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 – Atezolizumab (Reassessment Based on 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 atezolizumab, 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 atezolizumab on the date and entry into force of the resolutions is adopted as follows:

"Resolution of 16 March 2018
Entry into force on: 16 March 2018
BAnz AT 17 April 2018 B2

Second resolution of 2 August 2018
Entry into force on: 2 August 2018
BAnz AT 28 August 2018 B2

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 indication" are adopted as follows:

"New therapeutic indication (according to the marketing authorisation of 2 July 2018):

Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC)

- after prior platinum-based chemotherapy or
- who are considered cisplatin ineligible and whose tumours have a PD-L1 expression ≥ 5%.

Note:

The resolution of 20 June 2019 relates exclusively to the assessment of the additional benefit of atezolizumab in the sub-population: a) Urothelial carcinoma; patients who are not eligible for a treatment with cisplatin and whose tumours have a PD-L1 expression ≥ 5% (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 treatment with cisplatin and whose tumours have a PD-L1 expression ≥ 5% (first line)

Appropriate comparator therapy:

Chemotherapy according to the doctor's instructions

Extent and probability of the additional benefit of atezolizumab 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 treatment with cisplatin and whose tumours have a PD-L1 expression ≥ 5% (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 treatment with cisplatin and whose tumours have a PD-L1 expression ≥ 5% (first line)

Approx. 220–380 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 Tecentriq® (active ingredient: atezolizumab) at the following publicly accessible link (last access: 2 May 2019):

https://www.ema.europa.eu/documents/product-information/tecentriq-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 atezolizumab.

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 atezolizumab 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 treatment with cisplatin and whose tumours have a PD-L1 expression ≥ 5% (first line)

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Atezolizumab	€ 75,234.01
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

Atezolizumab	a)	€ 71	1	17	€ 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 01 October 2021.**

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