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
Selpercatinib (reassessment after the deadline: non-small cell lung cancer, RET fusion+, first-line)

From 18 June 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 pharmaceutical company submitted a dossier for the early benefit assessment of the active ingredient under assessment selpercatinib (Retsevmo) on 29 June 2022. For the resolution of 15 December 2022 made by the G-BA in this procedure, a time limit until 31 December 2025 was pronounced.

Pursuant to Section 4, paragraph 3, number 5 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 5 of the Rules of Procedure (VerfO), the procedure for the benefit assessment of the medicinal product Retsevmo recommences upon expiry of the deadline.

Pursuant to Section 4, paragraph 3, number 5 AM-NutzenV in conjunction with Chapter 5, Section 8, paragraph 1, number 5 VerfO, the pharmaceutical company submitted the final dossier to the G-BA on 17 December 2025.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 April 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 decision on whether an additional benefit of selpercatinib 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 selpercatinib.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have come to the following assessment:

2.1 Additional benefit of the medicinal product in relation to the appropriate comparator therapy

2.1.1 Approved therapeutic indication of Selpercatinib (Retsevmo) in accordance with the product information

Retsevmo as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.

Therapeutic indication of the resolution (resolution of 18 June 2026):

see therapeutic indication according to marketing authorisation.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

Appropriate comparator therapy:

– pembrolizumab as monotherapy

or

– atezolizumab as monotherapy

or

– cemiplimab as monotherapy

or

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

– nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)

or

– pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only patients with ECOG-PS 0-1 are eligible)

or

– atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)

or

– atezolizumab in combination with nab-paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)

or

– cemiplimab in combination with platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)

or

– durvalumab in combination with tremelimumab and platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)

b) <u>Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy</u>

Appropriate comparator therapy:

Individualised therapy with selection of

– pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy,
– atezolizumab as monotherapy (only patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells are eligible),
– atezolizumab in combination with bevacizumab, paclitaxel and carboplatin,
– atezolizumab in combination with nab-paclitaxel and carboplatin,
– nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy,
– cemiplimab in combination with platinum-based chemotherapy,
– durvalumab in combination with tremelimumab and platinum-based chemotherapy,
– carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive and
– carboplatin in combination with nab-paclitaxel

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. It is assumed in the present therapeutic indication that no molecularly stratified therapy (directed against ALK, BRAF, KRAS G12C, EGFR, HER2, METex14, NTRK or ROS1) will be considered for patients at the time of therapy with selpercatinib. Medicinal products with a corresponding marketing authorisation were therefore not considered. In addition, medicinal products for the treatment of NSCLC with exclusively squamous histology were not considered.

In terms of authorisation status, in addition to selpercatinib, the antibodies atezolizumab, bevacizumab, cemiplimab, durvalumab, ipilimumab, nivolumab, pembrolizumab, tislelizumab and tremelimumab, as well as the cytostatic agents cisplatin, docetaxel, etoposide, gemcitabine, ifosfamide, mitomycin, nab-paclitaxel, paclitaxel, pemetrexed, vindesine and vinorelbine are generally available for the treatment of advanced NSCLC.

On 2. For the present therapeutic indication, it is assumed that there is neither an indication for definitive chemoradiotherapy nor for definitive local therapy. Therefore, a non-medicinal treatment cannot be considered 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:

- Atezolizumab (resolutions of 2 April 2020, 19 November 2021 and 11 March 2025)
- Cemiplimab (resolutions of 20 January 2022 and 19 October 2023)
- Durvalumab (resolution of 5 October 2023)
- Ipilimumab (resolution of 3 June 2021)
- Nivolumab (resolution of 3 June 2021)
- Pembrolizumab (resolutions of 3 August 2017 and 19 September 2019)
- Selpercatinib (resolution of 15 December 2022)
- Tislelizumab (two resolutions of 18 June 2025)
- Tremelimumab (resolution of 5 October 2023)

Annex VI to Section K of the Pharmaceuticals Directive - Prescribability of approved medicinal products in non-approved therapeutic indications (off-label use):

- Carboplatin-containing medicinal products for advanced non-small cell lung cancer (NSCLC) – combination therapy

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 written statement of the scientific-medical societies 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.

For the determination of the appropriate comparator therapy, it is assumed that no molecularly stratified therapy (directed against ALK, BRAF, KRAS G12C, EGFR, HER2, METex14, NTRK or ROS1) will be considered for patients at the time of therapy with selpercatinib.

As RET fusion-positive NSCLC usually has a non-squamous histology[2,3,4], therapies that are explicitly indicated for squamous histology were also not considered for the appropriate comparator therapy.

For the present therapeutic indication, it is also generally assumed that there is neither an indication for definitive chemoradiotherapy nor for definitive local therapy.

Based on the available evidence on therapy options depending on PD-L1 expression, the appropriate comparator therapy differentiated into two sub-populations with a cut-off value of PD-L1 expression of 50% of tumour cells is determined.

According to the statements made by the clinical experts in the written statement procedure, the added value of immune checkpoint inhibitors in combination with chemotherapy, as well as their efficacy as monotherapy in the treatment of patients with advanced RET fusion-positive NSCLC has not yet been demonstrated with a sufficiently high level of evidence.

However, according to the present guidelines, in the case of RET fusion-positive NSCLC, those therapy options recommended as first-line therapy for patients without treatable tumour mutations (platinum-based chemotherapy or chemoimmunotherapy) are also considered. On this basis, the G-BA consider the (chemo)immunotherapies and chemotherapies to be appropriate comparator therapies overall in accordance with the recommendations on first-line treatment for patients with non-squamous cell carcinoma without treatable genetic alterations.

a) <u>Adults with advanced RET fusion-positive NSCLC with PD-L1 expression ≥ 50% of tumour cells; first-line therapy</u>

For first-line treatment of metastatic NSCLC with PD-L1 expression ≥ 50% of tumour cells, the guidelines recommend monotherapy with the immune checkpoint inhibitors atezolizumab, cemiplimab or pembrolizumab, regardless of histological status.

Furthermore, the present guidelines consider the combination therapies of an immune checkpoint inhibitor and a platinum-containing chemotherapy as an alternative to

[2] Kato et al., 2017. RET Aberrations in Diverse Cancers: Next-Generation Sequencing of 4,871 Patients. Clinical Cancer Research, 23, 1988.
[3] Takeuchi et al., 2012. RET, ROS1, and ALK fusions in lung cancer. Nat Med;18(3):378–81.
[4] Gautschi et al., 2017. Targeting RET in Patients With RET-Rearranged Lung Cancers: Results from the Global, Multicentre RET Registry. J Clin Oncol, 35, 1403-10.

immune checkpoint inhibitor monotherapies, especially for patients with burden of remission due to burdensome symptomatology, high tumour burden or rapid tumour growth. In terms of therapy selection, a distinction is made here between patients with a reduced general condition (ECOG-PS 2) and patients with a good general condition (ECOG-PS 0–1). The present guidelines refer to the limited data basis available for the treatment of patients with ECOG-PS 2. Accordingly, the combination therapies consisting of an immune checkpoint inhibitor and chemotherapy are recommended for patients with ECOG-PS 0–1.

For patients with non-squamous NSCLC, pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy, atezolizumab in combination with bevacizumab, paclitaxel and carboplatin, or atezolizumab in combination with nab-paclitaxel and carboplatin as well as tislelizumab in combination with pemetrexed and platinum-containing chemotherapy can be used.

The active ingredient tislelizumab is a new treatment option in the present therapeutic indication. The active ingredient was only recently approved. Based on the generally recognised state of medical knowledge, tislelizumab in combination with pemetrexed and platinum-containing chemotherapy is not determined as an appropriate comparator therapy for the present resolution.

The combination therapy of nivolumab and ipilimumab and two cycles of platinum-based chemotherapy, as well as cemiplimab in combination with platinum-based chemotherapy and durvalumab in combination with tremelimumab and platinum-based chemotherapy are also available as treatment options, regardless of histology.

Tislelizumab in combination with pemetrexed and platinum-containing chemotherapy is quite a new treatment option in the present therapeutic indication. Tislelizumab in combination with pemetrexed and platinum-containing chemotherapy is not currently considered an appropriate comparator therapy.

In summary, the G-BA consider it appropriate to determine the above-mentioned immune checkpoint inhibitors - as monotherapies and as combination therapy with platinum-containing chemotherapy - as appropriate comparator therapies. The combination therapies of immune checkpoint inhibitors and chemotherapies should only be used for patients with an ECOG-PS of 0 and 1 in accordance with the guideline recommendations.

For patient group a), it should be noted that the appropriate comparator therapy determined here comprises several therapy options. In this context, individual therapy options only represent a comparator therapy for the part of the patient population that has the patient and disease characteristics specified in brackets. The therapy options are only to be considered equally appropriate in the therapeutic indication, where the patient populations have the same characteristics. Any therapy option that is not restricted by the bracketed patient and disease characteristics can be used for demonstrating the additional benefit for the total population. If the appropriate comparator therapy comprises several therapy option alternatives without any restriction, the additional benefit for the total population can be demonstrated in comparison with one of these therapeutic alternatives. In contrast, the sole comparison with a therapy option that only represents a comparator therapy for part of the patient

population is generally insufficient to demonstrate the additional benefit for the total population.

It is pointed out that the marketing authorisation and dosage specifications in the product information for the active ingredients must be taken into account and any deviations must be justified separately.

b) Adults with advanced RET fusion-positive NSCLC with PD-L1 expression < 50% of tumour cells; first-line therapy

In the first-line treatment of metastatic NSCLC with PD-L1 expression < 50% of tumour cells, the therapy recommendations in the available evidence are made, in particular, depending on ECOG-PS and tumour histology.

Accordingly, the combination therapies of the immune checkpoint inhibitors atezolizumab, nivolumab or pembrolizumab and chemotherapies, depending on the tumour histology, are recommended for patients with an ECOG-PS of 0–1.

Within this defined framework, pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy, atezolizumab in combination with bevacizumab, paclitaxel and carboplatin, as well as atezolizumab in combination with nab-paclitaxel and carboplatin can be used for patients with non-squamous NSCLC.

The combination therapy of nivolumab and ipilimumab and two cycles of platinum-based chemotherapy, cemiplimab in combination with platinum-based chemotherapy, durvalumab in combination with tremelimumab and platinum-based chemotherapy, as well as atezolizumab as monotherapy (for patients with PD-L1 expression ≥ 10% on tumour-infiltrating immune cells) are also available as treatment options, regardless of histology.

With regard to the use of immune checkpoint inhibitors, the S3 guideline on lung cancer further states that patients with an ECOG-PS of 2, which is primarily due to the tumour disease rather than comorbidities, may also benefit from a combination of chemoimmunotherapy. Furthermore, the treatment decision depends on whether patients are suitable for treatment with immune checkpoint inhibitors.

According to the present guidelines, chemotherapy alone (without an immune checkpoint inhibitor) may represent a relevant therapy option, in particular, for patients with relevant comorbidities or patients who are ineligible for treatment with immune checkpoint inhibitors, with combination chemotherapy including two cytostatic agents being considered more effective than monochemotherapy.

With regard to the platinum derivative (cisplatin vs carboplatin) used in combination with a third-generation cytostatic, the S3 guideline on lung cancer first states that, whilst cisplatin achieves significantly higher remission rates and, depending on the third-generation cytostatic used, higher survival rates than carboplatin in some cases, more recent data, however, partly put these advantages into perspective. The choice of the platinum active ingredient is primarily based on the specific toxicity expected, with cisplatin having a higher toxicity.

Taking into account the significance of toxicity, particularly for patients with a reduced general condition and comorbidities, the G-BA consider it appropriate in the overall

assessment to determine carboplatin as the sole platinum component, whereby carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed), as well as the similarly recommended combination of carboplatin and nab-paclitaxel, are determined as appropriate comparator therapies. In contrast to cisplatin, carboplatin is not approved for the treatment of NSCLC, but can be prescribed for "off-label use" in patients (see Annex VI to Section K of the Pharmaceuticals Directive).

In the overall assessment, it should be noted that the treatment decision depends largely on patient-individual criteria.

The G-BA therefore determine an individualised therapy with selection of the therapy options listed above. The treatment decision is made, in particular, taking into account the general condition, comorbidities and risk factors associated with immunotherapy.

The decision on platinum-containing chemotherapy with or without an immune checkpoint inhibitor is made in accordance with the recommendations of the S3 guideline[5], depending on the general condition, comorbidities and risk factors associated with immunotherapy:

- Patients in good general condition (ECOG 0–1): platinum-containing chemotherapy *with* an immune checkpoint inhibitor
- Patients in good general condition (ECOG 0–1) who are ineligible for treatment with immune checkpoint inhibitors: platinum-containing chemotherapy *without* an immune checkpoint inhibitor
- Patients in poor general condition (ECOG 2), where limitations on physical resilience are primarily due to the tumour disease rather than comorbidities: platinum-containing chemotherapy *with* an immune checkpoint inhibitor
- Patients with comorbidities and/or poor general condition (ECOG 2), where limitations on physical resilience are primarily due to comorbidities rather than the tumour disease: carboplatin-containing chemotherapy *without* an immune checkpoint inhibitor

It is pointed out that the marketing authorisation and dosage specifications in the product information for the active ingredients must be taken into account and any deviations must be justified separately.

In addition, with regard to the appropriate comparator therapy for patient groups a) and b), it is pointed out that the results should be presented as the main analysis, summarising the respective patient groups, in the benefit assessment dossier, if suitable data are available from direct comparator studies that can be used to demonstrate an additional benefit in two patient groups separately according to PD-L1 expression status. In this case, complete subgroup analyses with the characteristics of the summarised patient groups should be presented.

[5] Oncology guideline programme, German Cancer Society (DKG), German Cancer Aid (DKH), Association of the Scientific-Medical Societies (AWMF). Prevention, diagnosis, treatment and after-care for lung cancer; S3 guideline; long version 4.0 [online]. AWMF registry number 020-007OL. Berlin (GER): Oncology guideline programme; 2025.

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

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

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

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

   An additional benefit is not proven.

b) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

   An additional benefit is not proven.

Justification:

The results from the ongoing, open-label, randomised, controlled phase III LIBRETTO-431 study for comparing selpercatinib with a combination therapy consisting of cisplatin or carboplatin and pemetrexed with or without pembrolizumab (hereinafter "platinum-based chemotherapy ± pembrolizumab") were submitted by the pharmaceutical company for the benefit assessment. The study has been ongoing since February 2020 at 103 study sites across North America, South America, Europe, Asia and Australia.

Adults with stage IIIB, IIIC or IV RET fusion-positive NSCLC, predominantly of non-squamous histology, who were ineligible for radical surgery or radiotherapy, were enrolled in the study. Patients were not permitted to have received any systemic therapy as pretreatment for their metastatic disease. Patients were required to have an Eastern Cooperative Oncology Group Performance Status (ECOG-PS) of 0, 1 or 2.

A total of 261 patients were enrolled and randomised in a 2:1 ratio to receive either treatment with selpercatinib (N = 159; intervention arm) or platinum-based chemotherapy ± pembrolizumab (N = 102; comparator arm). In the comparator arm, 83 patients were randomised to receive combination therapy consisting of platinum-based chemotherapy and pembrolizumab, whilst 19 patients received exclusively a platinum-based chemotherapy. The treatments in both treatment arms are largely in line with the respective product information. The PD-L1 tumour expression status was only partially assessed in the study. No data are available on the tumour PD-L1 expression status of 34.5% of the patients enrolled in the study. For a further 6.5%, it is merely documented that there is PD-L1 expression in the tumour, without specifying the exact PD-L1 tumour expression status.

The primary endpoint of the LIBRETTO-431 study is progression-free survival (PFS). Secondary endpoints were assessed in the categories of mortality, morbidity, health-related quality of life and side effects.

Two data cut-offs are available for the LIBRETTO-431 study:

- 1st data cut-off from 1 May 2023: pre-specified interim analysis, planned after the occurrence of 93 PFS events in the sub-population of patients eligible for treatment with pembrolizumab, and conducted after 98 PFS events
- 2nd data cut-off from 1 May 2024: a data cut-off required retrospectively by the US Food and Drug Administration (FDA) regulatory authority.

