Gemeinsamer Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Toripalimab (oesophageal squamous cell carcinoma, first-line, combination with cisplatin and paclitaxel)

From 2 July 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,
7. number of study participants who participated in the clinical studies at study sites within the scope of SGB V, and total number of study participants.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient toripalimab on 15 January 2026 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the G-BA (VerfO). Pursuant to Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the G-BA on 14 January 2026.

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 15 April 2026 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 toripalimab compared to the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG and the statements submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods[1] was not used in the benefit assessment of toripalimab.

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 toripalimab (Loqtorzi) in accordance with the product information

Loqtorzi, in combination with cisplatin and paclitaxel, is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma.

Therapeutic indication of the resolution (resolution of 02.06.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

Appropriate comparator therapy for toripalimab in combination with cisplatin and paclitaxel:

- nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (for patients with tumour cell PD-L1 expression ≥ 1%)

  or

- nivolumab in combination with ipilimumab (only for patients with tumour cell PD-L1 expression ≥ 1%)

  or

- pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (for patients with a combined positive score (CPS) ≥ 10)

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

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

Appropriate comparator therapy for toripalimab in combination with cisplatin and paclitaxel:

- cisplatin in combination with 5-fluorouracil

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

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

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

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

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for 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 for 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 toripalimab in combination with cisplatin and paclitaxel, medicinal products with the active ingredients 5-fluorouracil, cisplatin, mitomycin, nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy, nivolumab in combination with ipilimumab, pembrolizumab in combination with fluoropyrimidine- and platinum-based chemotherapy and tislelizumab in combination with platinum-based chemotherapy are approved for the present therapeutic indication.

On 2. A non-medicinal treatment option is not considered for the therapeutic indication in question. This does not affect the use of radiotherapy as a supportive therapy option.

On 3. Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V:
- Tislelizumab (resolution of 18 June 2025)
- Nivolumab (resolutions of 20 October 2022)
- Pembrolizumab (resolution of 5 May 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 indication according to Section 35a, paragraph 7 SGB V (see "Information on Appropriate Comparator Therapy").

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.

It is assumed that curative therapy is not an option for patients with unresectable oesophageal cancer.

According to the guidelines, the treatment decision in the first-line treatment of advanced, recurrent or metastatic, non-curatively treatable oesophageal squamous cell carcinoma is largely determined by the tumour cell PD-L1 expression or the Combined Positive Score (CPS). Against this background and taking into account the authorisation status of the medicinal products under consideration, a distinction is made between two sub-populations - depending on PD-L1 expression or the CPS value - for the determination of the appropriate comparator therapy:

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

According to the guideline recommendations, pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy should be used for patients with metastatic or locally advanced, non-curatively treatable oesophageal squamous cell carcinoma with a PD-L1 CPS ≥ 10, and nivolumab in combination with platinum- and fluoropyrimidine-based chemotherapy for those with a TPS ≥ 1%. In addition, the sole immunotherapy of nivolumab in combination with ipilimumab is also recommended for patients with a TPS ≥ 1%.

As part of the written statement procedure, the scientific-medical societies explain that the standard in the therapy of patients with unresectable, advanced, recurrent or metastatic oesophageal squamous cell carcinoma depends on PD-L1 expression and the specific authorisation conditions. Pembrolizumab in combination with platinum-containing chemotherapy and fluoropyrimidine at a CPS ≥ 10 and nivolumab in combination with platinum-containing chemotherapy and fluoropyrimidine or the sole immunotherapy of nivolumab in combination with ipilimumab – in each case, with tumour cell PD-L1 expression ≥ 1% – as well as tislelizumab in combination with platinum/fluoropyrimidine at a TAP score ≥ 5% are recommended.

The benefit assessment of pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy showed an indication of a considerable additional benefit for adults with CPS ≥ 10 compared with cisplatin in combination with 5-fluorouracil (resolution of 5 May 2022).

The benefit assessment of nivolumab showed an indication of a considerable additional benefit of nivolumab in combination with platinum- and fluoropyrimidine-based chemotherapy compared to cisplatin in combination with 5-fluorouracil for adults with tumour cell PD-L1 expression ≥ 1%. A hint for a considerable additional benefit of nivolumab in combination with ipilimumab compared to cisplatin in combination with 5-fluorouracil was determined for adults with tumour cell PD-L1 expression ≥ 1% (resolutions of 20 October 2022).

