Gemeinsamer Bundesausschuss

Justification

to the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Durvalumab (new therapeutic indication: limited-stage small cell lung cancer (LS-SCLC), following platinum-based chemoradiation therapy, monotherapy)

of 22 January 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 pass a resolution on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient durvalumab (Imfinzi) was listed for the first time on 15 October 2018 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices.

On 19 December 2024, the pharmaceutical company submitted an application for postponement of the date for the start of the benefit assessment procedure for durvalumab in the therapeutic indication: limited-stage small cell lung cancer, following platinum-based chemoradiation therapy, monotherapy in accordance with Section 35a, paragraph 5b SGB V.

The pharmaceutical company expected extensions of the marketing authorisation for the active ingredient durvalumab within the period specified in Section 35a paragraph 5b SGB V for multiple therapeutic indications at different times.

At their session on 6 February 2025, the G-BA approved the application pursuant to Section 35a paragraph 5b SGB V and postponed the relevant date for the start of the benefit assessment and the submission of a dossier for the benefit assessment for the therapeutic indication in question to four weeks after the marketing authorisation of the other therapeutic

indication of the therapeutic indication covered by the application, at the latest six months after the first relevant date. The marketing authorisation for the other therapeutic indication covered by the application according to Section 35a paragraph 5b SGB V was granted within the 6-month period.

For the therapeutic indication in question here "monotherapy for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy", durvalumab received the extension of the marketing authorisation as a major type 2 variation as defined according to Annex 2 No. 2 letter a to Regulation (EC) No. 1234/2008 of the Commission from 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7) on 12 March 2025. In accordance with the resolution of 6 February 2025, the benefit assessment of the active ingredient durvalumab in this new therapeutic indication therefore began no later than four weeks of the last marketing authorisation of durvalumab granted on 2 July 2025 in the therapeutic indication "combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy for the treatment of adults with resectable muscle invasive bladder cancer", i.e. no later than 1 August 2025.

On 25 July 2025, the pharmaceutical company submitted a dossier in due time in accordance with Section 4, paragraph 3, No. 3 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 2 of the Rules of Procedure of the G-BA (VerfO) for the active ingredient durvalumab with the therapeutic indication "monotherapy for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy".

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 3 November 2025 on the G-BA website (www.g-ba.de), therefore initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of durvalumab 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, as well of the addendum drawn up by the IQWiG on the benefit assessment. 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 durvalumab.

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

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

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

2.1.1 Approved therapeutic indication of Durvalumab (Imfinzi) in accordance with the product information

IMFINZI as monotherapy is indicated for the treatment of adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

Therapeutic indication of the resolution (resolution of 22.01.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Appropriate comparator therapy for durvalumab as monotherapy:

- Best supportive care

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 in accordance with the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

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

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

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

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

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

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

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

On 1. In addition to durvalumab, the active ingredients carboplatin, cisplatin, cyclophosphamide, doxorubicin, epirubicin, etoposide, ifosfamide, lomustine and vincristine are approved in the present therapeutic indication.

On 2. Radiotherapy (especially as part of chemoradiation therapy) and prophylactic cranial irradiation (PCI) are generally considered as non-medicinal treatment options for the treatment of limited-stage small cell lung cancer. However, with regard to the present therapeutic indication, it was assumed that these interventions have already been completed, which is why they are not included in the appropriate comparator therapy.

On 3. No corresponding resolutions are available.

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as 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 from the Drugs Commission of the German Medical Association (AkdÄ) is available.

The available evidence shows that no specific standard therapy has yet been established for patients with limited-stage small cell lung cancer whose disease has not progressed following simultaneous chemoradiation therapy. This is also confirmed in the written statement of the AkdÄ.

The G-BA therefore determine best supportive care as an appropriate comparator therapy against the background of the patient's stage of disease, which is potentially associated with symptoms. Best Supportive Care (BSC) is understood as the therapy that ensures the best possible, patient-individually optimised, supportive treatment to alleviate symptoms and improve quality of life.

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

A change in the appropriate comparator therapy requires a resolution by the G-BA linked to the prior review of the criteria according to Chapter 5 Section 6, paragraph 3 Rules of Procedure.

2.1.3 Extent and probability of the additional benefit

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

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Indication of a considerable additional benefit

Justification:

The pharmaceutical company presented results from the ADRIATIC study to prove the additional benefit.

The ongoing double-blind phase III RCT ADRIATIC is a triple-arm study. The present benefit assessment is based on the durvalumab arm (intervention arm) and the placebo-controlled arm (comparator arm). The third intervention arm, in which the combination of durvalumab and tremelimumab is being investigated, has not yet been unblinded and is not the subject of this assessment.

Patients with unresectable, limited-stage small cell lung cancer (LS-SCLC) who had previously received 4 cycles of simultaneous chemoradiation therapy were enrolled in the study. Enrolment in the study with 3 cycles of chemotherapy was also permitted if disease was controlled and no additional benefit was expected from a further cycle. The chemotherapy consisted of platinum-based doublet chemotherapy in combination with etoposide. Radiotherapy had to have been started by the end of the 2nd cycle of chemotherapy at the latest.

Patients who achieved a complete response, a partial response or stable disease after the end of simultaneous chemoradiation therapy and did not show disease progression were enrolled in the study and randomised to the intervention arm (N = 264) or comparator arm (N = 266). The data from the 1st predefined data cut-off from 15.01.2024 form the basis.

Extent and probability of the additional benefit

Mortality

In the ADRIATIC study, overall survival is defined as the time (in months) between randomisation and death from any cause.

For the endpoint of overall survival, there was a statistically significant difference in favour of durvalumab compared to best supportive care.

The extent of the prolongation achieved in overall survival is assessed as a significant improvement.

Morbidity

Progression-free survival (failure of the curative therapeutic approach)

Patients in the present therapeutic indication were treated with simultaneous chemoradiation therapy. Simultaneous chemoradiation therapy represents a curative therapeutic approach in the treatment of limited-stage small cell lung cancer (LS-SCLC) in adults.

If the disease persists or recurs after therapy (relapse), this means that the curative therapeutic approach has failed. The failure of a curative therapeutic approach is fundamentally considered to be patient-relevant.

No endpoint was planned for the ADRIATIC study to specifically assess the failure of the curative therapeutic approach. In the dossier, the pharmaceutical company presented the data on progression-free survival (PFS) and discussed the patient relevance in the context of the curative therapeutic approach.

In the view of the G-BA, the PFS endpoint is unsuitable in the present setting to adequately reflect the failure of the curative therapeutic approach. In the ADRIATIC study, PFS was operationalised as the time from randomisation to disease progression or death from any cause, depending on which event occurred first. Accordingly, the PFS only reflects events in which disease progression has occurred in the course of observation. Relapses or events (beyond progression events) with which the non-achievement of the absence of disease during the course of the observation could be shown are not part of the operationalisation of the PFS.

This does not allow a sufficient assessment to be made as to whether and in how many patients the curative therapeutic approach has failed. The PFS endpoint is not used for the present assessment. The results are only presented additionally in the resolution.

Symptomatology

Disease symptomatology was surveyed in the ADRIATIC study using the EORTC QLQ-C30 questionnaire and the EORTC QLQ-LC13 additional module as well as the PGIS. The pharmaceutical company submitted post hoc responder analyses in each case for the time to 1st deterioration by ≥ 10 points, on which the present assessment is based.

EORTC QLQ-C30 and EORTC QLQ-LC13

For the symptomatology surveyed using the EORTC QLQ-C30, there was no statistically significant difference between the treatment arms for each of the endpoints "fatigue", "nausea and vomiting", "pain", "dyspnoea", "insomnia", "appetite loss", "constipation" and "diarrhoea".
For the symptomatology surveyed using the additional module EORTC QLQ-LC13, there was no statistically significant difference between the treatment arms for each of the endpoints "fatigue", "nausea and vomiting", "cough", "haemoptysis", "dyspnoea", "chest pain", "pain in other parts of the body", "wounded mouth", "dysphagia", "peripheral neuropathy" and "alopecia".

For the endpoint "pain in the arm or shoulder", there was a statistically significant difference to the advantage of durvalumab compared to best supportive care, whereby the extent of this difference was classified as small.

PGI-S

For the symptomatology surveyed using the Patient Global Impression of Severity (PGI-S), there was no statistically significant difference between the treatment arms.

Health status

EQ-5D, visual analogue scale

Health status was surveyed using the visual analogue scale (VAS) of the EQ-5D questionnaire and operationalised as the time to 1st deterioration by ≥ 15 points. However, there was no statistically significant difference between the treatment arms for this endpoint.

Overall, there was only an advantage of durvalumab for the endpoint "pain in the arm or shoulder". In the overall analysis of the results on morbidity, this is considered inadequate to derive an advantage for the endpoint category of morbidity overall, thus not resulting in any relevant difference for the benefit assessment.

Quality of life

Health-related quality of life was surveyed using the EORTC QLQ-C30 questionnaire and used after operationalisation as the time to first deterioration by ≥ 10 points.
For the health-related quality of life surveyed using the EORTC QLQ-C30, there was no statistically significant difference between the treatment arms for each of the endpoints "global health status", "physical functioning", "role functioning", "cognitive functioning", "emotional functioning" and "social functioning".

Overall, neither an advantage nor a disadvantage was thus identified for the endpoint category of health-related quality of life.

Side effects

Adverse events (AEs) in total

In the ADRIATIC study, almost all patients in the control and intervention arms experienced an AE. The results are only presented additionally.

