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
Mirvetuximab soravtansine (reassessment of an orphan drug after exceeding the EUR 30 million limit (ovarian, fallopian tube or primary peritoneal cancer, FRα-positive, platinum-resistant, after 1 to 3 prior therapies))

From 16 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.

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

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

2. Key points of the resolution

The active ingredient mirvetuximab soravtansine (Elahere) was listed for the first time on 15 December 2024 in the "LAUER-TAXE®", the extensive German registry of available drugs and their prices. Elahere for the treatment of ovarian, fallopian tube or primary peritoneal cancer is approved as a medicinal product for the treatment of rare diseases under Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999.

At their session on 5 June 2025, the G-BA decided on the benefit assessment of mirvetuximab soravtansine in the therapeutic indication "Monotherapy for the treatment of adults with folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1-3 prior systemic treatment regimens" in accordance with Section 35a SGB V.

If the sales of the orphan drug through the statutory health insurance at pharmacy sales prices and outside the scope of SHI-accredited medical care, including value-added tax, exceed an amount of € 30 million in the last twelve calendar months, the pharmaceutical company must

submit evidence in accordance with Chapter 5, Section 5, paragraphs 1 to 6 Rules of Procedure (VerfO) within three months of being requested to do so by the Federal Joint Committee, and in this evidence, must demonstrate the additional benefit compared to the appropriate comparator therapy.

By letter dated 20 November 2025, the pharmaceutical company was requested to submit a dossier for the benefit assessment according to Section 35a SGB V by 1 March 2026, due to exceeding the EUR 30 million turnover limit within the period from December 2024 to September 2025. Pursuant to Section 4, paragraph 3, number 4 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 6 Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the G-BA on 30 October 2025.

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

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

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 Mirvetuximab soravtansine (Elahere) in accordance with the product information

Elahere as monotherapy is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens (see section 4.2).

Therapeutic indication of the resolution (resolution of 16.07.2026):

See the approved therapeutic indication

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

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

Adult patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior therapies

Appropriate comparator therapy for mirvetuximab soravtansine:

- Paclitaxel (with or without bevacizumab for bevacizumab-naïve patients)

or

- pegylated liposomal doxorubicin (with or without bevacizumab for bevacizumab-naïve patients)

or

- topotecan (with or without bevacizumab for bevacizumab-naïve patients)

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. With regard to the authorisation status, the active ingredients bevacizumab, carboplatin, cisplatin, cyclophosphamide, doxorubicin, pegylated liposomal doxorubicin, epirubicin, etoposide, melphalan, paclitaxel, topotecan and treosulfan are available for the treatment of platinum-resistant epithelial ovarian, fallopian tubes, or primary peritoneal cancer.

To date, apart from mirvetuximab soravtansine, no medicinal treatments have been approved specifically for the treatment of folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer.

On 2. A non-medicinal treatment is not considered in the present therapeutic indication.

On 3. No corresponding resolutions or assessments of the G-BA are available.

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"). There is a joint written statement from the German Society for Haematology and Medical Oncology (DGHO), the German Society of Gynaecology and Obstetrics (DGGG) for the guideline programme Oncology (AWMF, German Cancer Society, German Cancer Aid), and the North-East German Society for Gynaecological Oncology (NOGGO).

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.

When determining the appropriate comparator therapy, a response to platinum-containing pretreatment, with a recurrence-free interval of less than 6 months, is assumed for platinum-resistant, relapsing ovarian carcinoma. This also includes platinum-refractory ovarian carcinomas. These carcinomas do not respond to platinum-containing chemotherapy or progress within 4 weeks of the end of treatment.

In accordance with the S3 guideline "Diagnosis, Therapy and After-care for Malignant Ovarian Tumours", patients with platinum-resistant and/or platinum-refractory

recurrent ovarian carcinoma should receive non-platinum-containing monochemotherapy if there is an indication for chemotherapy. According to the S3 guideline, the following cytostatic agents may be considered: paclitaxel, topotecan, pegylated liposomal doxorubicin and gemcitabine. The active ingredient gemcitabine is not approved for the present therapeutic indication.

Furthermore, according to the S3 guideline, bevacizumab in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin may be used for the treatment of patients with platinum-resistant recurrence, provided that the patients are suitable for bevacizumab and have not previously received therapy containing bevacizumab or therapy with another VEGF inhibitor or a substance targeting the VEGF receptor.

According to written statements from scientific-medical societies, the treatment standard for patients with platinum-resistant ovarian, primary peritoneal or fallopian tube cancer is a therapy according to doctor's instructions, taking into account monochemotherapy with paclitaxel, pegylated liposomal doxorubicin, topotecan or gemcitabine (off-label use), if applicable, in combination with bevacizumab (for bevacizumab-naïve patients).

In the overall assessment, the G-BA determined paclitaxel, pegylated liposomal doxorubicin and topotecan (for bevacizumab-naïve patients, with or without bevacizumab) as equally appropriate comparator therapies.

The appropriate comparator therapy determined here includes several therapy options. These therapy options are equally appropriate for the comparator therapy. The additional benefit can be demonstrated compared to one of the therapy options mentioned.

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 mirvetuximab soravtansine is assessed as follows:

Adult patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior therapies

Indication of a considerable additional benefit.

Justification:

For the assessment of the additional benefit of mirvetuximab soravtansine in the therapeutic indication of high grade serous epithelial ovarian cancer after one to three prior therapies, the pharmaceutical company presented data from the multicentre, open-label, randomised phase III MIRASOL and FORWARD 1 studies as well as a meta-analysis of these two studies.

MIRASOL study

The MIRASOL study is a multicentre, open-label, randomised phase III study conducted between 2020 and 2024 to investigate the efficacy and safety of mirvetuximab in adult patients with high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens and whose tumours have a high folate receptor-alpha (FRα) level. Female patients with an ECOG Performance Status (PS) of 0-1 were enrolled in the study. The study is being conducted in 136 study sites in Asia, Australia, Europe and the USA.

A total of 453 patients were enrolled in the study and randomised in a 1:1 ratio into the intervention arm (mirvetuximab soravtansine, N = 227) and the comparator arm (therapy according to doctor's instructions with selection of paclitaxel, pegylated liposomal doxorubicin and topotecan, N = 226).

The primary endpoint of the study was progression-free survival (PFS). Other endpoints were overall survival and endpoints in the categories of morbidity, health-related quality of life and side effects.

For the benefit assessment, the results of the final data cut-off from 26.09.2024 are used.

FORWARD 1 study

The FORWARD 1 study is a multicentre, open-label, randomised phase III study conducted between 2017 and 2020 to investigate the efficacy and safety of mirvetuximab in adult patients with high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens and whose tumours are folate receptor-alpha (FRα) positive (medium or high expression). Female patients with an ECOG PS of 0-1 were enrolled in the study. The study is being conducted in 101 study sites, mainly in Europe and the USA.

A total of 366 patients were enrolled in the study and randomised in a 2:1 ratio into the intervention arm (mirvetuximab soravtansine, N = 248) and the comparator arm (therapy according to doctor's instructions with selection of paclitaxel, pegylated liposomal doxorubicin and topotecan, N = 118). Randomisation was stratified according to "number of prior therapies (1 or 2 vs 3)", "FRα-level (≥ 75% of tumour cells with membrane staining vs ≥ 50% and < 75% of tumour cells with membrane staining)" and according to "choice of IC chemotherapy prior to randomisation (paclitaxel vs pegylated liposomal doxorubicin (PLD) vs topotecan)".

The primary endpoint of the study was progression-free survival (PFS). Other endpoints were overall survival and endpoints in the categories of morbidity, health-related quality of life and side effects.

In the dossier, the pharmaceutical company presented data on the benefit assessment-relevant sub-population of patients with ovarian cancer and high FRα-expression, corresponding to the therapeutic indication according to the product information. This post-hoc defined modified population comprises 116 patients in total, with 82 patients in the treatment arm and 34 patients in the control arm.

For the benefit assessment, the results of the final data cut-off from 18.03.2020 are used.

Meta-analysis

In addition to the results of the individual studies, the pharmaceutical company presented a post-hoc meta-analytical evaluation of the MIRASOL and FORWARD 1 studies in the dossier.

The summary of the two studies is considered appropriate and the results of the meta-analysis are used as a basis for the benefit assessment alongside the results of the individual studies.

Limitations of the MIRASOL and FORWARD 1 studies

As part of the evaluation of the implementation of the appropriate comparator therapy in the IQWiG's dossier assessment, a separate assessment of the additional benefit was conducted for patients for whom monotherapy with paclitaxel, PLD, or topotecan or a combination therapy with bevacizumab constitutes a suitable therapy. This took place against the backdrop that the comparators paclitaxel, pegylated liposomal doxorubicin and topotecan were used in both studies as part of a therapy according to doctor's instructions; a combination with bevacizumab was not an option in either study. In the EPAR, the EMA describes that the selection of comparators is almost in line with the current guideline recommendations, but also points out that chemotherapy in combination with bevacizumab is recommended for patients without contraindications and without prior exposure to bevacizumab.

Based on both studies, a combination therapy with bevacizumab would have been an option for a maximum of 27% of patients in accordance with the requirements in the product information at the time of enrolment in the study. It is not clear from the data presented in the benefit assessment procedure why bevacizumab-naïve patients in the study did not receive bevacizumab-containing chemotherapy, especially since up to 18% of patients received bevacizumab as part of the subsequent therapy. It therefore remains unclear whether a significant percentage of patients would have been suitable for bevacizumab-containing therapy**.**

This gives rise to uncertainty regarding the transferability to the German healthcare context.

In this assessment, the G-BA do not carry out a separate assessment of the additional benefit for patients for whom monotherapy with paclitaxel, PLD or topotecan, or a combination therapy with bevacizumab, constitutes a suitable therapy.

<u>Extent and probability of the additional benefit</u>

<u>Mortality</u>

Overall survival in the MIRASOL and FORWARD 1 studies was operationalised as the time from randomisation to death from any cause.

For the endpoint of overall survival, the MIRASOL study and the meta-analysis showed a statistically significant advantage in favour of mirvetuximab soravtansine. The extent of the prolongation achieved in overall survival is assessed as a relevant improvement.

Progression-free survival

Progression-free survival (PFS) was operationalised in the MIRASOL and FORWARD 1 studies as the time from randomisation to occurrence of radiological disease progression or death from any cause, whichever occurred first. The endpoint was collected in both studies by principal investigators on site as well as using BICR, and was assessed according to the RECIST criteria version 1.1. For the PFS endpoint, both the MIRASOL study and the meta-analysis showed a statistically significant advantage in favour of mirvetuximab soravtansine.

The PFS endpoint is a composite endpoint comprising endpoints of the mortality and morbidity categories. The endpoint component "Mortality" is already surveyed via the endpoint "Overall survival" as an independent endpoint. The morbidity component assessment was not done in a symptom-related manner but exclusively by means of imaging (disease progression assessed by radiology according to the RECIST version 1.1 criteria).

Taking into account the aspects mentioned above, there are different opinions within the G-BA regarding the patient relevance of the PFS endpoint. The overall statement on the additional benefit remains unaffected.

Symptomatology

Symptomatology was assessed using the instruments EORTC QLQ-C30, EORTC QLQ-OV28, EQ-5D-VAS, PGIS (only in the MIRASOL study) and FOSI (only in the FORWARD 1 study).

The return rates are below 70% in the control arm at the first scheduled follow-up survey (week 8/9), and are therefore unsuitable for the benefit assessment.

Quality of life

EORTC QLQ-C30 and EORTC QLQ-OV28

Health-related quality of life was assessed using the EORTC QLQ-C30 and EORTC QLQ-OV28 instruments.

The return rates are below 70% in the control arm at the first scheduled follow-up survey (week 8/9), and are therefore unsuitable for the benefit assessment.

Side effects

Total adverse events (AEs)

In the MIRASOL and FORWARD 1 studies, AEs occurred in both study arms in almost all patients. The results were only presented additionally.

Serious adverse events (SAEs); severe AEs (CTCAE grade 3 or 4) and therapy discontinuation due to adverse events

For the endpoints of SAEs, severe AEs and therapy discontinuation due to AEs, there were statistically significant differences to the advantage of mirvetuximab soravtansine.

Specific AEs

Detailed analysis of the specific adverse events showed statistically significant differences to the disadvantage of mirvetuximab soravtansine with regard to eye disorders (AEs and severe AEs) and pneumonitis (AEs). Detailed analysis showed statistically significant differences to the advantage of mirvetuximab soravtansine with regard to dyspnoea (AEs), stomatitis (AEs), skin and subcutaneous tissue disorders (AEs), small bowel obstruction (SAEs), blood and lymphatic system disorders (severe AEs) and fatigue (severe AEs).

Overall, a clear advantage of mirvetuximab soravtansine over paclitaxel, pegylated liposomal doxorubicin or topotecan was observed in the endpoint category of side effects.

Overall assessment

For the benefit assessment, results on mortality, morbidity, quality of life and side effects from the open-label, randomised, controlled phase III MIRASOL and FORWARD 1 studies as well as the meta-analysis of these two studies comparing mirvetuximab soravtansine with a therapy according to doctor's instructions with selection of paclitaxel, pegylated liposomal doxorubicin and topotecan are available.

For the endpoint of overall survival, the MIRASOL study and the meta-analysis showed a statistically significant advantage in favour of mirvetuximab soravtansine. The extent of the prolongation achieved in overall survival is assessed as a relevant improvement.

No assessable data on morbidity and health-related quality of life are available.

For the endpoint category of side effects, there were statistically significant advantages for SAEs, severe AEs and therapy discontinuation due to AEs, which are assessed as a significant improvement. In detail, there were advantages and disadvantages for specific AEs.

In the overall assessment, the G-BA identified a considerable additional benefit of mirvetuximab soravtansine for patients with folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior therapies due to relevant advantages in overall survival and clear advantages in side effects.

Reliability of data (probability of additional benefit)

This benefit assessment is based on the results of the open-label, randomised, controlled phase III MIRASOL and FORWARD 1 studies as well as the meta-analysis of these two studies.

The risk of bias is considered to be low at study level and for the endpoints of overall survival and side effects.

No assessable data on morbidity and health-related quality of life are available. In view of the fact that high significance is attributed to statements on quality of life especially in the advanced palliative setting, there is uncertainty regarding the reliability of data.

A significant percentage of bevacizumab-naïve patients did not receive bevacizumab in the FORWARD 1 and MIRASOL studies, even though they were, in principle, suitable for it. The reasons for this were not documented in the studies. This gives rise to uncertainty regarding the transferability to the German healthcare context.

Overall, the G-BA derive an indication of the identified additional benefit in terms of reliability of data.

2.1.4 Summary of the assessment

The present assessment is the new benefit assessment of the medicinal product Elahere with the active ingredient mirvetuximab soravtansine due to exceeding the EUR 30 million turnover limit.

Mirvetuximab soravtansine (Elahere) as monotherapy was approved for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens.

The results from the open-label, randomised, controlled phase III MIRASOL and FORWARD 1 studies as well as a meta-analysis of these two studies are available for the benefit assessment. In both studies, mirvetuximab soravtansine was compared with a therapy according to doctor's instructions with selection of paclitaxel, pegylated liposomal doxorubicin and topotecan.

Paclitaxel, pegylated liposomal topotecan and topotecan – each with or without bevacizumab – were determined as equally appropriate comparator therapies for bevacizumab-naïve patients.

For the endpoint of overall survival, there was a statistically significant difference to the advantage of mirvetuximab soravtansine, the extent of which was assessed as a relevant improvement.

No assessable data on morbidity and health-related quality of life are available.

In terms of side effects, there were clear advantages for the SAEs, severe AEs and therapy discontinuation due to AEs, as well as advantages and disadvantages for specific AEs in detail.

