, both neoadjuvant and adjuvant therapeutic concepts are considered according to the available evidence and the recommendations in guidelines. The appropriate comparator therapy was determined on the assumption that the decision in favour of neoadjuvant therapy was made in the present therapeutic indication.

The recommendations in the guidelines on neoadjuvant therapy options are made, depending on the respective tumour stage. The neoadjuvant therapy options mentioned include chemotherapy, combined chemoimmunotherapy and simultaneous chemo-radiotherapy.

The S3 guideline recommends combined chemoimmunotherapy for patients with resectable tumours (without EGFR and ALK alteration) in tumour stages II and IIIA3/IIIB (T3N2 only) and includes a recommendation for anti-neoplastic induction therapy.

In their written statement, the scientific-medical societies mention a platinum-based combination chemotherapy - should a neoadjuvant therapeutic approach be chosen - which is combined with an immune checkpoint inhibitor (nivolumab or pembrolizumab) in the case of positive PD-L1 status (TPS ≥ 1%). In this context, the scientific-medical societies point out that pembrolizumab is also approved in this indication for patients with PD-L1 expression < 1%, although the studies did not show any benefit of immunotherapy in this subgroup.

In the benefit assessment, a hint for a non-quantifiable additional benefit of nivolumab in combination with platinum-based chemotherapy was identified for the neoadjuvant treatment of resectable NSCLC with tumour cell PD-L1 expression ≥ 1% (resolution of 01.02.2024).

Pembrolizumab in combination with platinum-based chemotherapy, followed by pembrolizumab as monotherapy for adjuvant treatment is another combined chemoimmunotherapy, the use of which has been approved regardless of PD-L1 expression. No additional benefit could be identified in the corresponding benefit assessment (resolution of 17.10.2024), as no suitable data were available for the comparison with the appropriate comparator therapy (patient group: tumour cell PD-L1 expression ≥ 1%) or the data showed no advantage compared with neoadjuvant chemotherapy (patient group: tumour cell PD-L1 expression < 1%).

The active ingredients nivolumab and durvalumab are further new treatment options in the present therapeutic indication, which are used in combination with platinum-

based chemotherapy in neoadjuvant treatment and as monotherapy in adjuvant treatment. Nivolumab is approved here only for adult patients with tumour cell PD-L1 expression ≥ 1%, and durvalumab for adult patients without EGFR mutations or ALK translocations. No additional benefit could be identified in the corresponding benefit assessments of nivolumab (resolution of 04.12.2025) and durvalumab (resolution of 22.01.2026) respectively, as no suitable data were available for the comparison with the appropriate comparator therapy. The active ingredients were only recently approved for these therapeutic indications (nivolumab: marketing authorisation on 15.05.2025, durvalumab: marketing authorisation on 31.03.2025). These treatment options are not determined as the appropriate comparator therapy as their significance cannot yet be conclusively assessed in the present treatment setting.

The available guidelines do not contain any clear statements on the treatment option of neoadjuvant systemic therapy with chemotherapy alone.

The guidelines do not mention any specific chemotherapeutic active ingredients or combinations of active ingredients for stage II. For stage IIIA3, a combination of cisplatin and a taxane should preferably be used. The platinum derivatives cisplatin or carboplatin in combination with vinorelbine, paclitaxel, docetaxel, gemcitabine or pemetrexed are considered to be effective combinations.

Depending on the tumour stage, simultaneous chemoradiotherapy is a further standard in the preoperative treatment setting. According to the guidelines, chemotherapy for simultaneous chemoradiotherapy is based on platinum-based (cisplatin or carboplatin) combination chemotherapy. No sufficiently clear standard can be established for the other components of chemotherapy in addition to cisplatin or carboplatin.

The above-mentioned active ingredients or combinations of active ingredients - cisplatin and carboplatin, each in combination with a third-generation cytostatic - are not approved for the neoadjuvant therapy of resectable NSCLC outside of chemoimmunotherapy. It cannot be concluded from the present evidence that the off-label use of medicinal products is generally preferable to the use of medicinal products approved in the therapeutic indication according to the generally recognised state of medical knowledge. The requirements for exceptionally determining the off-label use of medicinal products as appropriate comparator therapy in accordance with Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) are therefore not met.

Taking into account the therapy recommendations for chemoimmunotherapy, nivolumab in combination with platinum-based therapy, followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression ≥ 1%) and pembrolizumab in combination with platinum-based therapy, followed by adjuvant treatment with pembrolizumab were determined as appropriate comparator therapies in the overall assessment.

The monitoring wait-and-see approach includes the follow-up examinations recommended according to the current state of medical knowledge.

Change in the appropriate comparator therapy

In the originally determined appropriate comparator therapy, the nivolumab therapy option was determined to be neoadjuvant treatment with nivolumab in combination with platinum-based therapy, followed by adjuvant treatment with best supportive care (only for patients with tumour cell PD-L1 expression ≥ 1%).

In the resolution on durvalumab for the same field of indication (resolution of 22.01.2026), the nivolumab therapy option was determined to be neoadjuvant treatment with nivolumab in combination with platinum-based therapy, followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression ≥ 1%). According to the assessment by the clinical experts involved in the associated written statement procedure, this appropriate comparator therapy was in line with the current therapy standard in the therapeutic indication.

On this basis, the G-BA consider it appropriate to adjust the appropriate comparator therapy accordingly for the present resolution. For the present resolution, in terms of the nivolumab therapy option, neoadjuvant treatment with nivolumab in combination with platinum-based therapy, followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression ≥ 1%) was therefore determined to be the appropriate comparator therapy.

The relevant 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 tislelizumab is assessed as follows:

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

An additional benefit is not proven.

Justification:

The pharmaceutical company did not submit any data for the assessment of the additional benefit in the treatment of adults with resectable NSCLC at high risk of recurrence using tislelizumab in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment. Therefore, an additional benefit is not proven.

2.1.4 Summary of the assessment

The present assessment is a benefit assessment of a new therapeutic indication for the active ingredient tislelizumab. The therapeutic indication assessed here is as follows:

"Tevimbra, in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of adult patients with resectable NSCLC at high risk of recurrence."

The appropriate comparator therapy was determined to be

- neoadjuvant treatment with nivolumab in combination with platinum-based therapy, followed by monitoring wait-and-see approach *or*
- neoadjuvant treatment with pembrolizumab in combination with platinum-based therapy, followed by adjuvant treatment with pembrolizumab

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No data were submitted by the pharmaceutical company that would allow an assessment of the additional benefit. An additional benefit is therefore not proven.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

In the dossier submitted by the pharmaceutical company, there tends to be an overestimation of the number of patients in the SHI target population, as the pharmaceutical company uses percentages that refer to lung cancers without limitation of the scope to NSCLC. Furthermore, the pharmaceutical company included stage IIIB patients in the target population, even though they were not enrolled in the RATIONALE 315 approval study.

In order to ensure a consistent determination of the patient numbers in the present therapeutic indication, the G-BA refer to the derivation of the target population used as a basis in the resolution on the benefit assessment of pembrolizumab (resolution of 17 October 2024). These figures were also used in the procedure for nivolumab (resolution of 4 December 2025) and durvalumab (resolution of 22 January 2026). A more valid estimate of the number of patients in the SHI target population is available here; this can be used despite continuing uncertainties.

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 Tevimbra (active ingredient: tislelizumab) at the following publicly accessible link (last access: 10 March 2026):

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

Treatment with tislelizumab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with non-small cell lung cancer, as well as specialists in internal medicine and pulmonology or specialists in pulmonary medicine and other doctors from other specialist groups participating in the Oncology Agreement.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (including patient identification card).

The training material contains, in particular, information and warnings about immune-mediated side effects as well as infusion-related reactions.

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 January 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

For tislelizumab, the recommended dose in the neoadjuvant phase is 200 mg in combination with platinum-based chemotherapy every 3 weeks for 3 cycles, followed by adjuvant treatment with 400 mg tislelizumab as monotherapy every 6 weeks for up to 8 cycles.