Serious AEs (SAEs), severe AEs (CTCAE grade ≥ 3) and discontinuation due to AEs

There were no statistically significant differences between the treatment arms for the endpoints of SAEs, severe AEs and discontinuation due to AEs.

PRO-CTCAE

In the study, AEs were also surveyed using the Patient-Reported Outcome – Common Terminology Criteria for Adverse Events (PRO-CTCAE). No suitable data are available for this endpoint due to the non-transparent selection process and the incomprehensible selection of items to depict symptomatic AEs.

Specific AEs

Immune-mediated serious AEs (SAEs) and immune-mediated severe AEs (CTCAE grade ≥ 3) and pneumonitis (AEs)

For the endpoints of immune-mediated SAEs, immune-mediated severe AEs and pneumonitis (AEs), there was a statistically significant difference to the disadvantage of durvalumab compared to best supportive care.

For the endpoint category of side effects, disadvantages of durvalumab can be observed in detail for some specific AEs, with immune-mediated AEs showing low absolute frequencies to the disadvantage of durvalumab. The disadvantages are not reflected in the overall rates for SAEs, severe AEs and discontinuation due to AEs. Overall, neither an advantage nor a disadvantage of durvalumab compared to best supportive care was identified for the side effects, or no relevant difference for the benefit assessment.

Overall assessment

Results on mortality, morbidity, health-related quality of life and side effects from the randomised, multicentre, controlled ADRIATIC study are available for the assessment of the additional benefit of durvalumab in adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

For the endpoint of overall survival, there was a statistically significant difference to the advantage of durvalumab compared to best supportive care. Overall, the results of overall survival are considered a significant improvement.

In the endpoint category of morbidity, disease symptomatology (EORTC QLQ-C30 and -LC13) and health status (EQ-5D VAS) were surveyed. Overall, there was no relevant difference for the benefit assessment.

Neither an advantage nor a disadvantage was found for health-related quality of life (EORTC QLQ-C30).

In summary, for the side effects, disadvantages of durvalumab can be observed in detail for some specific AEs, with immune-mediated AEs showing low absolute frequencies to the disadvantage of durvalumab. The disadvantages are not reflected in the overall rates for SAEs, severe AEs and discontinuation due to AEs. Overall, neither an advantage nor a disadvantage of durvalumab compared to best supportive care was identified for the side effects, or no relevant difference for the benefit assessment.

Overall, due to the clear advantage in overall survival, the G-BA concluded a considerable additional benefit of durvalumab over best supportive care in adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

Reliability of data (probability of additional benefit)

The present assessment is based on the results of the double-blind, phase III ADRIATIC RCT.

The cross-endpoint risk of bias of the ADRIATIC study is estimated to be low.

For the endpoints of overall survival and discontinuation due to AEs, the risk of bias is rated as low.

With regard to the patient-reported endpoints on morbidity and health-related quality of life, there is an increased risk of bias due to the declining return rate of the respective questionnaires during the course of the study, the high percentage of patients not included in the evaluation (approx. 20%) and the percentage of patients with no further values during the course of the study (< 10%).

Overall, the available data basis is subject to uncertainties. However, these uncertainties are not rated so high as to justify a downgrading of the reliability of data.

The reliability of data for the additional benefit identified is classified in the “indication” category in the present assessment.

2.1.4 Summary of the assessment

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

The therapeutic indication assessed here is the treatment of limited-stage small cell lung cancer (LS-SCLC) in adults whose disease has not progressed following platinum-based chemoradiation therapy.

The G-BA determined the appropriate comparator therapy to be best supportive care.

The pharmaceutical company presented results from the ongoing double-blind triple-arm phase III ADRIATIC RCT to demonstrate the additional benefit. The present benefit assessment is based on the durvalumab arm (intervention arm) and the placebo-controlled arm (comparator arm).

For the endpoint of overall survival, there was a statistically significant difference to the advantage of durvalumab compared to best supportive care. Overall, the results of overall survival are considered a significant improvement.

In the endpoint category of morbidity, disease symptomatology (EORTC QLQ-C30 and -LC13) and health status (EQ-5D VAS) were surveyed. Overall, there was no relevant difference for the benefit assessment.

Neither an advantage nor a disadvantage was found for health-related quality of life (EORTC QLQ-C30).

In summary, for the side effects, disadvantages of durvalumab can be observed in detail for some specific AEs, with immune-mediated AEs showing low absolute frequencies to the disadvantage of durvalumab. The disadvantages are not reflected in the overall rates for SAEs, severe AEs and discontinuation due to AEs. Overall, neither an advantage nor a disadvantage of durvalumab compared to best supportive care was identified for the side effects, or no relevant difference for the benefit assessment.