In addition, further analyses dated 8 May 2024 which were carried out as part of the annual safety update (PSUR: periodic safety update report) are available.

The final analysis of the ongoing study is planned after the occurrence of at least 140 PFS events in the sub-population of patients eligible for pembrolizumab. In addition, a final data cut-off of overall survival is planned after approximately 175 deaths in the total population.

In the dossier, the pharmaceutical company fully presented the pre-specified 1st data cut-off from 1 May 2023. For the current 2nd data cut-off, they only presented results on overall survival. In addition, the pharmaceutical company presented analyses of adverse events carried out as part of the annual safety update.

<u>On the implementation of time limit requirements</u>

According to the justification for the resolution of 15 December 2022, the reason for the time limit lay in the fact that further relevant clinical data for the benefit assessment are expected from the LIBRETTO-431 study.

For the renewed benefit assessment after expiry of the deadline, the results of the final clinical study report on overall survival and on all other patient-relevant endpoints from the LIBRETTO-431 study should be presented in the dossier.

In the dossier, the pharmaceutical company presented the results for the pre-specified 1st data cut-off from 1 May 2023 and the 2nd data cut-off from 1 May 2024. In addition, the pharmaceutical company presented analyses dated 8 May 2024.

The final data cut-off for overall survival is planned after approximately 175 deaths in the total population and is not yet available at the time of the dossier assessment.

In view of the fact that the final analyses are still pending, it is considered appropriate to take the most recent data cut-off as the basis for this benefit assessment:

On the usability of the study results presented in the dossier:

In accordance with the regulation in Chapter 5, Section 18 of the Rules of Procedure of the G-BA, the benefit assessment examines whether there is evidence of an additional benefit of the medicinal product over the appropriate comparator therapy. The validity and completeness of the information in the dossier are also checked. The dossier template in Annex II must be used for compiling the documents. The data according to Chapter 5, Section 9, paragraph 1, numbers 4 to 8 of the Rules of Procedure of the G-BA must be processed and submitted in accordance with the requirements specified in Modules 1 to 5. If the benefit assessment shows that the preparation of the documents in the dossier deviates from the requirements specified in Section 9 to an extent that prevents a proper assessment of the additional benefit, the Federal Joint Committee may determine that the additional benefit is not proven, Chapter 5, Section 18, paragraph 1, sentence 4 of the Rules of Procedure of the G-BA.

IQWiG stated in the dossier assessment that the results of the LIBRETTO-431 study presented by the pharmaceutical company in the dossier as of the pre-specified 1st data cut-off were unsuitable for the benefit assessment.

IQWIG also state that the 2nd data cut-off for overall survival from 1 May 2024 from the LIBRETTO-431 study was required by the FDA and represents the most recent data cut-off. The interval between the 1st and 2nd data cut-offs is one year, which corresponds in this case to a 50.8% longer follow-up period for overall survival in the intervention arm and a 55.0% longer follow-up period in the comparator arm for the sub-population presented. As of the 1st data cut-off, 67 patients in the intervention arm (58.3%) and 27 patients in the comparator arm (37.0%) in the sub-population presented were still receiving the study medication. For these patients, data on patient-relevant endpoints in the categories of morbidity and health-related quality of life were accordingly collected further. IQWiG subsequently concluded that the 2nd data cut-off contains a relevantly higher information content. For the benefit assessment, the 2nd data cut-off from 1 May 2024 is therefore relevant. For this data cut-off, analyses must be carried out and submitted for all relevant endpoints collected in accordance with the module template. This also applies if a data cut-off was originally planned only for the evaluation of individual endpoints. However, the pharmaceutical company only presented

data on overall survival as of the 2nd data cut-off. In addition, the pharmaceutical company did provide data on adverse events as part of the annual safety update of 8 May 2024, meaning that up-to-date analyses of overall survival and side effects are available. However, there is a complete lack of up-to-date data on endpoints in the categories of morbidity and health-related quality of life.

Furthermore, the pharmaceutical company did not provide any analyses for these data in the dossier that are broken down by PD-L1 tumour expression status (PD-L1 ≥ 50% vs < 50%), not even in the form of subgroup analyses.

Overall, IQWiG conclude that the analyses of the current 2nd data cut-off are relevant for the benefit assessment. These were however not submitted in full by the pharmaceutical company. The dossier is therefore incomplete in terms of content. As a result, IQWiG were not able to carry out an adequate assessment of the study data.

As part of the written statement procedure, the pharmaceutical company stated that, in their view, the 1st data cut-off should be used for the benefit assessment, as it is pre-specified, complete and characterised by a low crossover rate. They also point out that both the 2nd data cut-off and the data cut-off as part of the annual safety update of 8 May 2024 are only selectively reported regulatory interim analyses, which are unsuitable for the benefit assessment. Furthermore, the pharmaceutical company state that they consider a joint analysis of the sub-populations according to PD-L1 expression status to be appropriate. As part of the written statement procedure, the pharmaceutical company subsequently submitted the missing Kaplan-Meier curves as of the 1st data cut-off, subgroup analyses for the 2nd data cut-off and the data cut-off as part of the annual safety update, as well as patient characteristics, duration of observation and subsequent therapies, broken down by PD-L1 expression status (≥ 50% vs < 50%).

After detailed consideration of IQWiG's statements on the shortcomings in the dossier, the G-BA concur with IQWiG's assessment. The information submitted subsequently by the pharmaceutical company in the written statement procedure does not lead to a different assessment, as the data on endpoints in the categories of morbidity and health-related quality of life as of the 2nd data cut-off are still missing. In summary, it is noted that the 2nd data cut-off represents the most recent and the relevant data cut-off for the benefit assessment. In this regard, the G-BA state that a significant information gain can be assumed for the 2nd data cut-off compared to the 1st data cut-off. The follow-up period for overall survival as of the 2nd data cut-off is 50.8% longer in the intervention arm and 55.0% longer in the comparator arm. Patient-reported endpoints were collected further for 58.3% of patients in the intervention arm and 37.0% in the comparator arm, meaning that, in addition to the endpoint of overall survival, the other patient-relevant endpoints of the 2nd data cut-off had to be processed and evaluated by the pharmaceutical company in the dossier. Consequently, in accordance with Chapter 5, Section 18, paragraph 1 of the Rules of Procedure of the G-BA, the G-BA, for their part, determine that the preparation of the documents in the dossier deviates from the requirements specified in Chapter 5, Section 9 of the Rules of Procedure of the G-BA to an extent that prevents a proper assessment of the additional benefit.

It is therefore concluded that the data presented are incomplete overall, which prevents a proper assessment. An additional benefit is therefore not proven.

2.1.4 Summary of the assessment

The present assessment is the renewed benefit assessment of the active ingredient selpercatinib due to the expiry of the resolution deadline of 15 December 2022.

"Retsevmo as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor."

In the therapeutic indication to be considered, two patient groups were distinguished by PD-L1 expression:

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

b) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

The G-BA determined the appropriate comparator therapy to be immune checkpoint inhibitors (if applicable, in combination with chemotherapy) for patient group a) and an individualised therapy with the selection of immune checkpoint inhibitors (if applicable, in combination with chemotherapy) and chemotherapy for patient group b).

Results from the ongoing, open-label, randomised, controlled phase III LIBRETTO-431 study comparing selpercatinib with a combination therapy consisting of cisplatin or carboplatin and pemetrexed with or without pembrolizumab were presented in the dossier. The results for the 1st data cut-off (1 May 2023) were presented in full; however, only results on overall survival were presented as of the current 2nd data cut-off (1 May 2024) required by the FDA. In addition, the pharmaceutical company presented data on adverse events as part of the annual safety update of 8 May 2024.

The follow-up period of the 2nd data cut-off was 50.8% longer in the intervention arm and 55.0% longer in the comparator arm compared to the 1st data cut-off. As of the 1st data cut-off, 58.3% of patients in the intervention arm and 37.0% of patients in the control arm were still undergoing treatment. For these patients, data on patient-relevant endpoints in the categories of morbidity and health-related quality of life were accordingly collected further. The 2nd data cut-off thus contains a relevantly higher information content. However, this data cut-off has been processed incompletely in the dossier, as only results on overall survival were presented. In addition, the pharmaceutical company did provide data on adverse events as part of the annual safety update of 8 May 2024, meaning that up-to-date analyses of overall survival and side effects are available. However, there is a complete lack of up-to-date data on endpoints in the categories of morbidity and health-related quality of life.

