Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Avelumab (Reassessment after the Repeal of Orphan Drug Status (Metastatic Merkel Cell Carcinoma))

of 1 October 2020

At its session on 1 October 2020 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 on DD Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

I. Annex XII will be amended as follows:

1. The information on avelumab in accordance with the resolution of 16 March 2018 (Federal Gazette, BAnz AT 25 April 2018 B2) is hereby repealed.

2. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of avelumab in accordance with the resolution of 14 May 2020:

Avelumab

Resolution of: 1 October 2020
Entry into force on: 1 October 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 18 September 2017):

Bavencio is indicated as monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (MCC).

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

Adult patients with metastatic Merkel cell carcinoma (MCC); first-line treatment:

Appropriate comparator therapy for avelumab:

Therapy according to the doctor's instructions

Extent and probability of the additional benefit of avelumab compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

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

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/risk of bias	Summary
Mortality	∅	There are no suitable data for the benefit assessment.
Morbidity	∅	There are no suitable data for the benefit assessment.
Health-related quality of life	∅	There are no suitable data for the benefit assessment.
Side effects	∅	There are no suitable data for the benefit assessment.
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. 370–720 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 Bavencio® (active ingredient: avelumab) at the following publicly accessible link (last access: 19 June 2020):

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

Treatment with avelumab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in skin and venereal diseases, and specialists participating in the Oncology Agreement who are experienced in the treatment of patients with Merkel cell carcinoma.

According to the requirements for risk minimisation activities in the EPAR (European Public Assessment Report), the pharmaceutical company must provide the following information material on avelumab:

− Information brochure for patients
− Patient pass

The information material shall include, in particular, instructions on how to deal with the immune-mediated side effects potentially occurring with avelumab.

4. Treatment costs

Annual treatment costs:

Adult patients with metastatic Merkel cell carcinoma (MCC); first-line treatment:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Avelumab	€ 96,406.09
Appropriate comparator therapy:	
Therapy according to the doctor's instructions	different for each individual patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2020

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
Avelumab	Surcharge for the preparation of parenteral solutions with monoclonal antibodies	€ 71	1	26.1	€ 1,853.10

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 1 October 2020.

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

Berlin, 1 October 2020

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

Prof. Hecken