Overall, due to the clear advantage in overall survival, the G-BA concluded a considerable additional benefit of durvalumab over best supportive care in adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

The reliability of data for the additional benefit identified is classified in the “indication” category in the present assessment.

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

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

The G-BA base their resolution on the information provided by the pharmaceutical company.

Based on the information provided by the pharmaceutical company in the written statement, but retaining 76.32% as the lower limit for patients whose disease is not progressive, a range of approximately 670 to 1,750 patients results for the SHI target population.

There are uncertainties for patients completing platinum-based chemoradiation therapy in that, on the one hand, the specific inclusion criteria of the STIMULI study make it questionable to what extent such therapy reflects everyday care and, on the other, the study only assumed completion of chemoradiation therapy after 4 cycles.

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 Imfinzi (active ingredient: durvalumab) at the following publicly accessible link (last access: 28 October 2025):

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

Treatment with durvalumab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with 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.

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 November 2025).

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

For the cost representation, one year is assumed for all medicinal products.

The (daily) doses recommended in the product information or in the labelled publications were used as the basis for calculation.

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

Treatment period:

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Durvalumab	1 x per 28-day cycle	1	1.0	13.0
Best supportive care	Different from patient to patient			
Appropriate comparator therapy				
Best supportive care	Different from patient to patient			

Consumption:

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Durvalumab	1,500 mg	1,500 mg	3 x 500 mg	13.0	39 x 500 mg
Best supportive care	Different from patient to patient				
Appropriate comparator therapy					
Best supportive care	Different from patient to patient				

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Durvalumab 500 mg	1 CIS	€ 2,083.83	€ 1.77	€ 115.72	€ 1,966.34
Best supportive care	Not calculable				
Appropriate comparator therapy					
Best supportive care	Not calculable				
Abbreviations: CIS = concentrate for the preparation of an infusion solution					

LAUER-TAXE® last revised: 15 November 2025

Costs for additionally required SHI services:

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

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

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

Other SHI services:

The special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe) (Sections 4 and 5 of the Pharmaceutical Price Ordinance) from 1 October 2009 is not fully used to calculate costs. Alternatively, the pharmacy sales price publicly accessible in the directory services according to Section 131 paragraph 4 SGB V is a suitable basis for a standardised calculation.

According to the currently valid version of the special agreement on contractual unit costs of retail pharmacist services (Hilfstaxe), surcharges for the production of parenteral preparations containing cytostatic agents a maximum amount of € 100 per ready-to-use preparation, and for the production of parenteral solutions containing monoclonal antibodies a maximum of € 100 per ready-to-use 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 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 health insurance funds and pharmaceutical companies. The designation is not associated with a statement as to the extent to which a therapy with the assessed medicinal products in combination with the designated medicinal products corresponds to the generally recognised state of medical knowledge. The examination was carried out exclusively on the basis of the possibility under Medicinal Products Act to use the medicinal products in combination therapy in the assessed therapeutic indication based on the product information; the generally recognised state of medical knowledge or the use of the medicinal products in the reality of care were not the subject of the examination due to the lack of an assessment mandate of the G-BA within the framework of Section 35a, paragraph 3, sentence 4 SGB V.

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

Justification for the findings on designation in the present resolution:

Adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation 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 authorised in monotherapy.

References:
Product information for durvalumab (Imfinzi); IMFINZI 50 mg/ml concentrate for the preparation of an infusion solution; last revised: July 2025

3. Bureaucratic costs calculation

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

4. Process sequence

At their session on 12 September 2023, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy took place once the positive opinion was granted. The Subcommittee on Medicinal Products determined the appropriate comparator therapy at their session on 18 February 2025.

On 25 July 2025, the pharmaceutical company submitted a dossier for the benefit assessment of durvalumab to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 5b VerfO.

By letter dated 28 July 2025 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with

new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient durvalumab.

The dossier assessment by the IQWiG was submitted to the G-BA on 30 October 2025, and the written statement procedure was initiated with publication on the G-BA website on 3 November 2025. The deadline for submitting statements was 24 November 2025.

The oral hearing was held on 8 December 2025.

By letter dated 9 December 2025, the IQWiG was commissioned with a supplementary assessment of data submitted in the written statement procedure. The addendum prepared by IQWiG was submitted to the G-BA on 2 January 2026.

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

The evaluation of the written statements received and the oral hearing was discussed at the session of the Subcommittee on 13 January 2026, and the proposed draft resolution was approved.

At their session on 22 January 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	12 September 2023	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	18 February 2025	New determination of the appropriate comparator therapy
Working group Section 35a	3 December 2025	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	8 December 2025	Conduct of the oral hearing, commissioning of the IQWiG with the supplementary assessment of documents
Working group Section 35a	17 December 2025 7 January 2026	Consultation on the dossier evaluation by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	13 January 2026	Concluding discussion of the draft resolution
Plenum	22 January 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 22 January 2026

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken