Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee 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

At their session on 16 July 2026, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the information on the active ingredient Mirvetuximab soravtansine in the version of the resolution of 16 June 2025 (Federal Gazette, BAnz AT 22.07.2025 B1) shall be replaced by the following information

Mirvetuximab soravtansine

Resolution of: 16 July 2026
Entry into force on: 16 July 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 14 November 2024):

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 July 2026):

See therapeutic indication according to marketing authorisation.

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

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:

– 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)

Extent and probability of the additional benefit of mirvetuximab soravtansine compared with paclitaxel, pegylated liposomal doxorubicin or topotecan:

Indication of a considerable additional benefit.

Study results according to endpoints:[1]

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑↑	Advantage in overall survival
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	↑↑	Advantages in SAEs, severe AEs and therapy discontinuation due to AEs. Advantages and disadvantages in the specific AEs, in detail. The disadvantages of specific AEs are particularly evident in eye disorders.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

Studies

MIRASOL

- Randomised, open-label, multicentre phase III study
- Mirvetuximab soravtansine vs therapy according to doctor's instructions[2]
- Final data cut-off from 26.09.2024

FORWARD 1

- Randomised, open-label, multicentre phase III study
- Mirvetuximab soravtansine vs therapy according to doctor's instructions[2]
- Relevant sub-population: post-hoc defined study population with high FRα status (≥ 75%)
- Final data cut-off from 18.03.2020

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-06) unless otherwise indicated.
[2] A selection of paclitaxel, pegylated liposomal doxorubicin and topotecan

Meta-analysis of the MIRASOL and FORWARD 1 studies

Mortality

Endpoint	Mirvetuximab soravtansine		Therapy according to doctor's instructions[2]		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Overall survival					
MIRASOL	227	16.9 [13.36; 19.78][b] 162 (71)	226	13.34 [11.36; 15.16][b] 177 (78)	0.67 [0.54; 0.84] 0.0004 AD = + 3.56 months
FORWARD 1	82	16.42 [12.42; 20.49][b] 51 (62)	34	11.41 [6.12; 18.10][b] 25 (74)	0.66 [0.40; 1.08] 0.10
Total[c]					0.67 [0.55; 0.82] 0.0001

Morbidity

Endpoint	Mirvetuximab soravtansine		Therapy according to doctor's instructions[2]		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value Absolute difference (AD)[a]
Progression-free survival according to BICR[3]					
MIRASOL	227	5.82 [4.93; 6.97] *164 (72)*	226	4.34 [3.52; 4.99] 127 (56)	0.70 [0.55; 0.89] 0.0043 AD = + 1.48 months
FORWARD 1	82	5.68 [4.04; 8.15] 59 (72)	34	3.22 [1.51; 5.49] 26 (76)	0.62 [0.38; 1.02] 0.069
Total	309	5.75 [5.39; 6.87] 223 (72)	260	4.30 [3.22; 4.86] 153 (59)	0.69 [0.56; 0.86] 0.0011 AD = + 1.45 months

[3] Data from the pharmaceutical company's dossier dated 23.06.2026

Endpoint	Mirvetuximab soravtansine		Therapy according to doctor's instructions[2]		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Effect estimator [95% CI] p value Absolute difference (AD)[a]
EORTC QLQ-C30	No suitable data available.				
EORTC QLQ-OV28	No suitable data available.				
EQ-5D-VAS	No suitable data available.				
PGIS[d]	No suitable data available.				
FOSI[e]	No suitable data available.				

Health-related quality of life

Endpoint	Mirvetuximab soravtansine		Therapy according to doctor's instructions[2]		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event in months [95% CI] *Patients with event n (%)*	Effect estimator [95% CI] p value Absolute difference (AD)[a]
EORTC QLQ-C30	No suitable data available.				
EORTC QLQ-OV28	No suitable data available.				

Side effects

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Mirvetuximab soravtansine**		**Therapy according to doctor's instructions[2]**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event months [95% CI] *Patients with event n (%)*	HR [95% CI] p value
Total adverse events (presented additionally)					
MIRASOL	218	0.12 [0.07; 0.21][b] 211 (97)	207	0.23 [0.21; 0.25][b] 194 (94)	-
FORWARD 1	79	0.09 [0.07; 0.14][b] 79 (100)	32	0.12 [0.07; 0.23][b] 32 (100)	-
Serious adverse events (SAEs)					
MIRASOL	218	n.r. [13.78; n.c.][b] 55 (25)	207	7.75 [6.58; n.c.][b] 69 (33)	0.55 [0.38; 0.79]; 0.001
FORWARD 1	79	22.38 [22.38; n.c.][b] 22 (28)	32	7.06 [1.75; n.c.][b] 13 (41)	0.44 [0.21; 0.92]; 0.033 AD =-+ 15.32 months
Total[c]					0.51 [0.37; 0.71]; 0.001
Severe adverse events (CTCAE grade 3 or 4)					
MIRASOL	218	7.27 [4.85; 10.97][b] 97 (44)	207	3.24 [2.23; 4.07][b] 113 (55)	0.54 [0.41; 0.72] < 0.0001 AD = + 4.03 months
FORWARD 1	79	7.34 [4.37; n.c.][b] 37 (47)	32	2.07 [0.71; 2.39][b] 20 (62)	0.44 [0.25; 0.79] 0.008 AD = + 5.27 months
Total[c]					0.51 [0.40; 0.66]; < 0.001
Therapy discontinuation due to adverse events					
MIRASOL	218	n.r. [17; n.c.][b] 25 (11)	207	18.19 [12.72; n.c.][b] 31 (15)	0.44 [0.25; 0.78]; 0.004
FORWARD 1	79	n.r. [14.05; n.c.][b] 11 (14)	32	n.r. [4.30; n.c.][b] 7 (22)	0.41 [0.15; 1.11]; 0.089