Tislelizumab in combination with platinum-based chemotherapy is another first-line treatment option for adults whose tumours express PD-L1 with a TAP score ≥ 5%. The benefit assessment of tislelizumab in combination with platinum-based chemotherapy did not show any additional benefit thereof for adults whose tumours express PD-L1 with a TAP score ≥ 5% and also have a tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10 (resolution of 18 June 2025). Taking into account the benefit assessment and given that its therapeutic significance cannot be conclusively assessed, tislelizumab in combination with platinum-based chemotherapy is not determined to be an appropriate comparator therapy.

In the overall assessment, the G-BA determined pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (at CPS ≥ 10), nivolumab in combination with platinum- and fluoropyrimidine-based chemotherapy (with tumour cell PD-L1 expression ≥ 1%) or nivolumab + ipilimumab (with tumour cell PD-L1 expression ≥ 1%) as the appropriate comparator therapy in each case for patient population a). 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 alternative therapy options are only to be considered equally appropriate in the therapeutic indication, where the patient populations have the same characteristics.

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

According to the S3 guideline recommendation, patients with metastatic or locally advanced, non-curatively treatable oesophageal squamous cell carcinoma with a CPS < 10 and a tumour cell PD-L1 expression < 1% may be treated with a combination therapy consisting of a platinum derivative and a fluoropyrimidine or a taxane as palliative systemic chemotherapy. According to the guideline, combination therapy of cisplatin with a fluoropyrimidine (5-fluorouracil or capecitabine) was often used in the underlying clinical studies. Capecitabine, oxaliplatin and taxanes are not approved in the indication and are therefore not determined as the appropriate comparator therapy.

As part of the written statement procedure, the scientific-medical societies explain that a combination chemotherapy of cisplatin and 5-fluorouracil is the standard for patients with a low PD-L1 expression corresponding to CPS < 10 or tumour cell PD-L1 expression < 1%. In addition, in their written statement on the question of comparator therapy, the scientific-medical societies state that the presumably equally effective combination therapy with FOLFOX - due to its lower toxicity - can also be recommended despite the unavailability of comparator data. The combination chemotherapy FOLFOX is not approved for the present indication and is therefore not determined as an appropriate comparator therapy.

In the overall assessment, the G-BA determined cisplatin in combination with 5-fluorouracil as the appropriate comparator therapy for patient population b).

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

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

2.1.3 Extent and probability of the additional benefit

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

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

An additional benefit is not proven.

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

An additional benefit is not proven.

Justification:

In the dossier, the pharmaceutical company did not identify any studies for direct comparison of toripalimab in combination with cisplatin and paclitaxel with the appropriate comparator therapy for the patient populations a) and b). In the dossier, they present the results of the

JUPITER-06 study. The pharmaceutical company did not derive an additional benefit compared with the appropriate comparator therapy.

JUPITER-06 study

JUPITER-06 is a randomised, double-blind, two-arm, placebo-controlled, multicentre phase III study comparing toripalimab in combination with cisplatin and paclitaxel with placebo in combination with cisplatin and paclitaxel. The study commenced in January 2019 and was completed in September 2023. It was conducted in China.

Adults with histologically or cytologically confirmed, unresectable, advanced, recurrent or metastatic oesophageal squamous cell carcinoma, for whom curative treatment was no longer an option, were enrolled in the study.

The 514 patients enrolled in the study were randomised in a 1:1 ratio to the intervention arm (N = 257) and the control arm (N = 257). It was stratified by Eastern Cooperative Oncology Group Performance Status (ECOG-PS) (0 vs 1) and prior radiotherapy (yes vs no).

In addition to the primary endpoint of progression-free survival, endpoints in the categories of mortality, morbidity, health-related quality of life and side effects were collected.

The pharmaceutical company presented the results of the data cut-offs of 22.03.2021 and 23.02.2023 in the dossier.

Conclusion

The data from the JUPITER-06 study are unsuitable for the assessment of the additional benefit of toripalimab in combination with cisplatin and paclitaxel. The comparator therapy of the study was the combination of cisplatin and paclitaxel. Neither for patient population a) nor for patient population b) does this correspond to the determined appropriate comparator therapy. Consequently, the appropriate comparator therapy has not been implemented for either patient population, and no suitable data are therefore available for an assessment of the additional benefit. An additional benefit of toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma is therefore not proven.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Loqtorzi with the active ingredient toripalimab.

Toripalimab, in combination with cisplatin and paclitaxel, is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma.

In the therapeutic indication to be considered, 2 patient groups were distinguished by tumour cell PD-L1 expression:

a) Adults with oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

b) Adults with oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line therapy

Nivolumab in combination with chemotherapy, nivolumab in combination with ipilimumab or pembrolizumab in combination with chemotherapy was determined as the appropriate comparator therapy for patient population a).

Cisplatin in combination with 5-fluorouracil was determined as the appropriate comparator therapy for patient population b).

For both patient groups, the pharmaceutical company presented the JUPITER-06 RCT comparing toripalimab in combination with cisplatin and paclitaxel with placebo in combination with cisplatin and paclitaxel.

The data from the study are unsuitable for the assessment of the additional benefit, since neither for patient population a) nor for b) does the comparator therapy correspond to the appropriate comparator therapy determined. Consequently, the appropriate comparator therapy has not been implemented, and no suitable data are therefore available for an assessment of the additional benefit. An additional benefit of toripalimab in combination with cisplatin and paclitaxel is therefore not proven.

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

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

The resolution is based on information provided by the pharmaceutical company in the dossier on the benefit assessment. The information on patient numbers is subject to uncertainty. There are therefore uncertainties regarding the distribution of the stages of the disease at the time of diagnosis. There are uncertainties regarding the distinction between resectable and unresectable tumours, as it is not clear from the source whether the percentage of patients undergoing surgery with curative intent was derived exclusively from a patient group, whose patients were at stage III at the time of diagnosis. In addition, the percentage does not refer exclusively to oesophageal squamous cell carcinomas, but also includes other oesophageal histologies. Furthermore, there are uncertainties regarding the percentage of patients in stage III at the time of diagnosis with a resectable tumour, and those in stages I and II at the time of diagnosis, taking disease progression into account.

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 Loqtorzi (active ingredient: toripalimab) at the following publicly accessible link (last access: 17 April 2026):

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

Therapy with toripalimab should only be initiated and monitored by specialists in internal medicine, haematology and oncology, experienced in the treatment of patients with oesophageal carcinoma, as well as specialists in internal medicine and gastroenterology and other specialists from other specialist groups participating in the Oncology Agreement.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide a patient identification card which contains, in particular, information on potential immune-mediated side effects.

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: 1 May 2026).

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

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

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

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

Treatment period:

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line 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				
Toripalimab in combination with cisplatin and paclitaxel				
Toripalimab	1 x per 21-day cycle	17.4	1	17.4
Cisplatin	1 x per 21-day cycle	17.4	1	17.4
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Appropriate comparator therapy				
Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (for patients with tumour cell PD-L1 expression ≥ 1%)				
Nivolumab	1 x per 14-day cycle	26.1	1	26.1
	or			
	1 x per 28-day cycle	13.0	1	13.0
Cisplatin[2]	1 x per 28-day cycle	13.0	1	13.0
5-FU[2]	1 x on day 1-5 of a 28-day cycle	13.0	5	65.0
nivolumab in combination with ipilimumab (for patients with tumour cell PD-L1 expression ≥ 1%)				
Nivolumab	1 x per 14-day cycle	26.1	1	26.1

[2] Shown as an example, based on the information under 5.1 in the product information for nivolumab.