It is therefore concluded that the data presented are incomplete overall, which prevents a proper assessment. 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).

For the number of German patients with lung cancer, the projected incidence for 2024 (59,851 patients)[6] is used as the basis for the calculations.

The following calculation steps are used to narrow down this patient group to the target population:

1. The percentage of lung cancer patients with NSCLC is between 73.6% and 83.6% (44,050 to 50,035 patients).

2. Of these, 46.63% of patients are at stage IV[7] at the time of initial diagnosis. Of the remaining 53.37% of patients, who are at stages I–IIIB, 37.7% thereof progress to stage IV[8] in 2022. The percentage of patients in stage IIIB/IIIC ranges from 4.5% to 6.1%[9]. The total number of patients is 34,073 to 38,703.

3. The percentage of patients with RET fusion is 0.6% to 0.9% (264 to 450 patients).

4. First-line therapy is administered in 67.2% of cases (178 to 303 patients).

5. In 28.9% (51 to 87 patients), PD-L1 expression was ≥ 50% and in 71.1% (126 to 215 patients) < 50%[10].

6. Taking into account 87.3% of SHI-insured patients, there are 155 to 264 patients in first-line therapy (PD-L1 expression ≥ 50%: 45 to 76 patients; PD-L1 expression < 50%: 110 to 188 patients).

Due to uncertainties regarding the data basis in the target population in Germany, both an overestimation and an underestimation of patient numbers are possible.

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 Retsevmo (active ingredient: selpercatinib) at the following publicly accessible link (last access: 9 June 2026):

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

Treatment with selpercatinib 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.

RET testing

[6] Robert Koch Institute, Society of Epidemiological Cancer Registries in Germany. Cancer in Germany for 2019/2020, 2024
[7] Benefit assessment procedure D-923 tremelimumab
[8] Tumour Registry Munich ICD-10 C34: Non-small cell BC Survival [online]. 2022. URL: https://www.tumorregister-muenchen.de/facts/surv/sC34N_G-ICD-10-C34-Nicht-kleinzell.-BC-Survival.pdf
[9] Benefit assessment procedure D-935 cemiplimab
[10] Benefit assessment procedure D-705 cemiplimab

The presence of an RET gene fusion should be confirmed by a validated test prior to treatment with Retsevmo.

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 April 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

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

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/patient/year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

For carboplatin, a cycle duration of 3 weeks is used. For the use of carboplatin in the off-label indication "combination therapy for advanced NSCLC", Annex VI of the Pharmaceuticals Directive specifies the following dosage: up to 500 mg/m² BSA (body surface area) or AUC 6.0 (area under the curve). The use of carboplatin in combination with nab-paclitaxel is also based on a dosage of 500 mg/m^2 BSA.

For nivolumab, the recommended dose is 360 mg every 3 weeks in combination with 1 mg/kg BW (body weight) ipilimumab every 6 weeks and platinum-based chemotherapy every 3 weeks, whereby treatment with 360 mg nivolumab intravenously every 3 weeks in combination with 1 mg/kg BW ipilimumab intravenously every 6 weeks continues after 2 cycles of chemotherapy.

According to the product information for cisplatin, the typical dosage in the case of combination therapy for the treatment of non-small cell lung cancer is 80 mg/m^2 BSA, which is used for the combination with vinorelbine.

According to the product information of the concomitant active ingredient, the single dose of cisplatin in combination with gemcitabine is 75 – 100 mg/m² BSA, in combination with docetaxel or pemetrexed 75 mg/m² BSA and in combination with paclitaxel 80 mg/m² BSA.

The two pembrolizumab doses of 200 mg every 3 weeks or 400 mg every 6 weeks recommended according to the product information are listed in the cost representation.

During the subcutaneous administration of atezolizumab in combination with bevacizumab, paclitaxel and carboplatin, atezolizumab is initially administered in an induction phase lasting 4 or 6 cycles in combination with bevacizumab, paclitaxel and carboplatin every 3 weeks, followed by a maintenance phase in combination with bevacizumab every 3 weeks.

During subcutaneous administration of atezolizumab in combination with nab-paclitaxel and carboplatin, atezolizumab is administered in an induction phase lasting 4 or 6 cycles in combination with carboplatin and nab-paclitaxel every 3 weeks, followed by the maintenance phase with atezolizumab monotherapy every 3 weeks.

Durvalumab is administered in combination with tremelimumab and platinum-based chemotherapy every 3 weeks for 4 cycles, followed by durvalumab monotherapy and histology-based maintenance treatment with pemetrexed every 4 weeks including a fifth dose of tremelimumab in week 16.

Treatment period:

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Selpercatinib	Continuously, 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
Pembrolizumab as monotherapy				
Pembrolizumab	1 x per 21-day cycle	17.4	1	17.4
	or			
	1 x per 42-day cycle	8.7	1	8.7
Atezolizumab as monotherapy				
Atezolizumab	1 x per 21-day cycle	17.4	1	17.4
Cemiplimab as monotherapy				
Cemiplimab	1 x per 21-day cycle	17.4	1	17.4
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)				
Nivolumab	1 x per 21-day cycle	17.4	1	17.4
Ipilimumab	1 x per 42-day cycle	8.7	1	8.7
Carboplatin	1 x per 21-day cycle	2	1	2
Cisplatin	1 x per 21-day cycle	2	1	2
Docetaxel	1 x per 21-day cycle	2	1	2
Gemcitabine	2 x per 21-day cycle	2	2	4

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Nab-paclitaxel	3 x per 21-day cycle	2	3	6
Paclitaxel	1 x per 21-day cycle	2	1	2
Pemetrexed	1 x per 21-day cycle	2	1	2
Vinorelbine	2 x per 21-day cycle	2	2	4
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only patients with ECOG-PS 0-1 are eligible)				
Pembrolizumab	1 x per 21-day cycle	17.4	1	17.4
	or			
	1 x per 42-day cycle	8.7	1	8.7
Pemetrexed	1 x per 21-day cycle	17.4	1	17.4
Carboplatin	1 x per 21-day cycle	17.4	1	17.4
Cisplatin	1 x per 21-day cycle	17.4	1	17.4
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)				
Induction therapy				
Atezolizumab	1 x per 21-day cycle	4 – 6	1	4 – 6
Bevacizumab	1 x per 21-day cycle	4 – 6	1	4 – 6
Paclitaxel	1 x per 21-day cycle	4 – 6	1	4 – 6
Carboplatin	1 x per 21-day cycle	4 – 6	1	4 – 6
Maintenance treatment				
Atezolizumab	1 x per 21-day cycle	11.4 – 13.4	1	11.4 – 13.4
Bevacizumab	1 x per 21-day cycle	11.4 – 13.4	1	11.4 – 13.4
Atezolizumab in combination with nab-paclitaxel and carboplatin (only patients with ECOG-PS 0-1 are eligible)				
Induction therapy				

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Atezolizumab	1 x per 21-day cycle	4 – 6	1	4 – 6
Carboplatin	1 x per 21-day cycle	4 – 6	1	4 – 6
Nab-paclitaxel	3 x per 21-day cycle	4 – 6	3	12 – 18
Maintenance treatment				
Atezolizumab	1 x per 21-day cycle	11.4 – 13.4	1	11.4 – 13.4
Cemiplimab in combination with platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)				
Cemiplimab	1 x per 21-day cycle	17.4	1	17.4
Carboplatin	1 x per 21-day cycle	17.4	1	17.4
Cisplatin	1 x per 21-day cycle	17.4	1	17.4
Docetaxel	1 x per 21-day cycle	17.4	1	17.4
Gemcitabine	2 x per 21-day cycle	17.4	2	34.8
Nab-paclitaxel	3 x per 21-day cycle	17.4	3	52.2
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Pemetrexed	1 x per 21-day cycle	17.4	1	17.4
Vinorelbine	2 x per 21-day cycle	17.4	2	34.8
durvalumab in combination with tremelimumab and platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)				
Durvalumab	1 x per 21-day cycle	4	1	4
Tremelimumab	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

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Gemcitabine	2 x per 21-day cycle	4	2	8
Nab-paclitaxel	3 x per 21-day cycle	4	3	12
Paclitaxel	1 x per 21-day cycle	4	1	4
Pemetrexed	1 x per 21-day cycle	4	1	4
Vinorelbine	2 x per 21-day cycle	4	2	8
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed				
Durvalumab	1 x per 28-day cycle	10	1	10.0
Tremelimumab	1 x in week 16	1	1	1
Pemetrexed	1 x per 28-day cycle	10	1	10.0

b) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Selpercatinib	Continuously, 2 x daily	365.0	1	365.0
Appropriate comparator therapy				
Individualised therapy with selection of				
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy				
Pembrolizumab	1 x per 21-day cycle	17.4	1	17.4
	or			
	1 x per 42-day cycle	8.7	1	8.7
Pemetrexed	1 x per 21-day cycle	17.4	1	17.4

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Carboplatin	1 x per 21-day cycle	17.4	1	17.4
Cisplatin	1 x per 21-day cycle	17.4	1	17.4
Atezolizumab as monotherapy (only patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells are eligible)				
Atezolizumab	1 x per 21-day cycle	17.4	1	17.4
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin				
Induction therapy				
Atezolizumab	1 x per 21-day cycle	4 – 6	1	4 – 6
Bevacizumab	1 x per 21-day cycle	4 – 6	1	4 – 6
Paclitaxel	1 x per 21-day cycle	4 – 6	1	4 – 6
Carboplatin	1 x per 21-day cycle	4 – 6	1	4 – 6
Maintenance treatment				
Atezolizumab	1 x per 21-day cycle	11.4 – 13.4	1	11.4 – 13.4
Bevacizumab	1 x per 21-day cycle	11.4 – 13.4	1	11.4 – 13.4
Atezolizumab in combination with nab-paclitaxel and carboplatin				
Induction therapy				
Atezolizumab	1 x per 21-day cycle	4 – 6	1	4 – 6
Carboplatin	1 x per 21-day cycle	4 – 6	1	4 – 6
Nab-paclitaxel	3 x per 21-day cycle	4 – 6	3	12 – 18
Maintenance treatment				
Atezolizumab	1 x per 21-day cycle	11.4 – 13.4	1	11.4 – 13.4
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy				
Nivolumab	1 x per 21-day cycle	17.4	1	17.4
Ipilimumab	1 x per 42-day cycle	8.7	1	8.7

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Carboplatin	1 x per 21-day cycle	2	1	2
Cisplatin	1 x per 21-day cycle	2	1	2
Docetaxel	1 x per 21-day cycle	2	1	2
Gemcitabine	2 x per 21-day cycle	2	2	4
Nab-paclitaxel	3 x per 21-day cycle	2	3	6
Paclitaxel	1 x per 21-day cycle	2	1	2
Pemetrexed	1 x per 21-day cycle	2	1	2
Vinorelbine	2 x per 21-day cycle	2	2	4
Cemiplimab in combination with platinum-based chemotherapy				
Cemiplimab	1 x per 21-day cycle	17.4	1	17.4
Carboplatin	1 x per 21-day cycle	17.4	1	17.4
Cisplatin	1 x per 21-day cycle	17.4	1	17.4
Docetaxel	1 x per 21-day cycle	17.4	1	17.4
Gemcitabine	2 x per 21-day cycle	17.4	2	34.8
Nab-paclitaxel	3 x per 21-day cycle	17.4	3	52.2
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Pemetrexed	1 x per 21-day cycle	17.4	1	17.4
Vinorelbine	2 x per 21-day cycle	17.4	2	34.8
Durvalumab in combination with tremelimumab and platinum-based chemotherapy				
Durvalumab	1 x per 21-day cycle	4	1	4
Tremelimumab	1 x per 21-day cycle	4	1	4

Name of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
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
Nab-paclitaxel	3 x per 21-day cycle	4	3	12
Paclitaxel	1 x per 21-day cycle	4	1	4
Pemetrexed	1 x per 21-day cycle	4	1	4
Vinorelbine	2 x per 21-day cycle	4	2	8
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed				
Durvalumab	1 x per 28-day cycle	10.0	1	10.0
Tremelimumab	1 x in week 16	1	1	1
Pemetrexed	1 x per 28-day cycle	10.0	1	10.0
Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive				
Carboplatin	1 x per 21-day cycle	17.4	1	17.4
Docetaxel	1 x per 21-day cycle	17.4	1	17.4
Gemcitabine	2 x per 21-day cycle	17.4	2	34.8
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Pemetrexed	1 x per 21-day cycle	17.4	1	17.4
Vinorelbine	2 x per 21-day cycle	17.4	2	34.8
Carboplatin in combination with nab-paclitaxel				
Carboplatin	1 x per 21-day cycle	17.4	1	17.4
Nab-paclitaxel	3 x per 21-day cycle	17.4	3	52.2

Consumption:

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "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)[11].

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

a) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

Name 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					
Selpercatinib	160 mg	320 mg	4 x 80 mg	365.0	1,460 x 80 mg
Appropriate comparator therapy					
Pembrolizumab as monotherapy					
Pembrolizumab	200 mg	200 mg	2 x 100 mg	17.4	34.8 x 100 mg
	or				
	400 mg	400 mg	4 x 100 mg	8.7	34.8 x 100 mg
Atezolizumab as monotherapy					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	17.4	17.4 x 1,875 mg
Cemiplimab as monotherapy					
Cemiplimab	350 mg	350 mg	1 x 350 mg	17.4	17.4 x 350 mg
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)					
Nivolumab	360 mg	360 mg	3 x 120 mg	17.4	52.2 x 120 mg
Ipilimumab	1 mg/kg = 77.7 mg	77.7 mg	2 x 50 mg	8.7	17.4 x 50 mg
Carboplatin	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	2	2 x 1,000 mg
Cisplatin	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	2	2 x 50 mg + 2 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	2	2 x 10 mg + 2 x 50 mg + 2 x 100 mg
	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	2	4 x 100 mg
Docetaxel	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 160 mg	2	2 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	4	8 x 200 mg + 8 x 1,000 mg
Nab-paclitaxel	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	6	12 x 100 mg

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	2	4 x 100 mg + 2 x 150 mg
Pemetrexed	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	2	2 x 1,000 mg
Vinorelbine	25 mg/m² – 30 mg/m² = 47.8 mg – 57.3 mg	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	4	4 x 50 mg – 4 x 50 mg + 4 x 10 mg
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients with ECOG-PS 0-1)					
Pembrolizumab	200 mg	200 mg	2 x 100 mg	17.4	34.8 x 100 mg
	or				
	400 mg	400 mg	4 x 100 mg	8.7	34.8 x 100 mg
Pemetrexed	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Carboplatin	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Cisplatin	75 mg/m² = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	17.4	17.4 x 50 mg + 17.4 x 100 mg
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)					
Induction therapy					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	4 – 6	4 x 1,875 mg – 6 x 1,875 mg
Bevacizumab	7.5 mg/kg = 582.8 mg	582.8 mg	1 x 400 mg + 2 x 100 mg	4 – 6	4 x 400 mg + 8 x 100 mg – 6 x 400 mg + 12 x 100 mg
	or				
	15 mg/kg = 1,165.5 mg	1,165.5 mg	3 x 400 mg	4 – 6	12 x 400 mg – 18 x 400 mg
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	1 x 150 mg + 2 x 100 mg	4 – 6	4 x 150 mg + 8 x 100 mg – 6 x 150 mg + 12 x 100 mg
Carboplatin	500 mg/m²	955 mg	1 x 1,000 mg	4 – 6	4 x 1,000 mg

