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: muscle invasive bladder cancer (MIBC), neoadjuvant/ adjuvant therapy after cystectomy, combination with gemcitabine and cisplatin)

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. requirement 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 2 July 2025, durvalumab received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, sentence 7).

On 25 July 2025, i.e. at the latest within four weeks after informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company have submitted a dossier in due time in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with

Chapter 5 Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient durvalumab with the new therapeutic indication

"IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC)."

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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), thus initiating the written statement procedure. In addition, an oral hearing was held.

The G-BA came to a resolution on whether an additional benefit of 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:

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 in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC).

Therapeutic indication of the resolution (resolution of 22 January 2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy

Appropriate comparator therapy for durvalumab in combination with gemcitabine and cisplatin:

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

A therapy regimen consisting of

- neoadjuvant treatment with cisplatin in combination with gemcitabine

  followed by radical cystectomy and:

  - monitoring wait-and-see approach

    or

  - nivolumab (only suitable for patients with tumour cell PD-L1 expression ≥ 1% and at high risk of recurrence after radical resection)

<u>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):</u>

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 cisplatin, doxorubicin, methotrexate, gemcitabine and nivolumab are approved for the present therapeutic indication.

On 2. In the present therapeutic indication, radiotherapy and surgery are basically considered as non-medicinal treatment.

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

- Nivolumab: resolution of 20 October 2022

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 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.

Current guidelines recommend cisplatin-based chemotherapy for the neoadjuvant treatment of muscle invasive urothelial carcinoma for patients who are eligible for cisplatin-based therapy. Accordingly, a number of different cisplatin-based combination chemotherapies were investigated. In particular, the American Urological Association guideline states that the question of the most suitable cisplatin-based combination chemotherapy has not yet been conclusively clarified. Overall, a relevant significance is however described in particular for the combination of cisplatin and gemcitabine, as well as for dd-MVAC (dose-dense methotrexate-vinblastine-doxorubicin-cisplatin). However, the combination chemotherapy dd-MVAC is not approved for the present therapeutic indication.

The G-BA have therefore determined cisplatin in combination with gemcitabine as the appropriate comparator therapy for neoadjuvant treatment.

Nivolumab is approved for the adjuvant treatment of muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression ≥ 1% in adults at high risk of recurrence after radical resection and is recommended at different strengths according to the available guidelines, with the current S3 guideline making a strong recommendation. By resolution of 20 October 2022, a hint for a non-quantifiable additional benefit of nivolumab over the monitoring wait-and-see approach was identified for patients who are ineligible for cisplatin-based therapy or have already received neoadjuvant treatment. The period of validity of the resolution for this

patient group was limited since further clinical data from the pivotal study are expected, which are relevant for assessment of the benefits of the medicinal product.

The current guidelines do not recommend any (specific) adjuvant therapy for patients with muscle invasive urothelial carcinoma (MIUC) without tumour cell PD-L1 expression ≥ 1% and at high risk of recurrence after neoadjuvant cisplatin-containing chemotherapy and radical resection, meaning that the monitoring wait-and-see approach is considered appropriate for these patients. The monitoring wait-and-see approach should be based on appropriate follow-up examinations, taking into account the current state of medical knowledge.

In the overall analysis of the available evidence, nivolumab is determined to be an equally appropriate comparator therapy for the adjuvant therapy phase in addition to the monitoring wait-and-see approach, whereby nivolumab is only considered for patients with tumour cell PD-L1 expression ≥ 1% in adults at a high risk of recurrence after radical resection in accordance with the marketing authorisation.

The appropriate comparator therapy determined here includes several therapeutic alternatives. 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 therapeutic alternatives are only to be considered equally appropriate in the therapeutic indication, where the patient populations have the same characteristics.

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:

<u>Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy</u>

Indication of a minor additional benefit.

Justification:

To demonstrate the additional benefit, the pharmaceutical company presented the results from the ongoing, open-label, randomised, controlled phase III NIAGARA study comparing durvalumab in combination with gemcitabine + cisplatin (neoadjuvant) and subsequent durvalumab monotherapy (adjuvant) after radical cystectomy versus gemcitabine + cisplatin (neoadjuvant) followed by the monitoring wait-and-see approach after radical cystectomy. The study has been conducted at 168 study sites in Europe, North and South America, and Asia since November 2018.

Adult patients with histologically or cytologically proven resectable muscle invasive bladder cancer (tumour stage: T2-T4aN0/1M0) who are eligible for cisplatin-based chemotherapy were enrolled in the study. The patients fulfil the criteria for assessing eligibility for cisplatin according to the specifications of the current S3 guideline and the recommendations of the German Society for Haematology and Medical Oncology (DGHO): Patients with ECOG-PS ≤ 1

and a creatinine clearance ≥ 40 ml/min were enrolled. Patients with New York Heart Association class III or IV heart failure, audiometric hearing loss according to CTCAE grade ≥ 2 and peripheral polyneuropathy according to CTCAE grade ≥ 2 were excluded. In addition, patients were not allowed to have been pretreated with systemic chemotherapy or immunotherapy.

A total of 1,063 patients were enrolled in the study and randomised in a 1:1 ratio to either treatment with durvalumab + gemcitabine + cisplatin (neoadjuvant), followed by durvalumab (adjuvant) (N = 533) or to treatment with gemcitabine + cisplatin (neoadjuvant), followed by the monitoring wait-and-see approach (N = 530). Randomisation was performed using the Interactive Voice Response System (IVRS), stratified by clinical tumour status (T2N0 vs > T2N0), renal function (adequate renal function vs borderline renal function) and tumour programmed cell death ligand 1 (PD-L1) expression status, determined using the VENTANA PD-L1 (SP263) assay, according to tumour cell score 25/ immune cells present+ (high vs low/ negative).

In the comparator arm, patients were not actively treated for their bladder cancer during the adjuvant treatment phase. However, the best possible, patient-individually optimised and supportive treatment was provided in both arms of the study to alleviate symptoms. However, the investigations carried out do not fully reflect the guideline recommendations. Nevertheless, the patients were examined closely and specifically to assess their health status and relapses, so that it can be concluded overall that the monitoring wait-and-see approach was implemented sufficiently in the adjuvant phase of the comparator arm.

Treatment was given in the neoadjuvant phase for both treatment arms until completion of therapy in line with the protocol (4 cycles), disease progression leading to the exclusion of radical cystectomy, unacceptable toxicity or therapy discontinuation as decided by the doctor or patient. In the adjuvant phase, treatment for the intervention arm continued until completion of the therapy in line with the protocol (8 cycles), disease progression, unacceptable toxicity or therapy discontinuation as decided by the doctor or patient. A changeover of patients from the intervention arm to the therapy of the comparator arm was not allowed.

In addition to the primary endpoints of pathological complete response (pCR) and event-free survival (EFS), endpoints in the categories of mortality (overall survival), morbidity, health-related quality of life and side effects were assessed.

So far, the following data cut-offs have been collected for the NIAGARA study:

- Data cut-off from 14 January 2022 (interim analysis 1): pre-specified interim analysis for the pCR endpoint
- Data cut-off from 29 April 2024 (interim analysis 2): final analysis for the EFS endpoint (only introduced in amendment 4 to the study protocol of 1 June 2021).

The pharmaceutical company submitted evaluations on all endpoints for interim analysis 2 (most recent data cut-off) in the dossier. This data cut-off was initially not pre-specified and was only introduced in study protocol version 5.0 (1 June 2021). The pharmaceutical company justified the interim analysis 2 with the fact that the sample size calculation was performed for the entire ITT population, as the original sample size calculation was performed on the basis of the population of patients with adequate renal function. There is no indication of potential results-driven planning as the interim analysis 1 was conducted on 14 January 2022 and therefore post-dates the amendment to the study protocol. For the present benefit assessment, the results of the interim analysis 2 are therefore used.

