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)
Erdafitinib (urothelial carcinoma, FGFR3 alterations, pretreated with PD-(L)1 inhibitor)

of 18 June 2025

At their session on 18 June 2025, 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 Erdafitinib as follows:

Erdafitinib

Resolution of: 18 June 2025
Entry into force on: 18 June 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 22 August 2024):

Balversa as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting.

Therapeutic indication of the resolution (resolution of 18 June 2025):

See new therapeutic indication according to marketing authorisation.

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

a1) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for and have not yet received cisplatin-containing chemotherapy; second-line treatment

Appropriate comparator therapy:

- Cisplatin in combination with gemcitabine

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

An additional benefit is not proven.

a2) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are *not* eligible for cisplatin-containing chemotherapy; second-line treatment

Appropriate comparator therapy:

– Vinflunine

or

– Docetaxel

or

– Paclitaxel

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

An additional benefit is not proven.

b) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for chemotherapy; third-line treatment

Appropriate comparator therapy:

– Enfortumab vedotin

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a1) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for and have not yet received cisplatin-containing chemotherapy; second-line treatment

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		

a2) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are *not* eligible for cisplatin-containing chemotherapy; second-line treatment

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		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-01) unless otherwise indicated.

∅: No data available. n.a.: not assessable

b) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for chemotherapy; third-line treatment

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		

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

a1) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for and have not yet received cisplatin-containing chemotherapy; second-line treatment

Approx. 8 to 16 patients

a2) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are *not* eligible for cisplatin-containing chemotherapy; second-line treatment

Approx. 21 to 45 patients

b) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for chemotherapy; third-line treatment

Approx. 140 to 146 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 Balversa (active ingredient: erdafitinib) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 7 May 2025):

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

Treatment with erdafitinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology and urology, and specialists participating in the Oncology Agreement experienced in the treatment of adults with urothelial carcinoma.

4. Treatment costs

Annual treatment costs:

a1) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for and have not yet received cisplatin-containing chemotherapy; second-line treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Erdafitinib	€ 162,277.83
Appropriate comparator therapy: Cisplatin in combination with gemcitabine	
Cisplatin	€ 1,465.62
Gemcitabine	€ 7,016.88
Total:	€ 4,974.06
Additionally required SHI services:	€ 143.72 - € 151.60

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2025)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	13	€ 1,300
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	3	39	€ 3,900

a2) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are *not* eligible for cisplatin-containing chemotherapy; second-line treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Erdafitinib	€ 162,277.83
Appropriate comparator therapy: Vinflunine or docetaxel or paclitaxel	
Vinflunine	€ 80,312.14
Docetaxel	€ 8,527.22
Paclitaxel	€ 17,094.80

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2025)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Vinflunine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740

b) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for chemotherapy; third-line treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Erdafitinib	€ 162,277.83
Appropriate comparator therapy: Enfortumab vedotin	
Enfortumab vedotin	€ 91,404.29

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 June 2025)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Enfortumab vedotin	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 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:

a1) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for and have not yet received cisplatin-containing chemotherapy; second-line treatment

- 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 authorised in monotherapy.

a2) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are *not* eligible for cisplatin-containing chemotherapy; second-line treatment

- 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 authorised in monotherapy.

b) Adults with unresectable or metastatic urothelial carcinoma, harbouring susceptible FGFR3 genetic alterations after prior therapy with platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting, and who are eligible for chemotherapy; third-line treatment

- 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 authorised 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 centres within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product erdafitinib is a medicinal product placed on the market from 1 January 2025.

Insufficient information was provided on the number of study participants involved in the clinical studies of the medicinal product in the therapeutic indication under assessment, which were conducted or commissioned by the pharmaceutical company at study sites within the scope of SGB V, as well as on the total number of study participants.

Due to the insufficient information, it is therefore not possible to determine that the percentage of studyparticipants reached or exceeded the relevance threshold of at least 5 per cent.

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 18 June 2025.

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

Berlin, 18 June 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken