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
Tisotumab vedotin (cervical cancer, pretreated)

of 19 February 2026

At their session on 19 February 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. Annex XII shall be amended in alphabetical order to include the active ingredient Tisotumab vedotin as follows:

Tisotumab vedotin

Resolution of: 19 February 2026
Entry into force on: 19 February 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 28 March 2025):

Tivdak as monotherapy is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after systemic therapy.

Therapeutic indication of the resolution (resolution of 19 February 2026):

See therapeutic indication according to marketing authorisation.

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

a) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after platinum-based first-line chemotherapy, who have not been pretreated with a PD-(L)1 antibody and who are eligible for further systemic, antineoplastic standard therapy

Appropriate comparator therapy:

– Cemiplimab

Extent and probability of the additional benefit of tisotumab vedotin compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after
- platinum-free first-line chemotherapy without a PD-(L)1 antibody,
- first-line combination therapy consisting of chemotherapy and a PD-(L)1 antibody,
- sequential therapy with platinum-based chemotherapy and a PD-(L)1 antibody

who are eligible for further systemic, antineoplastic standard therapy

Appropriate comparator therapy:

Individualised therapy with selection of monotherapy with:

– Nab-paclitaxel
– Vinorelbine
– Ifosfamide
– Topotecan
– Pemetrexed

- Irinotecan
- Pembrolizumab (only patients with PD-L1-positive cervical cancer [CPS score ≥1] who have not been pretreated with a PD-(L)1 antibody are eligible)

Extent and probability of the additional benefit of tisotumab vedotin compared to the appropriate comparator therapy:

An additional benefit is not proven.

c) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after prior systemic therapy who are ineligible for further systemic, antineoplastic standard therapy

Appropriate comparator therapy:

- Best supportive care

Extent and probability of the additional benefit of tisotumab vedotin compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after platinum-based first-line chemotherapy, who have not been pretreated with a PD-(L)1 antibody and who are eligible for further systemic, antineoplastic standard therapy

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-112), unless otherwise indicated.

b) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after

- platinum-free first-line chemotherapy without a PD-(L)1 antibody,
- first-line combination therapy consisting of chemotherapy and a PD-(L)1 antibody,
- sequential therapy with platinum-based chemotherapy and a PD-(L)1 antibody

who are eligible for further systemic, antineoplastic standard therapy

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.

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

c) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after prior systemic therapy who are ineligible for further systemic, antineoplastic standard therapy

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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

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

a) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after platinum-based first-line chemotherapy, who have not been pretreated with a PD-(L)1 antibody and who are eligible for further systemic, antineoplastic standard therapy

and

b) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after

- platinum-free first-line chemotherapy without a PD-(L)1 antibody,
- first-line combination therapy consisting of chemotherapy and a PD-(L)1 antibody,
- sequential therapy with platinum-based chemotherapy and a PD-(L)1 antibody

who are eligible for further systemic, antineoplastic standard therapy

and

c) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after prior systemic therapy who are ineligible for further systemic, antineoplastic standard therapy

Approx. 380 to 1,450 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 Tivdak (active ingredient: tisotumab vedotin) at the following publicly accessible link (last access: 11 February 2026):

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

Therapy with tisotumab vedotin should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, who are experienced in the treatment of patients with cervical cancer, specialists in obstetrics and gynaecology, and other doctors from other specialist groups participating in the Oncology Agreement.

Prior to treatment with tisotumab vedotin and in the event of corresponding clinical indication, an eye examination should be carried out by an ophthalmologist. The patients' eyes must also be examined by the treating doctors prior to each infusion, including checking for normal eye movements. Prior to each infusion, patients must also be questioned and monitored by the treating doctors for evidence of disease or newly occurring or deteriorating eye symptoms and, if necessary, referred to an ophthalmologist as soon as possible. Patients must also be instructed to report any new or intensifying evidence of disease or eye symptoms to their treating doctor or specialist staff.

4. Treatment costs

Annual treatment costs:

a) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after platinum-based first-line chemotherapy, who have not been pretreated with a PD-(L)1 antibody and who are eligible for further systemic, antineoplastic standard therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tisotumab vedotin	€ 150,365.23
Additionally required SHI costs	€ 558.73 - € 804.85
Appropriate comparator therapy:	
Cemiplimab	€ 70,925.18

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 December 2025)

b) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after

- platinum-free first-line chemotherapy without a PD-(L)1 antibody,
- first-line combination therapy consisting of chemotherapy and a PD-(L)1 antibody,
- sequential therapy with platinum-based chemotherapy and a PD-(L)1 antibody

who are eligible for further systemic, antineoplastic standard therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tisotumab vedotin	€ 150,365.23
Additionally required SHI costs	€ 558.73 – € 804.85
Appropriate comparator therapy:	
Ifosfamide	€ 10,568.76 – € 14,624.70 (21-day cycle) or € 7,896.20 – € 10,926.50 (28-day cycle)
Irinotecan	€ 26,052.61
Nab-paclitaxel	€ 63,853.65
Pembrolizumab	€ 81,438.79
Pemetrexed	€ 18,621.48
Topotecan	€ 19,333.14

Designation of the therapy	Annual treatment costs/ patient
Vinorelbine	€ 6,263.31

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 December 2025)

c) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after prior systemic therapy who are ineligible for further systemic, antineoplastic standard therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Tisotumab vedotin	€ 150,365.23
Additionally required SHI costs	€ 558.73 – € 804.85
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Best supportive care	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 December 2025)

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:					
Tisotumab vedotin	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					
Cemiplimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Ifosfamide	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	65.0 or 87.0	€ 6,500 or € 8,700
Irinotecan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	52.1	€ 5,210
Nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	52.2	€ 5,220

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Topotecan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	5	87.0	€ 8,700
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	34.8	€ 3,480

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:

a) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after platinum-based first-line chemotherapy, who have not been pretreated with a PD-(L)1 antibody and who are eligible for further systemic, antineoplastic standard therapy

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

b) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after
   - platinum-free first-line chemotherapy without a PD-(L)1 antibody,
   - first-line combination therapy consisting of chemotherapy and a PD-(L)1 antibody,
   - sequential therapy with platinum-based chemotherapy and a PD-(L)1 antibody

   who are eligible for further systemic, antineoplastic standard therapy

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

c) Adult patients with recurrent or metastatic cervical cancer with disease progression on or after prior systemic therapy who are ineligible for further systemic, antineoplastic standard therapy

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

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 Tivdak (tisotumab vedotin) is a medicinal product placed on the market from 1 January 2025.

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 of the total number of study participants.

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

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 February 2026.

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

Berlin, 19 February 2026

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

Prof. Hecken