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
	or			
	1 x per 21-day cycle	17.4	1	17.4
Ipilimumab	1 x per 42-day cycle	8.7	1	8.7
pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (for patients with a combined positive score (CPS) ≥ 10)				
Pembrolizumab	1 x per 21-day cycle	17.4	1	17.4
	or			
	1 x per 42-day cycle	8.7	1	8.7
Cisplatin[3]	1 x per 21-day cycle	17.4	1	17.4
5-FU[3]	1 x on day 1-5 of a 21-day cycle	17.4	5	87.0

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line 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				
Toripalimab in combination with cisplatin and paclitaxel				
Toripalimab	1 x per 21-day cycle	17.4	1	17.4
Cisplatin	1 x per 21-day cycle	17.4	1	17.4
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Appropriate comparator therapy				
Cisplatin in combination with 5-FU				
Cisplatin	1 x per 21-day cycle	17.4	1	17.4
5-FU	1 x on day 1-5 of a 21-day cycle	17.4	5	87.0

Consumption:

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

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

[3] Shown as an example, based on the information under 5.1 in the product information for pembrolizumab.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "Microcensus 2017 – 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)[4].

As it is not always possible to achieve the exact target dose per day with the commercially available dosage strengths, in these cases rounding up or down to the next higher or lower available dose that can be achieved with the commercially available dosage strengths as well as the scalability of the respective dosage form.

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line 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					
Toripalimab in combination with cisplatin and paclitaxel					
Toripalimab	240 mg	240 mg	1 x 240 mg	17.4	17.4 x 240 mg
Cisplatin	75 mg/m² = 143.3 mg	143.3 mg	1 x 100 mg + 1 x 50 mg	17.4	17.4 x 100 mg + 17.4 x 50 mg
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	1 x 300 mg + 2 x 30 mg	17.4	17.4 x 300 mg + 34.8 x 30 mg
Appropriate comparator therapy					
Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (for patients with tumour cell PD-L1 expression ≥ 1%)					
Nivolumab	600 mg	600 mg	1 x 600 mg	26.1	26.1 x 600 mg
	or				
	1,200 mg	1,200 mg	2 x 600 mg	13.0	26.0 x 600 mg
Cisplatin	80 mg/m² = 152.8 mg	152.8 mg	1 x 100 mg + 1 x 50 mg + 1 x 10 mg	13.0	13.0 x 100 mg + 13.0 x 50 mg + 13.0 x 10 mg
5-FU	1,900 mg/m² = 1,528 mg	1,528 mg	1 x 2,500 mg	65.0	65.0 x 2,500 mg
nivolumab in combination with ipilimumab (for patients with tumour cell PD-L1 expression ≥ 1%)					
Nivolumab	3 mg/kg = 233.1 mg	233.1 mg	2 x 120 mg	26.1	52.2 x 120 mg
	or				
	360 mg	360 mg	3 x 120 mg	17.4	52.2 x 120 mg
Ipilimumab	1 mg/kg =	77.7 mg	2 x 50 mg	8.7	17.4 x 50 mg

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

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
	77.7 mg				
pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (for patients with a combined positive score (CPS) ≥ 10)					
Pembrolizumab	200 mg	200 mg	2 x 100 mg	17.4	34.8 x 100 mg
	or				
	400 mg	400 mg	4 x 100 mg	8.7	34.8 x 100 mg
Cisplatin	80 mg/m² = 152.8 mg	152.8 mg	1 x 100 mg + 1 x 50 mg + 1 x 10 mg	17.4	17.4 x 100 mg + 17.4 x 50 mg + 17.4 x 10 mg
5-FU	800 mg/m² = 1,528 mg	1,528 mg	1 x 2,500 mg	87.0	87.0 x 2,500 mg

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line 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					
Toripalimab in combination with cisplatin and paclitaxel					
Toripalimab	240 mg	240 mg	1 x 240 mg	17.4	17.4 x 240 mg
Cisplatin	75 mg/m² = 143.3 mg	143.3 mg	1 x 100 mg + 1 x 50 mg	17.4	17.4 x 100 mg + 17.4 x 50 mg
Paclitaxel	175 mg/m² = 334.3 mg	334.3 mg	1 x 300 mg + 2 x 30 mg	17.4	17.4 x 300 mg + 34.8 x 30 mg
Appropriate comparator therapy					
Cisplatin in combination with 5-FU					
Cisplatin	100 mg/m² = 191.0 mg	191.0 mg	2 x 100 mg	17.4	34.8 x 100 mg
5-FU	1,000 mg/m² = 1,910 mg	1,910 mg	1 x 2,500 mg	87.0	87.0 x 2,500 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:

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line 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					
Toripalimab 240 mg	1 CIS	€ 6,021.91	€ 1.77	€ 340.62	€ 5,679.52
Cisplatin 100 mg	1 CIS	€ 76.59	€ 1.77	€ 3.10	€ 71.72
Cisplatin 50 mg	1 CIS	€ 47.71	€ 1.77	€ 1.73	€ 44.21
Cisplatin 10 mg	1 CIS	€ 19.67	€ 1.77	€ 1.06	€ 16.84
Paclitaxel 300 mg	1 CIS	€ 845.77	€ 1.77	€ 39.60	€ 804.40
Paclitaxel 30 mg	1 CIS	€ 94.76	€ 1.77	€ 3.96	€ 89.03
Appropriate comparator therapy					
Cisplatin 100 mg	1 CIS	€ 76.59	€ 1.77	€ 3.10	€ 71.72
Cisplatin 50 mg	1 CIS	€ 47.71	€ 1.77	€ 1.73	€ 44.21
Cisplatin 10 mg	1 CIS	€ 19.67	€ 1.77	€ 1.06	€ 16.84
Fluorouracil 2,500 mg	1 SFI	€ 23.60	€ 1.77	€ 0.97	€ 20.86
Ipilimumab 50 mg	10 CIS	€ 3,489.23	€ 1.77	€ 195.98	€ 3,291.48
Nivolumab 120 mg	1 CIS	€ 1,539.71	€ 1.77	€ 84.64	€ 1,453.30
Nivolumab 600 mg	1 SFI	€ 3,021.74	€ 1.77	€ 169.28	€ 2,850.69
Paclitaxel 300 mg	1 CIS	€ 845.77	€ 1.77	€ 39.60	€ 804.40
Paclitaxel 30 mg	1 CIS	€ 94.76	€ 1.77	€ 3.96	€ 89.03
Pembrolizumab 100 mg	2 CIS	€ 4,876.44	€ 1.77	€ 275.20	€ 4,599.47
Abbreviations: CIS = concentrate for the preparation of an infusion solution; SII = solution for injection/infusion					

LAUER-TAXE® last revised: 1 May 2026

Costs for additionally required SHI services:

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

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

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

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	Treatment days/ year	Costs/ patient/ year
Medicinal product to be assessed							
Paclitaxel (toripalimab in combination with cisplatin and paclitaxel)							
Dexamethasone[5] 2 x 20 mg	50 TAB x 20 mg	€ 118.88	€ 1.77	€ 0.00	€ 117.11	17.4	€ 81.51
Dimetindene IV 1 mg/10 kg = 7.7 mg	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	17.4	€ 122.15
Cimetidine IV 300 mg	10 AMP x 200 mg	€ 22.56	€ 1.77	€ 1.42	€ 19.37	17.4	€ 67.41
Cisplatin							
Antiemetic treatment: In clinical practice, an appropriate antiemetic treatment is established before and/or after administration of cisplatin. The product information for cisplatin does not provide any specific information on this, which is why the necessary costs cannot be quantified.							
Hydration and forced diuresis (17.4 cycles)							
Mannitol 10% Inf. sol., 37.5 g/day	10 x 500 ml INF	€ 105.54	€ 5.28	€ 4.26	€ 96.00	17.4	€ 167.04
Sodium chloride 0.9% Inf. sol., 3 - 4.4 l/day	10 x 1,000 ml INF	€ 23.10	€ 1.16	€ 1.89	€ 20.05	17.4	€ 104.66 – € 174.44
Appropriate comparator therapy							
Cisplatin							
Antiemetic treatment: In clinical practice, an appropriate antiemetic treatment is established before and/or after administration of cisplatin. The product information for cisplatin does not provide any specific information on this, which is why the necessary costs cannot be quantified.							
Nivolumab in combination with fluoropyrimidine- and platinum-based combination chemotherapy (for patients with tumour cell PD-L1 expression ≥ 1%)							
Hydration and forced diuresis (13.0 cycles)							
Mannitol 10% Inf. sol., 37.5 g/day	10 x 500 ml INF	€ 105.54	€ 5.28	€ 4.26	€ 96.00	13.0	€ 124.80
Sodium chloride 0.9% Inf. sol.,	10 x 1,000 ml INF	€ 23.10	€ 1.16	€ 1.89	€ 20.05	13.0	€ 78.20 –

[5] Fixed reimbursement rate

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	Treatment days/ year	Costs/ patient/ year
3 - 4.4 l/day							€ 130.33
pembrolizumab in combination with platinum- and fluoropyrimidine-based chemotherapy (for patients with a combined positive score (CPS) ≥ 10) Cisplatin in combination with 5-FU							
Hydration and forced diuresis (17.4 cycles)							
Mannitol 10% Inf. sol., 37.5 g/day	10 x 500 ml INF	€ 105.54	€ 5.28	€ 4.26	€ 96.00	17.4	€ 167.04
Sodium chloride 0.9% Inf. sol., 3 - 4.4 l/day	10 x 1,000 ml INF	€ 23.10	€ 1.16	€ 1.89	€ 20.05	17.4	€ 104.66 – € 174.44
Abbreviations: AMP = ampoules; SFI = solution for injection; INF = infusion solution; TAB = tablets							

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Other SHI services:

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

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

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

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

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed

therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved

exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

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

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

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

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

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

<u>Concomitant active ingredient</u>

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

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2, paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with

the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

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

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

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

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

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

Designation

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

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

Exception to the designation

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

preceding findings were based.

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

Legal effects of the designation

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

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

Justification for the findings on designation in the present resolution:

a) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma with tumour cell PD-L1 expression ≥ 1% or a Combined Positive Score (CPS) ≥ 10; first-line therapy

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

   References:
   Product information for toripalimab (Loqtorzi); LOQTORZI 240 mg infusion solution concentrate; last revised: September 2025

b) Adults with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma who do not exhibit tumour cell PD-L1 expression ≥ 1% and do not have a Combined Positive Score (CPS) ≥ 10; first-line 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 toripalimab (Loqtorzi); LOQTORZI 240 mg infusion solution concentrate; last revised: September 2025

2.6 Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product Loqtorzi is a medicinal product placed on the market from 1 January 2025. In accordance with Section 35a, paragraph 3, sentence 5 SGB V, the G-BA must

determine whether a relevant percentage of the clinical studies on the medicinal product were conducted within the scope of SGB V. This is the case if the percentage of study participants who have participated in the clinical studies on the medicinal product to be assessed in the therapeutic indication to be assessed at study sites within the scope of SGB V is at least five per cent of the total number of study participants.

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

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

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5 per cent (0%) of the total number of study participants according to the information provided by the pharmaceutical company.

The information is reasonable in relation to the analysis population used by the pharmaceutical company. In comparison with the Common Technical Document (CTD), further studies, which were submitted to the regulatory authority for the assessment of the clinical efficacy and safety of the medicinal product in the therapeutic indication to be assessed, were identified. However, their inclusion does not alter the percentage mentioned above, as it is clear from the study registry entries that these studies were conducted exclusively in other countries.

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

3. Bureaucratic costs calculation

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

4. Process sequence

At their session on 12 August 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 14 January 2026, the pharmaceutical company submitted a dossier for the benefit assessment of toripalimab to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 14 January 2026 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 toripalimab.

The dossier assessment by the IQWiG was submitted to the G-BA on 13 April 2026, and the written statement procedure was initiated with publication on the G-BA website on 15 April 2026. The deadline for submitting written statements was 6 May 2026.

The oral hearing was held on 26 May 2026.

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

The evaluation of the written statements received and the oral hearing was discussed at the Subcommittee's session on 23 June 2026, and the draft resolution was conclusively discussed.

At their session on 2 July 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 August 2025	Determination of the appropriate comparator therapy
Working group Section 35a	20 May 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	26 May 2026	Conduct of the oral hearing
Working group Section 35a	3 June 2026 17 June 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	23 June 2026	Concluding discussion of the draft resolution
Plenum	2 July 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 2 July 2026

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

Dr Optendrenk