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: urothelial carcinoma, PD-L1 expression ≥ 1%, adjuvant treatment)

of 16 March 2023

At its session on 16 March 2023, the Federal Joint Committee (G-BA) resolved to amend Annex XII of 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. The information on the benefit assessment of the active ingredient Nivolumab in the version of the resolution of 20 October 2022 (BAnz AT 17.11.2022 B2) shall be amended as follows:

1. Number 1 "Additional benefit of the medicinal product in relation to the appropriate comparator therapy" shall be amended as follows:

   In the section under the heading “CA209-274 study: nivolumab vs placebo” in the table on side effects in the table row “severe adverse events (CTCAE grade ≥ 3)” in the column “nivolumab”, the information “0.84 [0.58; 1.23]; 0.380” is replaced by “9.49 [6.11; 13.80]; 74 (53.2)”.

2. Number 4 “Treatment costs” shall be replaced as follows:

The annual treatment costs shown refer to the first year of treatment.

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Nivolumab	€ 75,925.72
Appropriate comparator therapy:	
a) Adults with muscle invasive urothelial carcinoma with tumour cell PD-L1 expression ≥ 1%, who are at high risk of recurrence after undergoing complete resection and are eligible for cisplatin-containing therapy; adjuvant treatment	
Cisplatin in combination with gemcitabine	
Cisplatin	€ 1,506.05
Gemcitabine	€ 7,014.54
Total:	€ 8,520.59
Additionally required SHI costs	€ 242.72 - € 311.31
Cisplatin in combination with methotrexate	
Cisplatin	€ 2,015.79
Methotrexate	€ 3,088.85
Total:	€ 5,104.64
Additionally required SHI costs	€ 324.87 - € 416.67
b) Adults with muscle invasive urothelial carcinoma with tumour cell PD-L1 expression ≥ 1%, who are at high risk of recurrence after undergoing complete resection and are unsuitable for cisplatin-containing therapy, or have already received neoadjuvant treatment; adjuvant treatment	
Monitoring wait-and-see approach	incalculable

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2022)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Nivolumab (Cycle every 14 days)	Preparation for parenteral solution containing monoclonal antibodies	€ 71	1	26	€ 1,846.00
Nivolumab (Cycle every 28 days)	Preparation for parenteral solution containing monoclonal antibodies	€ 71	1	13	€ 923.00

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cisplatin (in combination with gemcitabine)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	13	€ 1,053.00
Cisplatin (in combination with methotrexate)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	39	€ 3,159.00
Methotrexate	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2,818.80

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 16 March 2023.

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

Berlin, 16 March 2023

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

Prof. Hecken