The recommended dose of nivolumab in the neoadjuvant phase is 360 mg in combination with platinum-based chemotherapy every 3 weeks for 4 cycles.

For pembrolizumab, the recommended dose in the neoadjuvant phase is 200 mg in combination with platinum-based chemotherapy every 3 weeks for 4 cycles or 400 mg every 6 weeks for 2 cycles, followed by adjuvant treatment with 200 mg pembrolizumab as monotherapy every 3 weeks for up to 13 cycles or 400 mg every 6 weeks for up to 7 cycles.

Consumption and the cost representation are based on the treatment cycles specified in the product information for tislelizumab, nivolumab and pembrolizumab, thus reflecting the entire treatment duration of the two time-limited therapies.

For the cost representation in the resolution, a cost range, which is made up of the lowest annual treatment costs for the combination therapy and the highest annual treatment costs

for the combination therapy, is shown for neoadjuvant treatment with tislelizumab, nivolumab and pembrolizumab in combination with platinum-based chemotherapy.

The active ingredient nivolumab to be assessed and the active ingredient pembrolizumab as a therapy option of the appropriate comparator therapy are each approved for the neoadjuvant treatment phase with "platinum-based chemotherapy". As no clear statements on options for neoadjuvant, platinum-based chemotherapy emerge from the guidelines, the platinum-based chemotherapy combinations recommended by the scientific-medical societies in the benefit assessment procedure for nivolumab (resolution of 01.02.2024) are mentioned for "platinum-based chemotherapy" both for the medicinal product to be assessed and for the appropriate comparator therapy.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "Microcensus 2021 – body measurements of the population" were applied (average body height: 1.72 m; average body weight: 77.7 kg). This results in a body surface area of 1.91 m² (calculated according to Du Bois 1916)[2].

The following combination therapies are cited as examples for the neoadjuvant treatment phase: 75 mg/m² BSA cisplatin and 25 mg/m² – 30 mg/m² BSA vinorelbine, 75 – 100 mg/m² BSA cisplatin in combination with 1,250 mg/m² BSA gemcitabine, 75 mg/m² BSA cisplatin in combination with 75 mg/m² BSA docetaxel, 75 mg/m² BSA cisplatin in combination with 500 mg/m² BSA pemetrexed and 80 mg/m² BSA cisplatin in combination with 175 mg/m² BSA paclitaxel.

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 69.2 kg, men 85.8 kg) and the average age of women and men in Germany in 2021 (women: 46 years, men: 43.4 years)[3] and the mean standard serum creatinine concentration (women: 0.75 mg/dl, men: 0.9 mg/dl).[4]

The mean value (AUC 5 = 700.8 mg, AUC 6 = 840.9 mg) formed from these doses for women (AUC 5 = 637 mg, AUC 6 = 764.3 mg) and men (AUC 5 = 764.5 mg, AUC 6 = 917.4 mg) was used as the basis for the sample calculation of the costs of carboplatin in the neoadjuvant treatment phase. The dosages of the concomitant active ingredients cited as examples correspond to those in combination with cisplatin.

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

[3] 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

[4] DocCheck Flexikon – Serum creatinine, URL: https://flexikon.doccheck.com/de/Serumkreatinin [last access on: 16.10.2025]

Adults with resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

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				
Tislelizumab in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment				
Neoadjuvant treatment: Tislelizumab + platinum-based chemotherapy				
Tislelizumab	1 x per 21-day cycle	3 – 4	1	3 – 4
Carboplatin	1 x per 21-day cycle	3 – 4	1	3 – 4
Cisplatin	1 x per 21-day cycle	3 – 4	1	3 – 4
Docetaxel	1 x per 21-day cycle	3 – 4	1	3 – 4
Gemcitabine	2 x per 21-day cycle	3 – 4	2	6 – 8
Paclitaxel	1 x per 21-day cycle	3 – 4	1	3 – 4
Pemetrexed[5]	1 x per 21-day cycle	3 – 4	1	3 – 4
Vinorelbine	2 x per 21-day cycle	3 – 4	2	6 – 8
Adjuvant treatment: Tislelizumab (monotherapy)				
Tislelizumab	1 x per 42-day cycle	8	1	8

