

# 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 Nab-Paclitaxel and Carboplatin) (Treatment Costs)

of 4 June 2020

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 26 May 2020 B2) 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:

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

- a) Adult patients with metastatic non-squamous non-small cell lung cancer and a Tumour Proportion Score [TPS] of  $\geq 50\%$  (PD-L1 expression) and without EGFR- or ALK-positive tumour mutations; first-line therapy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
<i>Induction therapy</i>	
Atezolizumab	€ 17,702.36 – 26,553.54
Carboplatin	€ 2,003.88 – 3,005.82

Designation of the therapy	Annual treatment costs/patient
Nab-paclitaxel	€ 8,985.84 – 13,478.76
<i>Maintenance treatment</i>	
Atezolizumab	€ 50,451.73 – 59,302.91
Total:	€ 87,994.99 – 93,489.85
Appropriate comparator therapy:	
Pembrolizumab	€ 101,243.99

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 March 2020

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
Nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	12–18	€ 972 – 1,458
Appropriate comparator therapy:					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	17.4	€ 1,235.40

- b) Adult patients with metastatic non-squamous non-small cell lung cancer and a Tumour Proportion Score [TPS] of < 50% (PD-L1 expression) and without EGFR- or ALK-positive tumour mutations; first-line therapy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
<i>Induction therapy</i>	
Atezolizumab	€ 17,702.36 – 26,553.54
Carboplatin	€ 2,003.88 – 3,005.82
Nab-paclitaxel	€ 8,985.84 – 13,478.76
<i>Maintenance treatment</i>	
Atezolizumab	€ 50,451.73 – 59,302.91
Total:	€ 87,994.99 – 93,489.85
Appropriate comparator therapy:	
<i>Cisplatin in combination with a third-generation cytostatic agent (docetaxel or gemcitabine or paclitaxel or pemetrexed or vinorelbine)</i>	
<i>Cisplatin plus docetaxel</i>	
Cisplatin	€ 2,007.44
Docetaxel	€ 21,230.61
Total	€ 23,238.05
Additionally required SHI service	€ 328.58 – 421.62
<i>Cisplatin plus gemcitabine</i>	
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
<i>Cisplatin plus paclitaxel</i>	
Cisplatin	€ 2,271.74
Paclitaxel	€ 20,749.85
Total	€ 23,021.59
Additionally required SHI service	€ 559.12 – 652.16
<i>Cisplatin plus pemetrexed</i>	
Cisplatin	€ 2,007.44
Pemetrexed	€ 68,656.57
Total	€ 70,664.01
Additionally required SHI service	€ 454.67 – 594.50
<i>Cisplatin plus vinorelbine</i>	
Cisplatin	€ 2,007.44 – 2,486.11
Vinorelbine	€ 4,716.97 – 5,686.32

Designation of the therapy	Annual treatment costs/patient
Total	€ 6,724.41 – 8,172.43
Additionally required SHI service	€ 328.58 – 421.62
<i>Carboplatin plus docetaxel</i>	
Carboplatin	€ 8,716.88
Docetaxel	€ 21,230.61
Total	€ 29,947.49
<i>Carboplatin plus gemcitabine</i>	
Carboplatin	€ 8,716.88
Gemcitabine	€ 8,193.66
Total	€ 16,910.54
<i>Carboplatin plus paclitaxel</i>	
Carboplatin	€ 8,716.88
Paclitaxel	€ 20,749.85
Total	€ 29,466.73
Additionally required SHI service	€ 230.54
<i>Carboplatin plus pemetrexed</i>	
Carboplatin	€ 8,716.88
Pemetrexed	€ 68,656.57
Total	€ 77,373.45
Additionally required SHI service	€ 126.09 – 172.88
<i>Carboplatin plus vinorelbine</i>	
Carboplatin	€ 8,716.88
Vinorelbine	€ 4,716.97 – 5,686.32
Total	€ 13,433.85 – 14,403.20
<i>Carboplatin in combination with nab-paclitaxel</i>	
Carboplatin	€ 8,716.88
Nab-paclitaxel	€ 39,088.40
Total	€ 47,805.28
<i>Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy</i>	
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

Designation of the therapy	Annual treatment costs/patient
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

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
Nab-paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	3	12–18	€ 972 – 1,458
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	€ 81	1	17.4	€ 1,409.40

Designation of the therapy	Type of service	Costs/ unit	Number / cycle	Number/ patient/ year	Costs/ patient/ year
	agents				
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](http://www.g-ba.de).

Berlin, 4 June 2020

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

Prof. Hecken

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