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 Atezolizumab (New Therapeutic Indication: NSCLC, Non-Squamous, First Line, Combination with Becavizumab, Paclitaxel and Carboplatin) (Treatment Costs)

of 4 June 2020

Benefit assessment procedure comprises several resolutions, please note the current version of the Pharmaceuticals Directive/Annex XII.

On 4 June 2020, the Federal Joint Committee (G-BA) resolved by written statement to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 MM YYYY (Federal Gazette, BAnz AT DD MM YYYY Bx) as follows:

I. In Annex XII, the information on the benefit assessment of the active ingredient atezolizumab in the version of the resolution of 2 April 2020 (Federal Gazette, BAnz AT 7 May 2020 B4) in section "4. Treatment costs" is amended as follows:

The information in section "4. Treatment costs" is to be replaced by the following information:

"Annual treatment costs:

a) Adults with metastatic non-squamous non-small cell lung cancer and a Tumour Proportion Score [TPS] of ≥ 50% (PD-L1 expression) and without EGFR mutations or ALK translocations; first-line therapy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Induction therapy	
Atezolizumab	€ 17,702.36 – 26,553.54
Carboplatin	€ 2,003.88 – 3,005.82
Paclitaxel	€ 4,770.08 – 7,155.12
Bevacizumab	€ 9,953.52 – 14,930.28

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Designation of the therapy	Annual treatment costs/patient
	or € 19,138.32 – 28,707.48
Maintenance treatment	
Atezolizumab	€ 50,451.73 – 59,302.91
Bevacizumab	€ 28,367.53 – 33,344.29 or € 54,544.21 – 64,113.37
Total:	€ 127,077.04 – 170,417.90
Appropriate comparator therapy:	
Pembrolizumab	€ 101,243.99

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 March 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
Medicinal product to be assessed:					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	4–6	€ 324 – 486
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	4–6	€ 324 – 486
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Appropriate comparator therapy:					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40

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b) Adults with metastatic non-squamous non-small cell lung cancer; and a Tumour Proportion Score [TPS] of ≥ 50% (PD-L1 expression); first-line therapy; or a EGFR mutant or ALK-positive NSCLC independent of the tumour proportion score [TPS] after pre-treatment with an appropriate targeted therapy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Induction therapy	
Atezolizumab	€ 17,702.36 – 26,553.54
Carboplatin	€ 2,003.88 – 3,005.82
Paclitaxel	€ 4,770.08 – 7,155.12
Bevacizumab	€ 9,953.52 – 14,930.28 or € 19,138.32 – 28,707.48
Maintenance treatment	
Atezolizumab	€ 50,451.73 – 59,302.91
Bevacizumab	€ 28,367.53 – 33,344.29 or € 54,544.21 – 64,113.37
Total	€ 127,077.04 – 170,417.90
Appropriate comparator therapy:	
Cisplatin in combination with a third-generation cytostatic agent (docetaxel or gemcitabine or paclitaxel or pemetrexed or vinorelbine)	
Cisplatin plus docetaxel	
Cisplatin	€ 2,007.44
Docetaxel	€ 21,230.61
Total	€ 23,238.05
Additionally required SHI service	€ 328.58 – 421.62
Cisplatin plus gemcitabine	
Cisplatin	€ 2,007.44 – 2,486.11
Gemcitabine	€ 8,193.66
Total	€ 10,201.10 – 10,679.77
Additionally required SHI service	€ 328.58 – 421.62
Cisplatin plus paclitaxel	
Cisplatin	€ 2,271.74
Paclitaxel	€ 20,749.85
Total	€ 23,021.59
Additionally required SHI service	€ 559.12 – 652.16
Cisplatin plus pemetrexed	
Cisplatin	€ 2,007.44

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Designation of the therapy	Annual treatment costs/patient
Pemetrexed	€ 68,656.57
Total	€ 70,664.01
Additionally required SHI service	€ 454.67 – 594.50
Cisplatin plus vinorelbine	
Cisplatin	€ 2,007.44 – 2,486.11
Vinorelbine	€ 4,716.97 – 5,686.32
Total	€ 6,724.41 – 8,172.43
Additionally required SHI service	€ 328.58 – 421.62
Carboplatin in combination with a third-generation cytostatic agent (docetaxel or gemcitabine or paclitaxel or pemetrexed or vinorelbine)	
Carboplatin plus docetaxel	
Carboplatin	€ 8,716.88
Docetaxel	€ 21,230.61
Total	€ 29,947.49
Carboplatin plus gemcitabine	
Carboplatin	€ 8,716.88
Gemcitabine	€ 8,193.66
Total	€ 16,910.54
Carboplatin plus paclitaxel	
Carboplatin	€ 8,716.88
Paclitaxel	€ 20,749.85
Total	€ 29,466.73
Additionally required SHI service	€ 230.54
Carboplatin plus pemetrexed	
Carboplatin	€ 8,716.88
Pemetrexed	€68,656.57
Total	€ 77,373.45
Additionally required SHI service	€ 126.09 – 172.88
Carboplatin plus vinorelbine	
Carboplatin	€ 8,716.88
Vinorelbine	€ 4,716.97 – 5,686.32
Total	€ 13,433.85 – 14,403.20
Carboplatin in combination with nab-paclitaxel	
Carboplatin	€ 8,716.88
nab-paclitaxel	€ 39,088.40
Total	€ 47,805.28
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy	

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Designation of the therapy	Annual treatment costs/patient
Pembrolizumab	€ 101,243.99
Pemetrexed	€ 68,656.57
Carboplatin	€ 8,716.88
Total	€ 178,617.44
Additionally required SHI service	€ 126.09 – 172.88
or	
Pembrolizumab	€ 101,243.99
Pemetrexed	€ 68,656.57
Cisplatin	€ 2,007.44
Total	€ 171,908.00
Additionally required SHI service	€ 454.67 – 594.50

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 March 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
Medicinal product to be assessed:					
Atezolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	4–6	€ 324 – 486
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	4–6	€ 324 – 486
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40

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Appropriate comparator therapy:					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2,818.80
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	2	34.8	€ 2,818.80
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	52.2	€ 4,228.20
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40

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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 4 June 2020.

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

Berlin, 4 June 2020

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

Prof. Hecken

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