Justification

Gemeinsamer Bundesausschuss

to the Resolution 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

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1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients. According to Section 35a, paragraph 6 SGB V, the G-BA may also arrange for a benefit assessment according to Section 35a, paragraph 1 SGB V for reimbursable medicinal products containing an active ingredient that is not a new active ingredient within the meaning of Section 35a, paragraph 1 SGB V if a new marketing authorisation with new data protection is granted for the medicinal product. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. Approved therapeutic indications,
2. Medical benefit,
3. Additional medical benefit in relation to the appropriate comparator therapy,
4. Number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. Treatment costs for statutory health insurance funds,
6. Requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and forms part of the Pharmaceuticals Directive.

According to Chapter 5, Section 20, paragraph 4 of the VerfO, the Subcommittee on Medicinal Products may, in the event of a need for change in the sense of a factual and mathematical correction with regard to the information according to Chapter 5, Section 20, paragraph 3, no. 2 (Number of patients or demarcation of patient groups eligible for treatment) or no. 4 (Treatment costs) of the VerfO, make the corresponding changes by mutual consent.

2. Key points of the resolution

At its session on 2 April 2020, the G-BA passed a resolution on the benefit assessment of atezolizumab in accordance with Section 35a SGB V. Following publication of the resolution on the website of the G-BA, the G-BA concluded that there is a need to adapt the information on treatment costs described in the resolution.

The appropriate comparator therapy “pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy” of the patient population “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" was not considered in section "4. Treatment costs".

The resolution is amended to include the annual treatment costs for the appropriate comparator therapy "pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy" at section "4. Treatment costs" for the patient population "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".

In accordance with the information in the justification of the resolution of 2 April 2020 and the product information, the calculation of the annual treatment costs is derived as follows.

Treatment duration:

Designation of the therapy	Treatment mode	Number of treatments/patient/year	Treatment duration/treatment (days)	Treatment days/patient/year
Appropriate comparator therapy				
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				
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy				
Pembrolizumab	1 × per 21-day cycle	17.4 cycles	1	17.4
+ pemetrexed	1 × per 21-day cycle	17.4 cycles	1	17.4
+ carboplatin	1 × per 21-day cycle	17.4 cycles	1	17.4
	or			
+ cisplatin	1 × per 21-day cycle	17.4 cycles	1	17.4

Usage and consumption:

Designation of the therapy	Dosage/ application	Dose/patient/treatment days	Consumption by potency/treatment day	Treatment days/ patient/ year	Annual average consumption by potency
Appropriate comparator therapy					
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-					

Designation of the therapy	Dosage/ application	Dose/patient/treatment days	Consumption by potency/treatment day	Treatment days/ patient/ year	Annual average consumption by potency
positive tumour mutations; first-line therapy					
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy					
Pembrolizumab	200 mg	200 mg	2 × 100 mg –	17.4	34.8 × 100 mg
Pemetrexed	500 mg/m² = 950 mg	950 mg	2 × 500 mg	17.4	34.8 × 500 mg
+ carboplatin	500 mg/m² = 950 mg	950 mg	1 × 600 mg + 1 × 450 mg	17.4	17.4 × 600 mg + 17.4 × 450 mg
	or				
+ cisplatin	75 mg/m² = 142.5 mg	142.5 mg	1 × 100 mg + 1 × 50 mg	17.4	17.4 × 100 mg + 17.4 × 50 mg

Costs:

Costs of the medicinal product:

Designation of the therapy	Package size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Appropriate comparator therapy					
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					
Pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy					
Pembrolizumab	1 CIS	€ 3,083.93	€ 1.77	€ 172.85	€ 2,909.31
Pemetrexed 500 mg	1 PIK	€ 2,533.30	€ 1.77	€ 558.64	€ 1,972.89
Carboplatin 450 mg	1 CIS	€ 227.97	€ 1.77	€ 10.29	€ 215.91

Designation of the therapy	Package size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Carboplatin 600 mg	1 CIS	€ 300.57	€ 1.77	€ 13.74	€ 285.06
Cisplatin 100 mg	1 CIS	€ 76.31	€ 1.77	€ 3.10	€ 71.44
Cisplatin 50 mg	1 CIS	€ 47.43	€ 1.77	€ 1.73	€ 43.93

Pharmaceutical retail price (LAUER-TAXE®) as last revised: 15 March 2020

The additionally required SHI services for cisplatin and pemetrexed described also apply for the combination therapy "pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy".

3. Written statement procedure according to Section 92, paragraph 3a SGB V

The Pharmaceuticals Directive does not require the submission of a written statement procedure according to Section 92, paragraph 3a SGB V. Pharmaceutical companies will not be adversely affected by the correction of the information on costs for the active ingredient; the amendment merely provides a factual and arithmetic correction of the presentation of costs.

4. Bureaucratic costs

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

5. Process sequence

Following the adoption of the resolution, the necessity of the adjustment in the resolution with regard to the calculation of the annual treatment costs of the appropriate comparator therapy in the resolution of 2 April 2020 on an amendment of the Pharmaceuticals Directive Annex XII – Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V – atezolizumab has become apparent.

The matter was discussed in the Working Group Section 35a as well as in the Subcommittee on Medicinal Products.

On 4 June 2020 the plenum unanimously adopted by written statement the amendment to the AM-RL with regard to a factual correction of the information on costs in the resolution of 2 April 2020.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	19 May 2020	Consultation on the facts of the case
Subcommittee on Medicinal Products	26 May 2020	Consultation on an amendment resolution regarding the information on costs in the resolution of 2 April 2020
Plenum	4 June 2020	Resolution by means of written statement on an amendment resolution regarding the information on costs in the resolution of 2 April 2020

Berlin, 4 June 2020

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

Prof. Hecken