In the overall assessment, there were relevant advantages in overall survival and clear advantages in side effects. No assessable data on morbidity and health-related quality of life are available. Overall, a considerable additional benefit of mirvetuximab soravtansine was identified.

The reliability of data for the additional benefit identified is classified in the "indication" category overall.

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 information presented by the pharmaceutical company in the dossier is subject to uncertainties. In this regard, it can be assumed that some patients do not suffer disease progression during second or third-line systemic therapy or a relapse thereafter in the same year, but later.

Further uncertainties arise, in particular, from the unclear transferability of the percentage values from the underlying literature to the respective calculation step.

Given that the significant uncertainties persist, taking into account the figures from the resolution of 5 June 2025 on the benefit assessment of mirvetuximab soravtansine, the G-BA consider that the information submitted by the pharmaceutical company in the present procedure does not constitute a better estimate.

Against this background and in order to ensure a consistent determination of the patient numbers in the present therapeutic indication, the G-BA refer to the derivation of the target population used as a basis in the resolution on the benefit assessment of mirvetuximab soravtansine dated 5 June 2025; this derivation can be used despite persisting uncertainties.

2.3 Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Elahere (active ingredient: mirvetuximab soravtansine) at the following publicly accessible link (last access: 30 June 2026):

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

Treatment with mirvetuximab soravtansine should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, experienced in the treatment of patients with ovarian cancer, as well as specialists in gynaecology, and other doctors from other specialist groups participating in the Oncology Agreement.

Prior to treatment with mirvetuximab soravtansine and in the event of eye symptoms, an eye examination should be carried out by an ophthalmologist. Prior to each cycle, patients should also be advised to report any new or deteriorating eye symptoms to the treating doctor or specialist staff.

2.4 Treatment costs

The treatment costs are based on the requirements of the product information and the information listed in the LAUER-TAXE® (last revised: 15 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:

Adult patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior therapies

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Mirvetuximab soravtansine				
Mirvetuximab soravtansine	1 x per 21-day cycle	17.4	1	17.4
Appropriate comparator therapy				
Paclitaxel (with or without bevacizumab for bevacizumab-naïve patients)				
Paclitaxel (monotherapy)				
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Paclitaxel in combination with bevacizumab				
Paclitaxel	1 x per 21-day cycle	17.4	1	17.4
Bevacizumab	1 x per 14-day cycle	26.1	1	26.1
Pegylated liposomal doxorubicin (with or without bevacizumab for bevacizumab-naïve patients)				
Pegylated liposomal doxorubicin (monotherapy)				

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Pegylated liposomal doxorubicin	1 x per 28-day cycle	13.0	1	13.0
Pegylated liposomal doxorubicin in combination with bevacizumab				
Pegylated liposomal doxorubicin	1 x per 28-day cycle	13.0	1	13.0
Bevacizumab	1 x per 14-day cycle	26.1	1	26.1
Topotecan (with or without bevacizumab for bevacizumab-naïve patients)				
Topotecan (monotherapy)				
Topotecan	1 x on day 1 - 5 of a 21-day cycle	17.4	5	87.0
Topotecan in combination with bevacizumab				
Topotecan	1 x on day 1 - 5 of a 21-day cycle	17.4	5	87.0
Bevacizumab	1 x per 21-day cycle	17.4	1	17.4

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.

For dosages depending on body weight (BW) or body surface area (BSA), the average body measurements from the official representative statistics "2025 Microcensus – body measurements of the population" were applied (average body height of women: 1.66 m, average body weight of women: 69.7 kg). This results in a body surface area of 1.78 m² (calculated according to Du Bois 1916)[2].

According to the product information, the recommended dose of mirvetuximab soravtansine is 6 mg/kg adjusted ideal body weight (AIBW) once every 3 weeks as an intravenous infusion. The use of the AIBW reduces the exposure variability between underweight and overweight patients.

