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 Pembrolizumab (new therapeutic indication: Melanoma, ≥ 12 to <18 years of age)

of 19 January 2023

At its session on 19 January 2023, 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. 4 to the information on the benefit assessment of Pembrolizumab in accordance with the resolution of 19 January 2023 for the indication "...as monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with Stage IIB, IIC or III melanoma and who have undergone complete resection":

Pembrolizumab

Resolution of: 19 January 2023
Entry into force on: 19 January 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 22 June 2022):

Keytruda as monotherapy is indicated for the treatment of adults and adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma.

Therapeutic indication of the resolution (resolution of 19 January 2023):

Keytruda as monotherapy is indicated for the treatment of adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma.

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

Adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma

Appropriate comparator therapy:

Therapy according to doctor's instructions

Extent and probability of the additional benefit of pembrolizumab (monotherapy) compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma

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

[1] Data from IQWiG's dossier assessment (A22-73)

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	n.c.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.c.	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.c.: not calculable

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

Adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma

approx. 1 - 4 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 Keytruda (active ingredient: pembrolizumab) at the following publicly accessible link (last access: 3 January 2023):

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

Treatment with pembrolizumab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology who are experienced in the treatment of patients with melanoma, as well as specialists in skin and sexually transmitted diseases, and specialists in paediatrics and adolescent medicine with specialisation in paediatric haematology and oncology, and other specialists participating in the Oncology Agreement.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients. The training material contains, in particular, instructions on the management of immune-mediated side effects potentially occurring with pembrolizumab as well as on infusion-related reactions.

4. Treatment costs

Annual treatment costs:

Adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pembrolizumab	€ 46,761.11 - € 93,522.22
Appropriate comparator therapy:	
Therapy according to doctor's instructions[2]	No data available

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 January 2023)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	17.4	€ 1,740

5. 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 Pembrolizumab

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with pembrolizumab for the treatment of adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma on the basis of the marketing authorisation under Medicinal Products Act:

Adolescents aged 12 years and older with advanced (unresectable or metastatic) melanoma

- No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

[2] The medicinal product combinations vemurafenib + cobimetinib (only for patients with BRAF V600 mutation); dabrafenib + trametinib (only for patients with BRAF V600 mutation); encorafenib + binimetinib (only for patients with BRAF V600 mutation) and the active ingredient nivolumab are suitable comparators for the present benefit assessment in the context of therapy according to doctor's instructions. All drug therapies that represent a suitable comparator for the present benefit assessment according to doctor's instructions are not approved in the present therapeutic indication for adolescents aged 12 years and older, which is why no costs are presented for these medicinal products.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 January 2023.

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

Berlin, 19 January 2023

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

Prof. Hecken