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Mirvetuximab soravtansine**		**Therapy according to doctor's instructions[2]**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event months [95% CI] *Patients with event n (%)*	HR [95% CI] p value
Total[c]					0.44 [0.27; 0.73]; 0.001
Specific adverse events					
Eye disorders (SOC, AEs)					
MIRASOL	218	2.14 [1.86; 3.06][b] 125 (57)	207	n.r. 18 (9)	7.48 [4.54; 12.34]; < 0.001
FORWARD 1	79	1.87 [1.17; 3.66][b] 51 (65)	32	n.r. [4.43; n.c.][b] 6 (19)	4.51 [1.91; 10.61]; < 0.001
Total[c]					6.73 [4.37; 10.38]; < 0.001
Eye disorders (SOC, severe AEs)					
MIRASOL	218	23.16 [22.63; n.c.][b] 34 (16)	207	n.r. 0 (0)	n.d.[f]; < 0.001
FORWARD 1	79	24.38 [10.28; n.c.][b] 11 (14)	32	n.r. 0 (0)	n.d.[f]; 0.183
Total[c]					n.d.[f, g]; < 0.001
Pneumonitis (PT collection[h], AEs)					
MIRASOL	218	n.r. [13.04; n.c.][b] 26 (12)	207	n.r. 1 (0.5)	0.04 [0.01; 0.16] < 0.0001
FORWARD 1	79	19.35 [16.47; n.c.][b] 11 (14)	32	n.r. 2 (6)	0.02 [0.01; 0.09] < 0.0001
Total[c]					4.62 [1.38; 15.42]; 0.003
Dyspnoea (PT, AEs)					
MIRASOL	218	n.r. 17 (8)	207	n.r. 27 (13)	0.32 [0.16; 0.65]; < 0.001

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Mirvetuximab soravtansine**		**Therapy according to doctor's instructions[2]**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event months [95% CI] *Patients with event n (%)*	HR [95% CI] p value
FORWARD 1	79	n.r. 10 (13)	32	n.r. [4.3; n.c.][b] 5 (16)	0.58 [0.18; 1.81]; 0.357
Total[c]					0.38 [0.21; 0.67]; < 0.001
Stomatitis (PT, AEs)					
MIRASOL	218	n.r. 8 (4)	207	n.r. [11.87; n.c.][b] 23 (11)	0.18 [0.08; 0.44]; < 0.001
FORWARD 1	79	n.r. 4 (5)	32	n.r. [2.62; n.c.][b] 9 (28)	0.15 [0.04; 0.48]; < 0.001
Total[c]					0.18 [0.09; 0.35]; < 0.001
Skin and subcutaneous tissue disorders (SOC, AEs)					
MIRASOL	218	30.84 [20.26; n.c.][b] 37 (17)	207	4.21 [3.08; 6.23][b] 76 (37)	0.29 [0.19; 0.44]; < 0.001
FORWARD 1	79	n.r. [7.12; n.c.][b] 16 (20)	32	2.37 [1.45; 3.91][b] 18 (56)	0.15 [0.07; 0.33]; < 0.001
Total[c]					0.24 [0.17; 0.35]; < 0.001
Small bowel obstruction (PT, SAEs)					
MIRASOL	218	n.r. 4 (2)	207	n.r. 10 (5)	0.24 [0.07; 0.76]; 0.010
FORWARD 1	79	n.r. 0 (0)	32	n.r. 2 (6)	n.r.; 0.016
Total[c]					0.18 [0.06; 0.56]; 0.001
Blood and lymphatic system disorders (SOC, severe AEs)					
MIRASOL	218	n.r. 6 (3)	207	n.r. 51 (25)	0.07 [0.03; 0.17]; < 0.001
FORWARD 1	79	n.r. 4 (5)	32	7.89 [1.45; n.c.][b] 9 (28)	0.06 [0.01; 0.28]; < 0.001

Endpoint **MedDRA system organ classes/ preferred terms/ AEs of special interest**	**Mirvetuximab soravtansine**		**Therapy according to doctor's instructions[2]**		Intervention vs control
	N	Median time to event in months [95% CI] *Patients with event n (%)*	N	Median time to event months [95% CI] *Patients with event n (%)*	HR [95% CI] p value
Total[c]					0.07 [0.03; 0.15]; < 0.001
Fatigue (PT, severe AEs)					
MIRASOL	218	n.r. 5 (2)	207	n.r. 11 (5)	0.31 [0.11; 0.90]; 0.024
FORWARD 1	79	n.r. 2 (3)	32	17.18 [n.c.][b] 2 (6)	0.27 [0.04; 1.98]; 0.213
Total[c]					0.30 [0.12; 0.78]; 0.010

a. Indication of absolute difference (AD) only in case of statistically significant difference; own calculation
b. Own calculation (indication in weeks converted to indication in months)
c. Calculated from an IPD meta-analysis (fixed-effect model)
d. Only collected in the MIRASOL study
e. Only collected in the FORWARD 1 study
f. The pharmaceutical company states that a HR cannot be calculated for the endpoints at which no events occurred in a study arm. One way of obtaining point and interval estimates for time-to-event analyses in such situations is to use the Firth correction to the Cox model in combination with profile likelihood methods for the 95% CI
g. The pharmaceutical company did not provide any information on the HR (including the 95% CI). In the present data set, with an event percentage of 16 or 14% respectively (n = 34 [MIRASOL] and n = 11 [FORWARD1]) in the intervention arm versus 0% (n = 0 [MIRASOL] and n = 0 [FORWARD 1]) in the control arm, and given the Kaplan-Meier curves that diverged markedly at an early stage of the study, a statistically significant difference to the disadvantage of mirvetuximab soravtansine can be assumed.
h. Corresponds to the operationalisation of the adverse event of special interest (AESI) in the MIRASOL study: includes the PTs "Interstitial lung disease", "Organising pneumonia", "Pneumonitis", "Pulmonary fibrosis" and "Respiratory failure"

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; HR = hazard ratio; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; vs = versus

2. Number of patients or demarcation of patient groups eligible for treatment

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

Approx. 630 to 1,300 patients

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.

4. Treatment costs

Annual treatment costs

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	Annual treatment costs/ patient
Medicinal product to be assessed:	
Mirvetuximab soravtansine	
Mirvetuximab soravtansine	€ 245,200.10
Additionally required SHI services	*€ 193.46 - € 195.96*
Appropriate comparator therapy:	
Paclitaxel (with or without bevacizumab for bevacizumab-naïve patients)	
Paclitaxel (monotherapy)	
Paclitaxel	€ 15,545.68
Additionally required SHI services	*€ 271.06*
Paclitaxel in combination with bevacizumab	
Paclitaxel	€ 15,545.68
Bevacizumab	€ 29,493.53
Total (paclitaxel + bevacizumab)	€ 45,039.21
Additionally required SHI services	*€ 271.06*
Pegylated liposomal doxorubicin (with or without bevacizumab for bevacizumab-naïve patients)	
Pegylated liposomal doxorubicin (monotherapy)	
Pegylated liposomal doxorubicin	€ 40,363.44
Pegylated liposomal doxorubicin in combination with bevacizumab	
Pegylated liposomal doxorubicin	€ 40,363.44
Bevacizumab	€ 29,493.53
Total (pegylated liposomal doxorubicin + bevacizumab)	€ 69,856.97
Topotecan (with or without bevacizumab for bevacizumab-naïve patients)	
Topotecan (monotherapy)	
Topotecan	€ 19,333.14
Topotecan in combination with bevacizumab	
Topotecan	€ 19,333.14
Bevacizumab	€ 30,684.55
Total (topotecan + bevacizumab)	€ 50,017.69

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 May 2026)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number / cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Mirvetuximab soravtansine					
Mirvetuximab soravtansine	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					
Paclitaxel (with or without bevacizumab for bevacizumab-naïve patients)					
Paclitaxel (monotherapy)					
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Paclitaxel in combination with bevacizumab					
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610
Pegylated liposomal doxorubicin (with or without bevacizumab for bevacizumab-naïve patients)					
Pegylated liposomal doxorubicin (monotherapy)					
Pegylated liposomal doxorubicin	Surcharge for production of a parenteral preparation	€ 100	1	13.0	€ 1,300

	containing cytostatic agents				
Pegylated liposomal doxorubicin in combination with bevacizumab					
Pegylated liposomal doxorubicin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13.0	€ 1,300
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	26.1	€ 2,610
Topotecan (with or without bevacizumab for bevacizumab-naïve patients)					
Topotecan (monotherapy)					
Topotecan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Topotecan in combination with bevacizumab					
Topotecan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740

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

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Patient group of 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.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. 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.

II. The resolution will enter into force on the day of its publication on the G-BA website on 16 July 2026.

The justification for this resolution will be published on the G-BA website at www.g-ba.de.

Berlin, 16 July 2026

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

Dr Optendrenk