[5] Only for patients with non-squamous histology

Appropriate comparator therapy				
Neoadjuvant treatment with nivolumab in combination with platinum-based therapy followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression ≥ 1%)				
Neoadjuvant treatment: Nivolumab + platinum-based chemotherapy				
Nivolumab	1 x per 21-day cycle	4	1	4
Carboplatin	1 x per 21-day cycle	4	1	4
Cisplatin	1 x per 21-day cycle	4	1	4
Docetaxel	1 x per 21-day cycle	4	1	4
Gemcitabine	2 x per 21-day cycle	4	2	8
Paclitaxel	1 x per 21-day cycle	4	1	4
Pemetrexed[5]	1 x per 21-day cycle	4	1	4
Vinorelbine	2 x per 21-day cycle	4	2	8
Adjuvant treatment: *Monitoring wait-and-see approach*				
Monitoring wait-and-see approach	Not calculable			
Neoadjuvant treatment with pembrolizumab in combination with platinum-based therapy followed by adjuvant treatment with pembrolizumab				
Neoadjuvant treatment: Pembrolizumab + platinum-based chemotherapy				
Pembrolizumab	1 x per 21-day cycle	4	1	4
	or			
	1 x per 42-day cycle	2	1	2
Carboplatin	1 x per 21-day cycle	4	1	4
Cisplatin	1 x per 21-day cycle	4	1	4
Docetaxel	1 x per 21-day cycle	4	1	4
Gemcitabine	2 x per 21-day cycle	4	2	8

Paclitaxel	1 x per 21-day cycle	4	1	4
Pemetrexed[5]	1 x per 21-day cycle	4	1	4
Vinorelbine	2 x per 21-day cycle	4	2	8
Adjuvant treatment: Pembrolizumab (monotherapy)				
Pembrolizumab	1 x per 21-day cycle	13	1	13
	or			
	1 x per 42-day cycle	7	1	7

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.

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					
Tislelizumab in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment					
Neoadjuvant treatment: Tislelizumab + platinum-based chemotherapy					
Tislelizumab	200 mg	200 mg	2 x 100 mg	3 – 4	6 x 100 mg – 8 x 100 mg
Carboplatin	AUC 5 – AUC 6 = 700.8 mg – 840.9 mg	700.8 mg – 840.9 mg	1 x 600 mg + 1 x 150 mg – 1 x 600 mg + 1 x 150 mg + 2 x 50 mg	3 – 4	3 x 600 mg + 3 x 150 mg – 4 x 600 mg + 4 x 150 mg + 8 x 50 mg

Cisplatin	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	3 – 4	3 x 50 mg + 3 x 100 mg – 4 x 50 mg + 4 x 100 mg
	80 mg/m^2 = 152.8 mg	152.8 mg	1 x 10 mg + 1 x 50 mg + 1 x 100 mg	3 – 4	3 x 10 mg + 3 x 50 mg + 3 x 100 mg – 4 x 10 mg + 4 x 50 mg + 4 x 100 mg
	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	3 – 4	6 x 100 mg – 8 x 100 mg
Docetaxel	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 160 mg	3 – 4	3 x 160 mg – 4 x 160 mg
Gemcitabine	1,250 mg/m^2 = 2,387.5 mg	2,387.5 mg	2 x 200 mg + 2 x 1,000 mg	6 – 8	12 x 200 mg + 12 x 1,000 mg – 16 x 200 mg + 16 x 1,000 mg
Paclitaxel	175 mg/m^2 = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	3 – 4	6 x 100 mg + 3 x 150 mg – 8 x 100 mg + 4 x 150 mg
Pemetrexed[5]	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	3 – 4	3 x 1,000 mg – 4 x 1,000 mg
Vinorelbine	25 mg/m^2 – 30 mg/m^2 = 47.8 mg – 57.3 mg	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	6 – 8	6 x 50 mg – 8 x 50 mg + 8 x 10 mg
Adjuvant treatment: Tislelizumab (monotherapy)					
Tislelizumab	400 mg	400 mg	4 x 100 mg	8	32 x 100 mg
Appropriate comparator therapy					
Neoadjuvant treatment with nivolumab in combination with platinum-based therapy followed by monitoring wait-and-see approach (only for patients with tumour cell PD-L1 expression ≥ 1%)					
Neoadjuvant treatment: Nivolumab + platinum-based chemotherapy					
Nivolumab	360 mg	360 mg	3 x 120 mg	4	12 x 120 mg