Extent and probability of the additional benefit

Mortality

In the NIAGARA study, overall survival is operationalised as the time between randomisation and death from any cause.

For the endpoint of overall survival, there was a statistically significant difference between the treatment groups in favour of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant). The extent of the prolongation achieved in overall survival is assessed as a relevant improvement.

The information on the follow-up therapies in the NIAGARA study shows that only a low dose of enfortumab vedotin in combination with pembrolizumab was administered. Enfortumab vedotin in combination with pembrolizumab represents a highly effective treatment option and the current therapy standard for patients in first-line therapy of unresectable or metastatic urothelial carcinoma who are eligible for platinum-based therapy. In view of the fact that the corresponding marketing authorisation of enfortumab vedotin in combination with pembrolizumab was granted only after the 1st data cut-off of the NIAGARA study, the low dose of enfortumab vedotin in combination with pembrolizumab administered as subsequent therapy is basically understandable. Nevertheless, it should be noted that the follow-up therapies in the NIAGARA study inadequately reflect the current standard of care.

Morbidity

Failure of the curative therapeutic approach (event rate and event-free survival (EFS))

This therapeutic indication represents a curative therapeutic approach: neoadjuvant therapy followed by adjuvant therapy after radical cystectomy. The lack of feasibility of the planned operation, unsuccessful performance of the operation and the recurrence after R0 resection means that the curative therapeutic approach has failed. Based on a curative therapeutic approach, the failure of the potential cure is basically patient-relevant.

In the NIAGARA study, the failure of the curative therapeutic approach was not directly assessed as an endpoint. In the pharmaceutical company's dossier, the events collected in the context of the primary endpoint of the NIAGARA study, the composite endpoint of event-free survival, were considered approximately as operationalisation for the endpoint for the present assessment.

In the benefit assessment dossier, the pharmaceutical company presented post hoc evaluations on event-free survival, for which they also presented the respective reasons within the components. In doing so, event-free survival was defined as the time from randomisation to the first occurrence of one of the following events:

- First recurrence of the disease after radical cystectomy
- Performance of a radical cystectomy not possible for medical reasons
  - Not eligible for surgery (e.g. reduced ECOG-PS)
  - Disease progression
  - AE
  - Doctor's decision
- Refusal of a radical cystectomy by the patient, or
  Intra-operative failure of radical cystectomy
  - Patients who refuse a radical cystectomy

- Patients with unsuccessful radical cystectomy (R1 resection, intra-operative decision)
- Patients who discontinued participation in the study after the expected date of cystectomy
- Death

– Death from any cause.

In the present therapeutic indication, this operationalisation is suitable to depict a failure of the curative therapeutic approach.

There was a statistically significant difference in both event rate and event-free survival to the advantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant).

In the analysis of both endpoints, an overall minor advantage was identified with regard to avoiding failure of the curative therapeutic approach for durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant).

Symptomatology (assessed using EORTC QLQ-C30 and PGIS)

Symptomatology was surveyed in the NIAGARA study using the EORTC QLQ-C30 and PGI-S questionnaires.

For the endpoints of fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation and diarrhoea surveyed using the EORTC QLQ-C30, there was no statistically significant difference between the treatment groups in each case.

In addition, for the symptomatology surveyed using the PGIS, there was no statistically significant difference between the treatment groups.

Health status (surveyed using EQ-5D VAS and PGIC)

Health status was surveyed in the NIAGARA study using the EQ-5D visual analogue scale and the PGI-C questionnaire.

For health status surveyed using the EQ-5D VAS, there was no statistically significant difference between the treatment groups in the total population. However, for this endpoint, there was an effect modification for the characteristic "clinical tumour status at baseline according to the Interactive Voice Response System (IVRS)". There was a statistically significant difference to the advantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant) for patients with tumour status > T2N0. For patients with tumour status T2N0, there was no statistically significant difference between the treatment groups. This does not result in any reliable conclusions for the overall statement and the result for the total population is used for the assessment.

