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)
Nivolumab (new therapeutic indication: melanoma (stage IIB or IIC), adjuvant treatment, ≥ 12 years, monotherapy)

of 21 March 2024

At its session on 21 March 2024, 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 is added after No. 5 to the information on the benefit assessment of Nivolumab in accordance with the resolution of 1 February 2024 on the therapeutic indication "neoadjuvant treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%":**

Nivolumab

Resolution of: 21 March 2024
Entry into force on: 21 March 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 21 August 2023):

Opdivo as monotherapy is indicated for the adjuvant treatment of adults and adolescents 12 years of age and older with stage IIB or IIC melanoma, or melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

Therapeutic indication of the resolution (resolution of 21 March 2024):

Nivolumab as monotherapy is indicated for the adjuvant treatment of adults and adolescents 12 years of age and older with stage IIB or IIC melanoma who have undergone complete resection.

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

Adults and adolescents 12 years of age and older for the adjuvant treatment of stage IIB or IIC melanoma who have undergone complete resection

Appropriate comparator therapy:

Pembrolizumab

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

An additional benefit is not proven.

Study results according to endpoints:

Adults and adolescents 12 years of age and older for the adjuvant treatment of stage IIB or IIC melanoma who have undergone complete resection

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

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
∅: No data available.
n.a.: not assessable

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

Adults and adolescents 12 years of age and older for the adjuvant treatment of stage IIB or IIC melanoma who have undergone complete resection

approx. 1,620 - 2,310 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 Opdivo (active ingredient: nivolumab) at the following publicly accessible link (last access: 12 March 2024):

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

Treatment with nivolumab 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 European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (incl. patient identification card).

The training material contains, in particular, information and warnings about immune-mediated side effects as well as infusion-related reactions.

4. Treatment costs

Annual treatment costs:

Adults and adolescents 12 years of age and older for the adjuvant treatment of stage IIB or IIC melanoma who have undergone complete resection

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nivolumab	€ 47,526.96 - € 75,915.32
Appropriate comparator therapy:	
Pembrolizumab	€ 47,705.74 - € 95,411.48

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 March 2024)

Costs for additionally required SHI services: not applicable

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13 - 26	€ 1,300 - € 2,600
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	8 - 17	€ 800 - € 1,700

5. Designation of 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 the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adults and adolescents 12 years of age and older for the adjuvant treatment of stage IIB or IIC melanoma who have undergone complete resection

– No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. Entry into force

1. **The resolution will enter into force on the day of its publication on the website of the G-BA on 21 March 2024.**

2. **The period of validity of the resolution is limited to 1 October 2024.**

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

Berlin, 21 March 2024

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

Prof. Hecken