Carboplatin	AUC 5 – AUC 6 = 700.8 mg – 840.9 mg	700.8 mg – 840.9 mg	1 x 600 mg + 1 x 150 mg – 1 x 600 mg + 1 x 150 mg + 2 x 50 mg	4	4 x 600 mg + 4 x 150 mg – 4 x 600 mg + 4 x 150 mg + 8 x 50 mg
Cisplatin	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	4	4 x 50 mg + 4 x 100 mg
	80 mg/m^2 = 152.8 mg	152.8 mg	1 x 10 mg + 1 x 50 mg + 1 x 100 mg	4	4 x 10 mg + 4 x 50 mg + 4 x 100 mg
	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	4	8 x 100 mg
Docetaxel	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 160 mg	4	4 x 160 mg
Gemcitabine	1,250 mg/m^2 = 2,387.5 mg	2,387.5 mg	2 x 200 mg + 2 x 1,000 mg	8	16 x 200 mg + 16 x 1,000 mg
Paclitaxel	175 mg/m^2 = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	4	8 x 100 mg + 4 x 150 mg
Pemetrexed[5]	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	4	4 x 1,000 mg
Vinorelbine	25 mg/m^2 – 30 mg/m^2 = 47.8 mg – 57.3 mg	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	8	8 x 50 mg – 8 x 50 mg + 8 x 10 mg
Adjuvant treatment: *Monitoring wait-and-see approach*					
Monitoring wait-and-see approach	Not calculable				
Neoadjuvant treatment with pembrolizumab in combination with platinum-based therapy followed by adjuvant treatment with pembrolizumab					
Neoadjuvant treatment: Pembrolizumab + platinum-based chemotherapy					
Pembrolizumab	200 mg	200 mg	2 x 100 mg	4	8 x 100 mg
	or				
	400 mg	400 mg	4 x 100 mg	2	8 x 100 mg