For health status surveyed using the PGIC, there was a statistically significant difference to the advantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant).

In summary, there was a minor benefit of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant), with regard to avoiding failure of the curative therapeutic approach in the morbidity endpoint category. There was also an advantage in terms of health status (surveyed using PGIC). There was no significant difference between the treatment groups in the endpoints on symptomatology.

Quality of life

The quality of life of patients is surveyed in the NIAGARA study using the functional scales of the EORTC QLQ-C30 questionnaire.

For the endpoints of role functioning and social functioning, there was no statistically significant difference between the treatment groups in the total population in each case. However, for this endpoint, there was an effect modification due to the “sex" characteristic. There was a statistically significant difference to the disadvantage of the intervention for women. There was no statistically significant difference between the treatment groups for men. This does not result in any reliable conclusions for the overall statement and the result for the total population is used for the assessment.

There was no statistically significant difference between the treatment groups for the endpoints of global health status, physical functioning, emotional functioning and cognitive functioning.

In summary, there was neither an advantage nor a disadvantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant), with regard to health-related quality of life in the endpoint category of quality of life.

Side effects

Total adverse events (AE) (presented additionally)

In the NIAGARA study, adverse events occurred in 99.4% of patients in the intervention arm and 99.8% of patients in the control arm.

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

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

Therapy discontinuation due to AEs

No suitable data are available for the endpoint of therapy discontinuation due to AEs. In the NIAGARA study, active therapy is administered in the intervention arm for the entire duration of the study, whereas in the comparator arm, active therapy is only administered in the neoadjuvant phase and further observation at the study visits takes place in the adjuvant phase. Thus, therapy discontinuation due to AEs in the comparator arm can only occur in the neoadjuvant phase. In the subsequent adjuvant phase, the event of therapy discontinuation can no longer be observed, even if adverse events occur that would have led to discontinuation of an active therapy. The results on the endpoint of therapy discontinuation due to AEs are therefore unsuitable for the present benefit assessment.

Immune-mediated SAEs and immune-mediated severe AEs

For the endpoints of immune-mediated SAEs and immune-mediated severe AEs, there was a statistically significant difference to the disadvantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant).

Other specific AEs

Skin and subcutaneous tissue disorders (system organ class (SOC), AEs), pulmonary embolism (preferred term (PT), SAEs) and cardiac disorders (SOC, severe AEs)

For the endpoints of skin and subcutaneous tissue disorders (SOC, AEs), pulmonary embolism (PT, SAEs) and cardiac disorders (SOC, severe AEs), there was a statistically significant difference to the disadvantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant).

Anaemia (PT, SAEs)

For the endpoint of anaemia (PT, SAEs), there was a statistically significant difference to the advantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant).

In summary, there was no statistically significant difference between the treatment groups with regard to serious AEs and severe AEs in the side effects category. No suitable data are available for the endpoint of discontinuation due to AEs. In detail, there were advantages and disadvantages in the specific AEs.

Overall assessment

The benefit assessment of durvalumab in combination with gemcitabine and cisplatin followed by durvalumab after radical cystectomy compared with gemcitabine in combination with cisplatin followed by the monitoring wait-and-see approach after radical cystectomy is based on the results of the NIAGARA study in the endpoint categories of mortality, morbidity, quality of life and side effects.

For the endpoint of overall survival, there was a statistically significant difference between the treatment groups in favour of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant). The extent of the prolongation achieved in overall survival is assessed as a relevant improvement.