The AIBW is calculated using the ideal body weight (IBW) of women as follows:

IBW = 0.9 × body height [cm] – 92

AIBW = ideal body weight (IBW [kg]) + 0.4 x (actual body weight [kg] - IBW)

[2] Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

According to the average body measurements for women taken from the official representative statistics "2025 Microcensus", the AIBW is 62.32 kg.

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.

Adult patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior therapies

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					
Mirvetuximab soravtansine					
Mirvetuximab soravtansine	6 mg/kg AIBW = 373.92 mg	373.92 mg	4 x 100 mg	17.4	69.6 x 100 mg
Appropriate comparator therapy					
Paclitaxel (with or without bevacizumab for bevacizumab-naïve patients)					
Paclitaxel (monotherapy)					
Paclitaxel	175 mg/m^2 = 311.5 mg	311.5 mg	1 x 300 mg + 1 x 30 mg	17.4	17.4 x 300 mg + 17.4 x 30 mg
Paclitaxel in combination with bevacizumab					
Paclitaxel	175 mg/m^2 = 311.5 mg	311.5 mg	1 x 300 mg + 1 x 30 mg	17.4	17.4 x 300 mg + 17.4 x 30 mg
Bevacizumab	10 mg/kg = 697 mg	697 mg	1 x 400 mg + 3 x 100 mg	26.1	26.1 x 400 mg + 78.3 x 100 mg
Pegylated liposomal doxorubicin (with or without bevacizumab for bevacizumab-naïve patients)					
Pegylated liposomal doxorubicin (monotherapy)					
Pegylated liposomal doxorubicin	50 mg/m^2 = 89 mg	89 mg	2 x 50 mg	13.0	26.0 x 50 mg
Pegylated liposomal doxorubicin in combination with bevacizumab					
Pegylated liposomal doxorubicin	50 mg/m^2 = 89 mg	89 mg	2 x 50 mg	13.0	26.0 x 50 mg
Bevacizumab	10 mg/kg = 697 mg	697 mg	1 x 400 mg + 3 x 100 mg	26.1	26.1 x 400 mg + 78.3 x 100 mg
Topotecan (with or without bevacizumab for bevacizumab-naïve patients)					
Topotecan (monotherapy)					
Topotecan	1.5 mg/m^2 = 2.67 mg	2.67 mg	1 x 3 mg	87.0	87.0 x 3 mg
Topotecan in combination with bevacizumab					
Topotecan	1.5 mg/m^2	2.67 mg	1 x 3 mg	87.0	87.0 x 3 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
	= 2.67 mg				
Bevacizumab	15 mg/kg = 1,045.50 mg	1,045.50 mg	2 x 400 mg + 3 x 100 mg	17.4	52.2 x 400 mg + 34.8 x 100 mg

Costs:

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

Costs of the medicinal products:

Adult patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior therapies

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					
Mirvetuximab soravtansine 100 mg	1 CIS	€ 3,734.76	€ 1.77	€ 210.00	€ 3,522.99
Appropriate comparator therapy					
Bevacizumab 100 mg	1 CIS	€ 176.43	€ 1.77	€ 9.14	€ 165.52
Bevacizumab 400 mg	1 CIS	€ 671.80	€ 1.77	€ 36.57	€ 633.46
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
Pegylated liposomal doxorubicin	1 CIS	€ 1,778.90	€ 1.77	€ 224.69	€ 1,552.44
Topotecan 3 mg	1 CIS	€ 236.46	€ 1.77	€ 12.47	€ 222.22
Abbreviations: CIS = concentrate for the preparation of an infusion solution					

LAUER-TAXE® last revised: 15 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.

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

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

Mirvetuximab soravtansine

Prophylactic premedication

According to the product information for mirvetuximab soravtansine, anti-inflammatory, antihistamine, antipyretic and antiemetic premedication is required; however, the antiemetic premedication is not specified in further detail and, as a result, cannot be quantified.

Eye examination

Before starting treatment with mirvetuximab soravtansine, an ophthalmological examination, including the assessment of visual acuity and a slit lamp examination, must be carried out.

