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: Dostarlimab (endometrial cancer, following prior treatment with a platinum-containing regimen)

of 2 December 2021

At its session on 2 December 2021, 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 (BAnz AT TT.MM.JJJJ BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient dostarlimab as follows:

Dostarlimab

Resolution of: 2 December 2021
Entry into force on: 2 December 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 21 April 2021):

Jemperli is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.

Therapeutic indication of the resolution (resolution from 2 December 2021):

see therapeutic indication according to marketing authorisation

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

Adult patients with dMMR/MSI-H recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen

Appropriate comparator therapy:

Therapy according to doctor's instructions

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

An additional benefit is not proven.

Study results according to endpoints:[1]

No adequate data are available to allow an assessment of the additional benefit.

[1] Data from the dossier assessment of the IQWiG (A21-84) and from the addendum (A21-139), unless otherwise indicated.

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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

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

approx. 230 to 3,360 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 Jemperli (active ingredient: dostarlimab) at the following publicly accessible link (last access: 8 November 2021):

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

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

This medicinal product was approved under "special conditions". This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

All doctors prescribing JEMPERLI must inform patients about the patient card and explain what to do in case of symptoms of immune-mediated side effects. The doctor provides each patient with a patient card.

The dMMR/MSI-H tumour status should be determined using a validated investigation method.

4. Treatment costs

The annual treatment costs shown refer to the first year of treatment.

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Dostarlimab	€ 97,273.83
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Therapy according to doctor's instructions[a]	
Medroxyprogesterone acetate	€ 712.63 - € 1,221.47
Megestrol acetate	€ 2,831.49 - € 11,325.95
Cisplatin monotherapy	€ 1,529.81 - € 3,824.52
additionally required SHI services	€ 245.49 - € 421.62
Doxorubicin monotherapy	€ 5,563.30 - € 7,243.79
Cisplatin + doxorubicin	
Cisplatin	€ 527.52
Doxorubicin	€ 1,918.38
Total:	€ 2,445.90
additionally required SHI services	€ 156.26 - € 188.84
Best supportive care	Different from patient to patient
[a] The active ingredients carboplatin and paclitaxel are suitable comparators for the present benefit assessment in the context of therapy according to doctor's instructions. However, these medicinal products are not approved in the present therapeutic indication, and therefore, no costs are presented for these medicinal products.	

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 November 2021)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Dostarlimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	10.7	€ 759.70
Cisplatin monotherapy	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1-5	13 - 87	€ 1,053 - € 7,047
Doxorubicin monotherapy	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Cisplatin (in combination with doxorubicin)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	6	€ 486
Doxorubicin (in combination with cisplatin)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	6	€ 486

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 2 December 2021.

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

Berlin, 2 December 2021

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

Prof. Hecken