# Resolution

Gemeinsamer Bundesausschuss

## of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Resolutions on the Benefit Assessment of Medicinal Products with New Active Ingredients in Accordance with Section 35a SGB V Pembrolizumab (Reassessment due to New Scientific Knowledge: Urothelial Carcinoma)



From 20 June 2019

At its session on 20. June 2019, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (Pharmaceuticals Directive) in the version dated 18 December 2008/22 January 2009 (BAnz. No. 49a of 31 March 2009), as last amended on TT. Monat JJJJ (BAnz AT TT.MM.JJJJ BX), as follows:

**I. The findings set out in Annex XII for the active ingredient pembrolizumab, as amended by the Resolution of 16 March 2018, shall remain part of the Pharmaceuticals Directive in accordance with the following amendments:**

**1. The information for pembrolizumab on the date and entry into force of the resolutions is adopted as follows:**

"First resolution of 16 March 2018
Entry into force on: 16 March 2018
BAnz AT 04.04.2018 B4

Second resolution of 2 August 2018
Entry into force on: 2 August 2018
BAnz AT 27.08.2018 B3

Third resolution of: 20. June 2019
Entry into force on: 20. June 2019
BAnz AT TT. MM JJJJ Bx"

**2. The findings under "New therapeutic indications" are adopted as follows:**

**"New therapeutic indications (according to the marketing authorisation of 6 July 2018):**

Keytruda is indicated as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-based therapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10.

Keytruda is indicated as monotherapy for the treatment of locally advanced or metastatic urothelial carcinoma after prior platinum-based therapy in adults.



Note:

The resolution of 20 June 2019 relates exclusively to the assessment of the additional benefit of pembrolizumab in the sub-population: a) Urothelial carcinoma; patients who are not eligible for cisplatin-based therapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10 (first line)".

**3. The findings under "1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy" for the patient population "a)" are adopted as follows:**

"a) Urothelial carcinoma; patients who are not eligible for cisplatin-based therapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10 (first line)

**Appropriate comparator therapy:**

Chemotherapy according to the doctor's instructions

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

An additional benefit is not proven.

**Study results according to endpoints:**

a) Urothelial carcinoma; patients who are not eligible for cisplatin-based therapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10 (first line)

There are no data that would allow for the assessment of the additional benefit.

**4. The findings under "2. Number of patients or demarcation of patient groups eligible for treatment" for patient population "a)" are adopted as follows**

"a) Urothelial carcinoma; patients who are not eligible for cisplatin-based therapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10 (first line)

Approx. 240–420 patients"

**5. The findings under "3. Requirements for a quality-assured application" are adopted as follows:**

"The requirements of 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 Keytruda® (active ingredient: pembrolizumab) at the following publicly accessible link (last access: 27 March 2019):

https://www.ema.europa.eu/documents/product-information/keytruda-epar-product-information_de.pdf

Only specialists in internal medicine, haematology, and oncology with experience treating patients with urothelial carcinoma, specialists in urology, and specialists participating in the Oncology Agreement may initiate and monitor treatment with pembrolizumab.

In accordance with the specifications of the EMA regarding additional measures for risk minimisation, the pharmaceutical company must provide training material and a patient card. Patients are requested to carry their patient cards with them at all times. The training material for health professionals and the patient card shall include, in particular, instructions on how to deal with the potential immune-mediated adverse reactions to pembrolizumab as well as infusion reactions".



**6. Under "4. Treatment costs", the findings on the annual treatment costs for the patient population "a)" are adopted as follows:**

"a) Urothelial carcinoma; patients who are not eligible for cisplatin-based therapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10 (first line)

| Designation of the therapy | Annual treatment costs/patient |
|---|---|
| Medicinal product to be assessed: | |
| Pembrolizumab | € 103,757.46 |
| Appropriate comparator therapy: | |
| patient-individualized | |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 01 June 2019)

Costs for additionally required SHI services: not applicable

Other services covered by SHI funds:

| Designation of the therapy | Type of service | Costs/ Unit | Number/ cycle | Number/ Patient/ year | Costs/ Patient/ year |
|---|---|---|---|---|---|
| Pembrolizumab | a) | € 71 | 1 | 8.5 - 17 | € 603.50 – € 1,207 |
| a) Surcharge for the preparation of a parenteral solution containing monoclonal antibodies” | | | | | |

## II. Entry into force

1. **The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 20 June 2019.**

2. **The period of validity of the resolution is limited to 1 July 2020.**



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

Berlin, 20 June 2019

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

Prof. Hecken