Designation of the therapy	Designation of the service	Number	Unit cost	Costs/ patient/ year
Mirvetuximab soravtansine				
Ophthalmological examination	Assessment of visual acuity and slit lamp microscopy (FSI: 51050)	1	€ 15.12	€ 15.12

Status of the Uniform Value Scale (UVS): 3rd quarter 2025

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							
Mirvetuximab soravtansine							
Dexamethasone IV 10 mg	10 SFI x 5 mg	€ 17.65	€ 1.77	€ 0.52	€ 15.36	17.4	€ 53.45
Dimetindene IV 1 mg/ 10 kg = 6.97 mg	5 SFI x 4 mg	€ 26.24	€ 1.77	€ 6.92	€ 17.55	17.4	€ 122.15
Paracetamol 500 mg - 1,000 mg	20 TAB x 500 mg	€ 3.47	€ 0.17	€ 0.15	€ 3.15	17.4	€ 2.74 -

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
	10 TAB x 1,000 mg	€ 3.32	€ 0.17	€ 0.14	€ 3.01		€ 5.24
Appropriate comparator therapy							
Paclitaxel							
Dexamethasone[3] 2 x 20 mg	50 TAB x 20 mg	€ 11.88	€ 1.77	€ 0.00	€ 117.11	17.4	€ 81.54
Dimetindene IV 1 mg/ 10 kg = 6.97 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
Abbreviations: AMP = ampoules; SFI = solution for injection; TAB = tablets							

LAUER-TAXE® last revised: 15 May 2026

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

[3] Fixed reimbursement rate

authorisation under Medicinal Products Act.

Basic principles of the assessed medicinal product

A designation in accordance with Section 35a, paragraph 3, sentence 4 SGB V requires that it is examined based on the product information for the assessed medicinal product whether it can be used in a combination therapy with other medicinal products in the assessed therapeutic indication. In the first step, the examination is carried out on the basis of all sections of the currently valid product information for the assessed medicinal product.

If the assessed medicinal product contains an active ingredient or a fixed combination of active ingredients in the therapeutic indication of the resolution (assessed therapeutic indication) and is approved exclusively for use in monotherapy, a combination therapy is not considered due to the marketing authorisation under Medicinal Products Act, which is why no designation is made.

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

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

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

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

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

Concomitant active ingredient

The concomitant active ingredient is a medicinal product with new active ingredients that can

be used in combination therapy with the assessed medicinal product for the therapeutic indication to be assessed.

For a medicinal product to be considered as a concomitant active ingredient, it must be classified as a medicinal product with new active ingredients according to Section 2, paragraph 1 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with the corresponding regulations in Chapter 5 of the Rules of Procedure of the G-BA as of the date of the present resolution. In addition, the medicinal product must be approved in the assessed therapeutic indication, whereby a marketing authorisation is sufficient only for a sub-area of the assessed therapeutic indication.

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

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

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

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

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

Designation

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

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

Exception to the designation

The designation excludes combination therapies for which - patient group-related - a

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

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

Legal effects of the designation

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

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

Justification for the findings on designation in the present resolution:

Adult patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior therapies

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

3. Bureaucratic costs calculation

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

4. Process sequence

At their session on 11 June 2024, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 23 January 2026, the pharmaceutical company submitted a dossier for the benefit assessment of mirvetuximab soravtansine to the G-BA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 6 VerfO.

By letter dated 26 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 mirvetuximab soravtansine.

The dossier assessment by the IQWiG was submitted to the G-BA on 28 April 2026, and the written statement procedure was initiated with publication on the G-BA website on 4 May 2026. The deadline for submitting written statements was 26 May 2026.

The oral hearing was held on 8 June 2026.

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

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 7 July 2026, and the draft resolution was conclusively discussed.

At their session on 16 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	11 June 2024	Determination of the appropriate comparator therapy
Working group Section 35a	3 June 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	8 June 2026	Conduct of the oral hearing
Working group Section 35a	17 June 2026 30 June 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	7 July 2026	Concluding discussion of the draft resolution
Plenum	16 July 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 16 July 2026

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

Dr Optendrenk