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
Durvalumab (new therapeutic indication: primary advanced or recurrent endometrial cancer, first-line therapy, combination with carboplatin and paclitaxel; maintenance treatment)

of 20 February 2025

At its session on 20 February 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. In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Durvalumab in accordance with the resolution of 6 June 2024 last modified on 19 September 2024:

Durvalumab

Resolution of: 20 February 2025
Entry into force on: 20 February 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 26 July 2024):

IMFINZI in combination with carboplatin and paclitaxel is indicated for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with IMFINZI as monotherapy in endometrial cancer that is mismatch repair deficient (dMMR).

Therapeutic indication of the resolution (resolution of 20 February 2025):

See new therapeutic indication according to marketing authorisation.

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

Adult patients with primary advanced endometrial carcinoma (Stage III or IV) or recurrent endometrial carcinoma with mismatch repair deficiency (dMMR) who:

- have not yet received systemic therapy as postoperative or adjuvant therapy for treatment of the primary advanced disease,
- have not yet received chemotherapy for treatment of the recurrence.

Appropriate comparator therapy:

Dostarlimab in combination with carboplatin and paclitaxel followed by Dostarlimab as monotherapy

Extent and probability of the additional benefit of durvalumab in combination with carboplatin and paclitaxel followed by maintenance treatment with durvalumab versus dostarlimab in combination with carboplatin and paclitaxel followed by dostarlimab as monotherapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adult patients with primary advanced endometrial carcinoma (Stage III or IV) or recurrent endometrial carcinoma with mismatch repair deficiency (dMMR) who:

- have not yet received systemic therapy as postoperative or adjuvant therapy for treatment of the primary advanced disease,
- have not yet received chemotherapy for treatment of the recurrence.

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

Adult patients with primary advanced endometrial carcinoma (Stage III or IV) or recurrent endometrial carcinoma with mismatch repair deficiency (dMMR) who:

- have not yet received systemic therapy as postoperative or adjuvant therapy for treatment of the primary advanced disease,
- have not yet received chemotherapy for treatment of the recurrence.

Approx. 380 to 1,520 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 Imfinzi (active ingredient: durvalumab) at the following publicly accessible link (last access: 28 November 2024):

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-87) unless otherwise indicated.

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

Treatment with durvalumab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in obstetrics and gynaecology, and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of patients with endometrial cancer.

4. Treatment costs

Annual treatment costs:
Adult patients with primary advanced endometrial carcinoma (Stage III or IV) or recurrent endometrial carcinoma with mismatch repair deficiency (dMMR) who:

- have not yet received systemic therapy as postoperative or adjuvant therapy for treatment of the primary advanced disease,
- have not yet received chemotherapy for treatment of the recurrence.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Durvalumab in combination with carboplatin and paclitaxel	
Durvalumab	€ 17,845.36 – € 26,768.04
Carboplatin	€ 1,268.44 – € 2,370.00
Paclitaxel	€ 3,573.72 – € 5,360.58
Maintenance treatment with durvalumab as monotherapy	
Durvalumab	€ 50,655.24 – € 59,594.40
Total	€ 82,281.92 – € 85,153.86
Appropriate comparator therapy:	
Dostarlimab in combination with carboplatin and paclitaxel	
Dostarlimab	€ 25,794.18
Carboplatin	€ 1,902.66
Paclitaxel	€ 5,360.58
Maintenance treatment with dostarlimab as monotherapy	
Dostarlimab	€ 49,008.94
Total	€ 82,066.36

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 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
Medicinal product to be assessed:					
Durvalumab in combination with carboplatin and paclitaxel					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4 – 6	€ 400 – € 600
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4 – 6	€ 400 – € 600
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4 – 6	€ 400 – € 600
Maintenance treatment with durvalumab as monotherapy					
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8.5 – 10.0	€ 850 – € 1,000
Appropriate comparator therapy:					
Dostarlimab in combination with carboplatin and paclitaxel					
Dostarlimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	6	€ 600

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	6	€ 600
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	6	€ 600
Maintenance treatment with dostarlimab as monotherapy					
Dostarlimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	5.7	€ 570

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:

Adult patients with primary advanced endometrial carcinoma (Stage III or IV) or recurrent endometrial carcinoma with mismatch repair deficiency (dMMR) who:

- have not yet received systemic therapy as postoperative or adjuvant therapy for treatment of the primary advanced disease,
- have not yet received chemotherapy for treatment of the recurrence.

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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 website of the G-BA on 20 February 2025.

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

Berlin, 20 February 2025

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

Prof. Hecken