The information on the follow-up therapies in the NIAGARA study shows that only a low dose of enfortumab vedotin in combination with pembrolizumab was administered. Enfortumab vedotin in combination with pembrolizumab represents a highly effective treatment option and the current therapy standard for patients in first-line therapy of unresectable or metastatic urothelial carcinoma who are eligible for platinum-based therapy. In view of the fact that the corresponding marketing authorisation of enfortumab vedotin in combination with pembrolizumab was granted only after the 1st data cut-off of the NIAGARA study, the low dose of enfortumab vedotin in combination with pembrolizumab administered as subsequent therapy is basically understandable. Nevertheless, it should be noted that the follow-up therapies in the NIAGARA study inadequately reflect the current standard of care.

With regard to the failure of the curative therapeutic approach, presented as event rate and event-free survival (EFS), an advantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant), is identified, the extent of which is assessed as a minor improvement. In the present curative treatment setting, the avoidance of the failure of the curative therapeutic approach is an essential therapeutic goal.

There was also an advantage in terms of health status (surveyed using PGIC).

Neither an advantage nor a disadvantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant), can be derived from the results on symptomatology (surveyed using EORTC QLQ-C30 and PGIS), health status (surveyed using EQ-5D VAS) and health-related quality of life (surveyed using EORTC QLQ-C30).

For the side effects, there was no statistically significant difference between the treatment groups with regard to the overall rates of serious AEs and severe AEs. No suitable data are

available for the endpoint of discontinuation due to AEs. In detail, there were advantages and disadvantages in the specific AEs.

The overall analysis showed a relevant advantage in overall survival and a minor advantage in the endpoint of failure of the curative therapeutic approach. There was also an advantage in terms of health status (surveyed using PGIC). With regard to the other endpoints on morbidity and health-related quality of life, neither an advantage nor a disadvantage of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant) can be derived.

As a result, a minor additional benefit of durvalumab in combination with gemcitabine and cisplatin (neoadjuvant), followed by durvalumab (adjuvant), compared with gemcitabine in combination with cisplatin, followed by the monitoring wait-and-see approach was identified.

Reliability of data (probability of additional benefit)

The underlying NIAGARA study is an ongoing, open-label, randomised controlled trial.

The risk of bias across endpoints for the NIAGARA study is rated as low at study level.

The risk of bias of the results for the endpoint of overall survival is rated as low.

The endpoint-specific risk of bias for the results of the endpoints on symptomatology, health status and health-related quality of life is classified as high due to the high percentage of patients who were not included in the evaluation and the lack of blinding in subjective endpoint assessment.

The risk of bias of the results on side effects is classified as high, as no information is available on the reasons for discontinuation in the adjuvant study phase.

Overall, an indication is derived for the reliability of data of the additional benefit identified.

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 as follows:

“IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC)."

For the benefit assessment, the pharmaceutical company presented the ongoing, open-label, randomised, controlled phase III NIAGARA study comparing durvalumab + gemcitabine + cisplatin (neoadjuvant) and subsequent durvalumab monotherapy (adjuvant) after radical cystectomy versus gemcitabine + cisplatin (neoadjuvant) followed by the monitoring wait-and-see approach after radical cystectomy.

For the endpoint of overall survival, there was a statistically significant difference between the treatment groups in favour of durvalumab + gemcitabine + cisplatin, followed by durvalumab. The extent of the prolongation achieved in overall survival is assessed as a relevant improvement.

The information on the follow-up therapies in the NIAGARA study shows that only a low dose of enfortumab vedotin + pembrolizumab was administered. Enfortumab vedotin + pembrolizumab represents a highly effective treatment option and the current therapy standard for patients in first-line therapy of unresectable or metastatic urothelial carcinoma

who are eligible for platinum-based therapy. In view of the fact that the corresponding marketing authorisation of enfortumab vedotin + pembrolizumab was granted only after the 1st data cut-off of the NIAGARA study, the low dose of enfortumab vedotin + pembrolizumab administered as subsequent therapy is basically understandable. Nevertheless, it should be noted that the follow-up therapies in the NIAGARA study inadequately reflect the current standard of care.

With regard to the failure of the curative therapeutic approach, presented as event rate and event-free survival, an advantage of durvalumab + gemcitabine + cisplatin, followed by durvalumab, is identified, the extent of which is assessed as a minor improvement. In the present curative treatment setting, the avoidance of the failure of the curative therapeutic approach is an essential therapeutic goal.

There was also an advantage in terms of health status (surveyed using PGIC).

Neither an advantage nor a disadvantage of durvalumab + gemcitabine + cisplatin, followed by durvalumab, can be derived from the results on symptomatology (surveyed using EORTC QLQ-C30 and PGIS), health status (surveyed using EQ-5D VAS) and health-related quality of life (surveyed using EORTC QLQ-C30).

For the side effects, there was no statistically significant difference between the treatment groups with regard to the overall rates of serious AEs and severe AEs. No suitable data are available for the endpoint of discontinuation due to AEs. In detail, there were advantages and disadvantages in the specific AEs.

The overall analysis showed a relevant advantage in overall survival and a minor advantage in the endpoint of failure of the curative therapeutic approach. There was also an advantage in terms of health status. With regard to the other endpoints on morbidity and health-related quality of life, neither an advantage nor a disadvantage of durvalumab in combination with gemcitabine and cisplatin, followed by durvalumab can be derived.

As a result, a minor additional benefit of durvalumab in combination with gemcitabine and cisplatin, followed by durvalumab, compared with gemcitabine in combination with cisplatin, followed by the monitoring wait-and-see approach was identified.

The reliability of data of the additional benefit identified is classified in the "Indication" category.

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 patient numbers from the dossier submitted by the pharmaceutical company.

The pharmaceutical company's procedure for estimating the number of patients in the SHI target population is mathematically plausible but shows methodological weaknesses. Overall, the information is however subject to uncertainties, which result primarily from the following aspects: In some cases, the calculation was based on percentages determined using patients whose disease is not in stages II or IIIA. In addition, the transferability of percentage values to previous populations is limited. Furthermore, patients for whom a cystectomy was originally planned, but who did not receive a cystectomy, were taken into account in the derivation of the patient numbers.

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: 17 September 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, specialists in urology, and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of patients with bladder cancer.

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.

According to the product information, the recommended dose of durvalumab in the neoadjuvant phase is 1,500 mg in combination with platinum-based chemotherapy every 3 weeks for 4 cycles, followed by adjuvant treatment with 1,500 mg durvalumab as monotherapy every 4 weeks for up to 8 cycles.

The treatment cycles for the active ingredients cisplatin and gemcitabine as concomitant active ingredients of the medicinal product to be assessed were presented for 3 cycles. As there is no specific information on the treatment cycles for neoadjuvant therapy in the product information, treatment with cisplatin in combination with gemcitabine in neoadjuvant therapy is presented in the appropriate comparator therapy according to the recommendation of the "S3 guideline on early detection, diagnosis, treatment and after-care of urinary bladder cancer"[2].

The recommended dose of nivolumab in adjuvant treatment is 240 mg in a 14-day cycle or 480 mg in a 28-day cycle as monotherapy for up to 12 months. As nivolumab is used after surgery, the costs are shown for the first year and the subsequent year.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements of 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).[3]

[2] **Oncology guideline programme, German Cancer Society (DKG), German Cancer Aid (DKH), Association of the Scientific-Medical Societies (AWMF).** Early detection, diagnosis, therapy and after-care of urinary bladder cancer; S3 guideline, version 3.0 [online]. AWMF registry number 032-038OL. Berlin (GER): Oncology guideline programme; 2025. [Accessed: 04.12.2025]. URL: https://www.leitlinienprogramm-onkologie.de/fileadmin/user_upload/Downloads/Leitlinien/Blasenkarzinom/Version_3/LL_Harnblasenkarzinom_Langversion_3.0.pdf

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

Treatment period:

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant 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				
Neoadjuvant treatment: Durvalumab in combination with cisplatin and gemcitabine				
Durvalumab	1 x per 21-day cycle	4.0	1	4.0
Cisplatin	1 x per 21-day cycle	4.0	1	4.0
Gemcitabine	3 x per 21-day cycle	4.0	3	12.0
Adjuvant treatment: Durvalumab (monotherapy)				
Durvalumab	1 x per 21-day cycle	8.0	1	8.0
Appropriate comparator therapy				
Neoadjuvant treatment: Cisplatin in combination with gemcitabine				
Cisplatin	1 x per 28-day cycle	3.0 - 4.0[2]	1	3.0 - 4.0
Gemcitabine	3 x per 28-day cycle	3.0 - 4.0[2]	3	9.0 – 12.0
Adjuvant treatment: Monitoring wait-and-see approach or nivolumab				
Monitoring wait-and-see approach	Not calculable			
Nivolumab	1 x per 14-day cycle	In the 1st year: 18.0 - 20.0 In the subsequent year: 6.0 – 8.0	1	In the 1st year: 18.0 - 20.0 In the subsequent year: 6.0 – 8.0
	or			

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	1 x per 28-day cycle	In the 1st year: 9.0 - 10.0 In the subsequent year: 3.0 – 4.0	1	In the 1st year: 9.0 - 10.0 In the subsequent year: 3.0 – 4.0

Consumption:

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant 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					
Neoadjuvant treatment: Durvalumab in combination with cisplatin and gemcitabine					
Durvalumab	1500 mg	1500 mg	3 x 500 mg	4.0	12 x 500 mg
Cisplatin	70 mg/m^2 = 133.7 mg	133.7 mg	1 x 100 mg + 1 x 50 mg	4.0	4 x 100 mg + 4 x 50 mg
Gemcitabine	1,000 mg/m^2 = 1,910 mg	1,910 mg	2 x 1,000 mg	12.0	24 x 1,000 mg
Adjuvant treatment: Durvalumab (monotherapy)					
Durvalumab	1500 mg	1500 mg	3 x 500 mg	8.0	24 x 500 mg
Appropriate comparator therapy					
Neoadjuvant treatment: Cisplatin in combination with gemcitabine					
Cisplatin	70 mg/m^2 = 133.7 mg	133.7 mg	1 x 100 mg + 1 x 50 mg	3.0 - 4.0	3 x 100 mg + 3 x 50 mg - 4 x 100 mg + 4 x 50 mg
Gemcitabine	1,000 mg/m^2 = 1,910 mg	1,910 mg	2 x 1,000 mg	9.0 - 12.0	18 x 1,000 mg - 24 x 1,000 mg

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Adjuvant treatment: Monitoring wait-and-see approach or nivolumab					
Monitoring wait-and-see approach	Not calculable				
Nivolumab	240 mg	240 mg	2 x 120 mg	In the 1st year: 18.0 - 20.0 In the subsequent year: 6.0 – 8.0	36 x 120 mg – 40 x 120 mg 12 x 120 mg – 16 x 120 mg
	or				
	480 mg	480 mg	4 x 120 mg	In the 1st year: 9.0 - 10.0 In the subsequent year: 3.0 – 4.0	36 x 120 mg – 40 x 120 mg 12 x 120 mg – 16 x 120 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:

Adults with resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant 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
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
Gemcitabine 1,000 mg	1 PIF	€ 102.35	€ 1.77	€ 10.62	€ 89.96
Appropriate comparator therapy					
Monitoring wait-and-see approach	Not calculable				
Nivolumab 120 mg	1 CIS	€ 1,539.71	€ 1.77	€ 84.64	€ 1,453.30
Abbreviations: CIS = concentrate for the preparation of an infusion solution, PIF = powder for the preparation of an injection or 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 resectable muscle invasive bladder cancer (MIBC) who are eligible for platinum-based chemotherapy; neoadjuvant and adjuvant therapy

No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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 27 May 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

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 1, number 2 VerfO.

By letter dated 29 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. The addendum prepared by IQWiG was submitted to the G-BA on 30 December 2025.

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	27 May 2025	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