Carboplatin	AUC 5 – AUC 6 = 700.8 mg – 840.9 mg	700.8 mg – 840.9 mg	1 x 600 mg + 1 x 150 mg – 1 x 600 mg + 1 x 150 mg + 2 x 50 mg	4	4 x 600 mg + 4 x 150 mg – 4 x 600 mg + 4 x 150 mg + 8 x 50 mg
Cisplatin	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	4	4 x 50 mg + 4 x 100 mg
	80 mg/m^2 = 152.8 mg	152.8 mg	1 x 10 mg + 1 x 50 mg + 1 x 100 mg	4	4 x 10 mg + 4 x 50 mg + 4 x 100 mg
	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	4	8 x 100 mg
Docetaxel	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 160 mg	4	4 x 160 mg
Gemcitabine	1,250 mg/m^2 = 2,387.5 mg	2,387.5 mg	2 x 200 mg + 2 x 1,000 mg	8	16 x 200 mg + 16 x 1,000 mg
Paclitaxel	175 mg/m^2 = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	4	8 x 100 mg + 4 x 150 mg
Pemetrexed[5]	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	4	4 x 1,000 mg
Vinorelbine	25 mg/m^2 – 30 mg/m^2 = 47.8 mg – 57.3 mg	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	8	8 x 50 mg – 8 x 50 mg + 8 x 10 mg
Adjuvant treatment: Pembrolizumab (monotherapy)					
Pembrolizumab	200 mg	200 mg	2 x 100 mg	13	26 x 100 mg
	or				
	400 mg	400 mg	4 x 100 mg	7	28 x 100 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					
Tislelizumab 100 mg	1 CIS	€ 1,826.19	€ 1.77	€ 101.00	€ 1,723.42
Carboplatin 50 mg	1 CIS	€ 34.62	€ 1.77	€ 1.11	€ 31.74
Carboplatin 150 mg	1 CIS	€ 83.04	€ 1.77	€ 3.40	€ 77.87
Carboplatin 600 mg	1 CIS	€ 300.84	€ 1.77	€ 13.74	€ 285.33
Cisplatin 10 mg	1 CIS	€ 17.53	€ 1.77	€ 0.30	€ 15.46
Cisplatin 50 mg	1 CIS	€ 47.71	€ 1.77	€ 1.73	€ 44.21
Cisplatin 100 mg	1 CIS	€ 76.59	€ 1.77	€ 3.10	€ 71.72
Docetaxel 160 mg	1 CIS	€ 515.78	€ 1.77	€ 23.94	€ 490.07
Gemcitabine 200 mg	1 PIF	€ 28.85	€ 1.77	€ 0.83	€ 26.25
Gemcitabine 1,000 mg	1 PIF	€ 102.35	€ 1.77	€ 10.62	€ 89.96
Paclitaxel 100 mg	1 CIS	€ 289.47	€ 1.77	€ 13.20	€ 274.50
Paclitaxel 150 mg	1 CIS	€ 428.54	€ 1.77	€ 19.80	€ 406.97
Pemetrexed 1,000 mg	1 CIS	€ 1,124.81	€ 1.77	€ 52.84	€ 1,070.20
Vinorelbine 10 mg	1 CIS	€ 38.90	€ 1.77	€ 1.31	€ 35.82
Vinorelbine 50 mg	1 CIS	€ 152.64	€ 1.77	€ 6.71	€ 144.16
Appropriate comparator therapy					
Nivolumab 120 mg	1 CIS	€ 1,539.71	€ 1.77	€ 84.64	€ 1,453.30
Pembrolizumab 100 mg	2 CIS	€ 4,962.26	€ 1.77	€ 280.10	€ 4,680.39
Carboplatin 50 mg	1 CIS	€ 34.62	€ 1.77	€ 1.11	€ 31.74
Carboplatin 150 mg	1 CIS	€ 83.04	€ 1.77	€ 3.40	€ 77.87
Carboplatin 600 mg	1 CIS	€ 300.84	€ 1.77	€ 13.74	€ 285.33
Cisplatin 10 mg	1 CIS	€ 17.53	€ 1.77	€ 0.30	€ 15.46
Cisplatin 50 mg	1 CIS	€ 47.71	€ 1.77	€ 1.73	€ 44.21
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Pemetrexed 1,000 mg	1 CIS	€ 1,124.81	€ 1.77	€ 52.84	€ 1,070.20
Vinorelbine 10 mg	1 CIS	€ 38.90	€ 1.77	€ 1.31	€ 35.82
Vinorelbine 50 mg	1 CIS	€ 152.64	€ 1.77	€ 6.71	€ 144.16
Abbreviations: CIS = concentrate for the preparation of an infusion solution, PIF = powder for the preparation of an infusion solution					

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Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Because there are no regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, no costs for additionally required SHI services had to be taken into account.

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 1 October 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.

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 resectable NSCLC at high risk of recurrence; neoadjuvant and adjuvant treatment

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 Tevimbra (tislelizumab); Tevimbra 100 mg concentrate for the preparation of an infusion solution; last revised: November 2025

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 3 September 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 17 September 2025, the pharmaceutical company submitted a dossier for the benefit assessment of tislelizumab to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 18 September 2025 in conjunction with the G-BA resolution 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 tislelizumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 17 December 2025, and the written statement procedure was initiated with publication on the G-BA website on 2 January 2026. The deadline for submitting statements was 23 January 2026.

The oral hearing took place on 9 February 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 was discussed at the Subcommittee's session on 10 March 2026, and the draft resolution was approved.

At their session on 19 March 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal products	3 September 2025	Determination of the appropriate comparator therapy
Working group Section 35a	4 February 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal products	9 February 2026	Conduct of the oral hearing
Working group Section 35a	18 February 2026 4 March 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal products	10 March 2026	Concluding discussion of the draft resolution
Plenum	19 March 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 19 March 2026

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

Prof. Hecken