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	= 955 mg				– 6 x 1,000 mg
Maintenance treatment					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	11.4 – 13.4	11.4 x 1,875 mg – 13.4 x 1,875 mg
Bevacizumab	7.5 mg/kg = 582.8 mg	582.8 mg	1 x 400 mg + 2 x 100 mg	11.4 – 13.4	11.4 x 400 mg + 22.8 x 100 mg – 13.4 x 400 mg + 26.8 x 100 mg
	or				
	15 mg/kg = 1,165.5 mg	1,165.5 mg	3 x 400 mg	11.4 – 13.4	34.2 x 400 mg – 40.2 x 400 mg
Atezolizumab in combination with nab-paclitaxel and carboplatin (only for patients with ECOG-PS 0-1)					
Induction therapy					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	4 – 6	4 x 1,875 mg – 6 x 1,875 mg
Carboplatin	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	4 – 6	4 x 1,000 mg – 6 x 1,000 mg
Nab-paclitaxel	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	12 – 18	24 x 100 mg – 36 x 100 mg
Maintenance treatment					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	11.4 – 13.4	11.4 x 1,875 mg – 13.4 x 1,875 mg
Cemiplimab in combination with platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)					
Cemiplimab	350 mg	350 mg	1 x 350 mg	17.4	17.4 x 350 mg
Carboplatin	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Cisplatin	75 mg/m² = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	17.4	17.4 x 50 mg + 17.4 x 100 mg
	80 mg/m² = 152.8 mg	152.8 mg	1 x 10 mg + 1 x 50 mg + 1 x 100 mg	17.4	17.4 x 10 mg + 17.4 x 50 mg + 17.4 x 100 mg
	100 mg/m² = 191 mg	191 mg	2 x 100 mg	17.4	34.8 x 100 mg
Docetaxel	75 mg/m² = 143.3 mg	143.3 mg	1 x 160 mg	17.4	17.4 x 160 mg
Gemcitabine	1,250 mg/m² = 2,387.5 mg	2,387.5 mg	2 x 200 mg + 2 x 1,000 mg	34.8	69.6 x 200 mg + 69.6 x 1,000 mg
Nab-paclitaxel	100 mg/m² = 191 mg	191 mg	2 x 100 mg	52.2	104.4 x 100 mg
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	17.4	34.8 x 100 mg + 17.4 x 150 mg
Pemetrexed	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Vinorelbine	25 mg/m² – 30 mg/m² = 47.8 mg – 57.3 mg	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	34.8	34.8 x 50 mg – 34.8 x 50 mg + 34.8 x 10 mg
Durvalumab in combination with tremelimumab and platinum-based chemotherapy (only patients with ECOG-PS 0-1 are eligible)					
Durvalumab	1,500 mg	1,500 mg	3 x 500 mg	4	12 x 500 mg
Tremelimumab	75 mg	75 mg	3 x 25 mg	4	12 x 25 mg
Carboplatin	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	4	4 x 1,000 mg
Cisplatin	75 mg/m² = 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/m² = 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/m² = 191 mg	191 mg	2 x 100 mg	4	8 x 100 mg
Docetaxel	75 mg/m² = 143.3 mg	143.3 mg	1 x 160 mg	4	4 x 160 mg
Gemcitabine	1,250 mg/m² =	2,387.5 mg	2 x 200 mg + 2 x 1,000 mg	8	16 x 200 mg + 16 x 1,000 mg

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	2,387.5 mg				
Nab-paclitaxel	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	12	24 x 100 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	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
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed					
Durvalumab	1,500 mg	1,500 mg	3 x 500 mg	10.0	30 x 500 mg
Tremelimumab	75 mg	75 mg	3 x 25 mg	1	3 x 25 mg
Pemetrexed	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	10.0	10 x 1,000 mg

b) Adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) with PD-L1 expression < 50% of tumour cells; first-line therapy

Name 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					
Selpercatinib	160 mg	320 mg	4 x 80 mg	365.0	1,460 x 80 mg
Appropriate comparator therapy					
Individualised therapy with selection of					
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy					
Pembrolizumab	200 mg	200 mg	2 x 100 mg	17.4	34.8 x 100 mg
	or				
	400 mg	400 mg	4 x 100 mg	8.7	34.8 x 100 mg
Pemetrexed	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Carboplatin	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Cisplatin	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	17.4	17.4 x 50 mg + 17.4 x 100 mg
Atezolizumab as monotherapy (only patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells are eligible)					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	17.4	17.4 x 1,875 mg
Atezolizumab in combination with bevacizumab, paclitaxel and carboplatin					
Induction therapy					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	4 – 6	4 x 1,875 mg – 6 x 1,875 mg
Bevacizumab	7.5 mg/kg = 582.8 mg	582.8 mg	1 x 400 mg + 2 x 100 mg	4 – 6	4 x 400 mg + 8 x 100 mg – 6 x 400 mg + 12 x 100 mg
	or				
	15 mg/kg = 1,165.5 mg	1,165.5 mg	3 x 400 mg	4 – 6	12 x 400 mg – 18 x 400 mg
Paclitaxel	175 mg/m^2 = 334.3 mg	334.3 mg	1 x 150 mg + 2 x 100 mg	4 – 6	4 x 150 mg + 8 x 100 mg

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
					– 6 x 150 mg + 12 x 100 mg
Carboplatin	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	4 – 6	4 x 1,000 mg – 6 x 1,000 mg
Maintenance treatment					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	11.4 – 13.4	11.4 x 1,875 mg – 13.4 x 1,875 mg
Bevacizumab	7.5 mg/kg = 582.8 mg	582.8 mg	1 x 400 mg + 2 x 100 mg	11.4 – 13.4	11.4 x 400 mg + 22.8 x 100 mg – 13.4 x 400 mg + 26.8 x 100 mg
	or				
	15 mg/kg = 1,165.5 mg	1,165.5 mg	3 x 400 mg	11.4 – 13.4	34.2 x 400 mg – 40.2 x 400 mg
Atezolizumab in combination with nab-paclitaxel and carboplatin					
Induction therapy					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	4 – 6	4 x 1,875 mg – 6 x 1,875 mg
Carboplatin	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	4 – 6	4 x 1,000 mg – 6 x 1,000 mg
Nab-paclitaxel	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	12 – 18	24 x 100 mg – 36 x 100 mg
Maintenance treatment					
Atezolizumab	1,875 mg	1,875 mg	1 x 1,875 mg	11.4 – 13.4	11.4 x 1,875 mg – 13.4 x 1,875 mg
Nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy					
Nivolumab	360 mg	360 mg	3 x 120 mg	17.4	52.2 x 120 mg

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Ipilimumab	1 mg/kg = 77.7 mg	77.7 mg	2 x 50 mg	8.7	17.4 x 50 mg
Carboplatin	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	2	2 x 1,000 mg
Cisplatin	75 mg/m² = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	2	2 x 50 mg + 2 x 100 mg
	80 mg/m² = 152.8 mg	152.8 mg	1 x 10 mg + 1 x 50 mg + 1 x 100 mg	2	2 x 10 mg + 2 x 50 mg + 2 x 100 mg
	100 mg/m² = 191 mg	191 mg	2 x 100 mg	2	4 x 100 mg
Docetaxel	75 mg/m² = 143.3 mg	143.3 mg	1 x 160 mg	2	2 x 160 mg
Gemcitabine	1,250 mg/m² = 2,387.5 mg	2,387.5 mg	2 x 200 mg + 2 x 1,000 mg	4	8 x 200 mg + 8 x 1,000 mg
Nab-paclitaxel	100 mg/m² = 191 mg	191 mg	2 x 100 mg	6	12 x 100 mg
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	2	4 x 100 mg + 2 x 150 mg
Pemetrexed	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	2	2 x 1,000 mg
Vinorelbine	25 mg/m² – 30 mg/m² = 47.8 mg – 57.3 mg	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	4	4 x 50 mg – 4 x 50 mg + 4 x 10 mg
Cemiplimab in combination with platinum-based chemotherapy					
Cemiplimab	350 mg	350 mg	1 x 350 mg	17.4	17.4 x 350 mg
Carboplatin	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Cisplatin	75 mg/m² = 143.3 mg	143.3 mg	1 x 50 mg + 1 x 100 mg	17.4	17.4 x 50 mg + 17.4 x 100 mg
	80 mg/m² = 152.8 mg	152.8 mg	1 x 10 mg + 1 x 50 mg + 1 x 100 mg	17.4	17.4 x 10 mg + 17.4 x 50 mg + 17.4 x 100 mg
	100 mg/m² = 191 mg	191 mg	2 x 100 mg	17.4	34.8 x 100 mg
Docetaxel	75 mg/m² = 143.3 mg	143.3 mg	1 x 160 mg	17.4	17.4 x 160 mg

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Gemcitabine	1,250 mg/m² = 2,387.5 mg	2,387.5 mg	2 x 200 mg + 2 x 1,000 mg	34.8	69.6 x 200 mg + 69.6 x 1,000 mg
Nab-paclitaxel	100 mg/m² = 191 mg	191 mg	2 x 100 mg	52.2	104.4 x 100 mg
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	17.4	34.8 x 100 mg + 17.4 x 150 mg
Pemetrexed	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Vinorelbine	25 mg/m² – 30 mg/m² = 47.8 mg – 57.3 mg	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg + 1 x 10 mg	34.8	34.8 x 50 mg – 34.8 x 50 mg + 34.8 x 10 mg
Durvalumab in combination with tremelimumab and platinum-based chemotherapy					
Durvalumab	1,500 mg	1,500 mg	3 x 500 mg	4	12 x 500 mg
Tremelimumab	75 mg	75 mg	3 x 25 mg	4	12 x 25 mg
Carboplatin	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	4	4 x 1,000 mg
Cisplatin	75 mg/m² = 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/m² = 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/m² = 191 mg	191 mg	2 x 100 mg	4	8 x 100 mg
Docetaxel	75 mg/m² = 143.3 mg	143.3 mg	1 x 160 mg	4	4 x 160 mg
Gemcitabine	1,250 mg/m² = 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
Nab-paclitaxel	100 mg/m² = 191 mg	191 mg	2 x 100 mg	12	24 x 100 mg
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	4	8 x 100 mg + 4 x 150 mg
Pemetrexed	500 mg/m² = 955 mg	955 mg	1 x 1,000 mg	4	4 x 1,000 mg
Vinorelbine	25 mg/m² – 30 mg/m²	47.8 mg – 57.3 mg	1 x 50 mg – 1 x 50 mg +	8	8 x 50 mg – 8 x 50 mg +

Name of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	= 47.8 mg – 57.3 mg		1 x 10 mg		8 x 10 mg
Antibody maintenance treatment and histology-based maintenance treatment with pemetrexed					
Durvalumab	1,500 mg	1,500 mg	3 x 500 mg	10.0	30 x 500 mg
Tremelimumab	75 mg	75 mg	3 x 25 mg	1	3 x 25 mg
Pemetrexed	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	10.0	10 x 1,000 mg
Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive					
Carboplatin	500 mg/m^2 = 955 mg	955 mg	2 x 450 mg + 2 x 50 mg	17.4	34.8 x 450 mg + 34.8 x 50 mg
Docetaxel	75 mg/m^2 = 143.3 mg	143.3 mg	1 x 160 mg	17.4	17.4 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	34.8	69.6 x 200 mg + 69.6 x 1,000 mg
Paclitaxel	175 mg/m^2 = 334.3 mg	334.3 mg	2 x 100 mg + 1 x 150 mg	17.4	34.8 x 100 mg + 17.4 x 150 mg
Pemetrexed	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 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	34.8	34.8 x 50 mg – 34.8 x 50 mg + 34.8 x 10 mg
Carboplatin in combination with nab-paclitaxel					
Carboplatin	500 mg/m^2 = 955 mg	955 mg	1 x 1,000 mg	17.4	17.4 x 1,000 mg
Nab-paclitaxel	100 mg/m^2 = 191 mg	191 mg	2 x 100 mg	52.2	104.4 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:

Name 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					
Selpercatinib 80 mg	112 HC	€ 3,799.36	€ 1.77	€ 213.69	€ 3,583.90
Appropriate comparator therapy					
Atezolizumab 1,875 mg	1 SFI	€ 4,164.65	€ 1.77	€ 234.55	€ 3,928.33
Bevacizumab 400 mg	1 CIS	€ 671.80	€ 1.77	€ 36.57	€ 633.46
Bevacizumab 100 mg	1 CIS	€ 176.43	€ 1.77	€ 9.14	€ 165.52
Carboplatin 1,000 mg	1 CIS	€ 494.47	€ 1.77	€ 22.93	€ 469.77
Carboplatin 450 mg	1 CIS	€ 228.27	€ 1.77	€ 10.30	€ 216.20
Carboplatin 50 mg	1 CIS	€ 34.70	€ 1.77	€ 1.11	€ 31.82
Cemiplimab 350 mg	1 CIS	€ 4,321.44	€ 1.77	€ 243.51	€ 4,076.16
Cisplatin 100 mg	1 CIS	€ 76.59	€ 1.77	€ 3.10	€ 71.72
Cisplatin 50 mg	1 CIS	€ 47.71	€ 1.77	€ 1.73	€ 44.21
Cisplatin 10 mg	1 CIS	€ 19.67	€ 1.77	€ 1.06	€ 16.84
Docetaxel 160 mg	1 CIS	€ 515.78	€ 1.77	€ 23.94	€ 490.07
Durvalumab 500 mg	1 CIS	€ 2,083.83	€ 1.77	€ 115.72	€ 1,966.34
Gemcitabine 1,000 mg	1 PIF	€ 102.35	€ 1.77	€ 10.62	€ 89.96
Gemcitabine 200 mg	1 PIF	€ 28.85	€ 1.77	€ 0.83	€ 26.25
Ipilimumab 50 mg	1 CIS	€ 3,489.23	€ 1.77	€ 195.98	€ 3,291.48
Nivolumab 120 mg	1 CIS	€ 1,539.71	€ 1.77	€ 84.64	€ 1,453.30
Nab-paclitaxel 100 mg	1 PIS	€ 429.36	€ 1.77	€ 19.84	€ 407.75
Paclitaxel 150 mg	1 CIS	€ 428.54	€ 1.77	€ 19.80	€ 406.97
Paclitaxel 100 mg	1 CIS	€ 289.47	€ 1.77	€ 13.20	€ 274.50
Pembrolizumab 100 mg	2 CIS	€ 4,876.44	€ 1.77	€ 275.20	€ 4,599.47
Pemetrexed 1,000 mg	1 CIS	€ 1,124.81	€ 1.77	€ 52.84	€ 1,070.20
Tremelimumab 25 mg	1 CIS	€ 1,779.95	€ 1.77	€ 98.36	€ 1,679.82
Vinorelbine 50 mg	1 CIS	€ 152.64	€ 1.77	€ 6.71	€ 144.16
Vinorelbine 10 mg	1 CIS	€ 38.90	€ 1.77	€ 1.31	€ 35.82
Abbreviations: HC = hard capsules; CIS = concentrate for the preparation of an infusion solution; SFI = solution for injection; PIF = powder for the preparation of an infusion solution; PIS = powder for the preparation of an infusion suspension					

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.

Non-prescription medicinal products that are reimbursable at the expense of the statutory health insurance according to Annex I of the Pharmaceuticals Directive (so-called OTC exception list) are not subject to the current medicinal products price regulation. Instead, in accordance with Section 129 paragraph 5aSGB V, when a non-prescription medicinal product is dispensed and invoiced in accordance with Section 300, a medicinal product dispensing price in the amount of the dispensing price of the pharmaceutical company plus the surcharges in accordance with Sections 2 and 3 of the Pharmaceutical Price Ordinance in the version valid on 31 December 2003 applies to the insured.

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

Name of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Appropriate comparator therapy							
Pemetrexed							
2 cycles Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy							
Dexamethasone 2 x 4 mg[12]	20 x 4 mg TAB	€ 24.61	€ 1.77	€ 1.05	€ 21.79	6	€ 21.79
Folic acid[13] 350 – 1,000 µg/day	50 x 400 µg TAB	€ 10.40	€ 0.52	€ 1.24	€ 8.64	49	€ 8.64 – € 14.74
	100 x 400 µg TAB	€ 17.60	€ 0.88	€ 1.98	€ 14.74		

[12] Fixed reimbursement rate

[13] The cost calculation for folic acid is based on the single dose of 400 µg of the non-divisible tablets available for cost calculation related to a dose range of 400 - 800 µg per day, even if a dose range of 350 - 1,000 µg is given in the product information.

Name of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Vitamin B12[12] 1,000 µg/day, every 3 cycles	5 x 1,000 µg SFI	€ 4.95	€ 0.25	€ 0.22	€ 4.48	1	€ 4.48
4 cycles, each of 21 days Durvalumab in combination with tremelimumab and platinum-based chemotherapy							
Dexamethasone 2 x 4 mg[12]	100 x 4 mg TAB	€ 79.54	€ 1.77	€ 5.40	€ 72.37	12	€ 17.37
Folic acid[13] 350 – 1,000 µg/day	100 x 400 µg TAB	€ 17.60	€ 0.88	€ 1.98	€ 14.74	84	€ 12.38 – € 24.76
Vitamin B12[12] 1,000 µg/day, every 3 cycles	10 × 1,000 µg AMP	€ 8.19	€ 0.41	€ 0.37	€ 7.41	2	€ 1.48
10 cycles, each of 28 days (antibody maintenance treatment and histology-based maintenance treatment with pemetrexed)							
Dexamethasone 2 x 4 mg[12]	100 x 4 mg TAB	€ 79.54	€ 1.77	€ 5.40	€ 72.37	30.0	€ 43.42
Folic acid[13] 350 – 1,000 µg/day	100 x 400 µg TAB	€ 17.60	€ 0.88	€ 1.98	€ 14.74	281.0	€ 41.42 – € 82.84
Vitamin B12[12] 1,000 µg/day, every 3 cycles	10 × 1,000 µg AMP	€ 8.19	€ 0.41	€ 0.37	€ 7.41	3.0	€ 2.22
17.4 cycles Pembrolizumab + pemetrexed + platinum-containing chemotherapy and Cemiplimab in combination with platinum-based chemotherapy and Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive							
Dexamethasone[12] 2 x 4 mg	100 x 4 mg TAB	€ 79.54	€ 1.77	€ 5.40	€ 72.37	52.2	€ 75.55
Folic acid[13] 350 – 1,000 µg/day	100 x 400 µg TAB	€ 17.60	€ 0.88	€ 1.98	€ 14.74	365	€ 53.80 – € 107.60
Vitamin B12[12] 1,000 µg/day, every 3 cycles	10 × 1,000 µg AMP	€ 8.19	€ 0.41	€ 0.37	€ 7.41	6.8	€ 5.04
Paclitaxel							
2 cycles Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy							
Dexamethasone[12] 2 x 20 mg PO	10 x 20 mg TAB	€ 32.42	€ 1.77	€ 0.00	€ 30.65	2	€ 30.65

Name of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Dimetindene IV 1 mg/10 kg BW = 7.8 mg	5 x 4 mg SFI	€ 26.24	€ 1.77	€ 6.92	€ 17.55	2	€ 17.55
Cimetidine 300 mg IV	10 x 200 mg AMP	€ 22.56	€ 1.77	€ 1.42	€ 19.37	2	€ 19.37
4 cycles Durvalumab in combination with tremelimumab and platinum-based chemotherapy							
Dexamethasone[12] 2 x 20 mg PO	10 x 20 mg TAB	€ 32.42	€ 1.77	€ 0.00	€ 30.65	4	€ 30.65
Dimetindene IV 1 mg/10 kg BW = 7.8 mg	5 x 4 mg SFI	€ 26.24	€ 1.77	€ 6.92	€ 17.55	4	€ 35.10
Cimetidine 300 mg IV	10 x 200 mg AMP	€ 22.56	€ 1.77	€ 1.42	€ 19.37	4	€ 19.37
4 – 6 cycles Atezolizumab + bevacizumab + paclitaxel + carboplatin							
Dexamethasone[12] 2 x 20 mg PO	10 x 20 mg TAB	€ 32.42	€ 1.77	€ 0.00	€ 30.65	4 – 6	€ 30.65 – € 52.32
	20 x 20 mg TAB	€ 54.09	€ 1.77	€ 0.00	€ 52.32		
Dimetindene IV 1 mg/10 kg BW = 7.8 mg	5 x 4 mg SFI	€ 26.24	€ 1.77	€ 6.92	€ 17.55	4 – 6	€ 30.65 – € 52.65
Cimetidine 300 mg IV	10 x 200 mg AMP	€ 22.56	€ 1.77	€ 1.42	€ 19.37	4 – 6	€ 19.37 – € 38.74
17.4 cycles, each of 21 days Carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive and Cemiplimab in combination with platinum-based chemotherapy							
Dexamethasone[12] 2 x 20 mg PO	50 x 20 mg TAB	€ 118.88	€ 1.77	€ 0.00	€ 117.11	17.4	€ 81.51
Dimetindene IV 1 mg/10 kg BW = 7.8 mg	5 x 4 mg SFI	€ 26.24	€ 1.77	€ 6.92	€ 17.55	17.4	€ 122.15
Cimetidine 300 mg IV	10 x 200 mg AMP	€ 22.56	€ 1.77	€ 1.42	€ 19.37	17.4	€ 67.41
Cisplatin							
Antiemetic treatment: In clinical practice, an appropriate antiemetic treatment is established before and/or after administration of cisplatin. The product information for cisplatin does not provide any specific information on this, which is why the necessary costs cannot be quantified.							

Name of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates	Treatment days/ year	Costs/ patient/ year
Hydration and forced diuresis 2 cycles (nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy)							
Mannitol 10% Inf. Sol., 37.5 g/day	10 x 500 ml INF	€ 105.54	€ 5.28	€ 4.26	€ 96.00	2	€ 96.00
Sodium chloride 0.9% Inf. Sol., 3 - 4.4 l/day	10 x 1,000 ml INF	€ 23.10	€ 1.16	€ 1.89	€ 20.05	2	€ 20.05
Hydration and forced diuresis 4 cycles Durvalumab in combination with tremelimumab and platinum-based chemotherapy							
Mannitol 10% Inf. Sol., 37.5 g/day	10 x 500 ml INF	€ 105.54	€ 5.28	€ 4.26	€ 96.00	4	€ 96.00
Sodium chloride 0.9% Inf. Sol., 3 - 4.4 l/day	10 x 500 ml INF	€ 13.28	€ 0.66	€ 0.96	€ 11.66	4	€ 34.98
	10 x 1,000 ml INF	€ 23.10	€ 1.16	€ 1.89	€ 20.05	4	€ 40.10
Hydration and forced diuresis 17.4 cycles (pembrolizumab + pemetrexed + platinum-containing chemotherapy and cemiplimab in combination with platinum-based chemotherapy)							
Mannitol 10% Inf. Sol., 37.5 g/day	10 x 500 ml INF	€ 105.54	€ 5.28	€ 4.26	€ 96.00	17.4	€ 167.04
Sodium chloride 0.9% Inf. Sol., 3 - 4.4 l/day	10 x 1,000 ml INF	€ 23.10	€ 1.16	€ 1.89	€ 20.05	17.4	€ 104.66 – € 174.44
Abbreviations: INF = infusion solution; AMP = ampoules; SFI = solution for injection; TAB = tablets							

Other SHI services:

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

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

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:

a) Adults with advanced RET fusion-positive NSCLC with PD-L1 expression ≥ 50% of tumour cells; first-line therapy

– No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient approved in monotherapy.

b) Adults with advanced RET fusion-positive NSCLC with PD-L1 expression < 50% of tumour cells; first-line therapy

– No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient approved in monotherapy.

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 10 September 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy took place. The Subcommittee on Medicinal Products newly determined the appropriate comparator therapy at their session on 12 August 2025.

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

By letter dated 18 December 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefits 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 selpercatinib.

The dossier assessment by the IQWiG was submitted to the G-BA on 26 March 2026, and the written statement procedure was initiated with publication on the G-BA website on 1 April 2026. The deadline for submitting written statements was 22 April 2026.

The oral hearing was held on 11 May 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 9 June 2026, and the draft resolution was conclusively discussed.

At their session on 18 June 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	10 September 2024	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	12 August 2025	New determination of the appropriate comparator therapy
Working group Section 35a	6 May 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	11 May 2026	Conduct of the oral hearing
Working group Section 35a	20 May 2026 3 June 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	9 June 2026	Concluding discussion of the draft resolution
Plenum	18 June 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 18 June 2026

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

Prof. Hecken