**Cemiplimab** (new therapeutic indication: non-small cell lung cancer, first-line, PD-L1 expression ≥ 1%, combination with platinum-based chemotherapy)

Resolution of: 19 October 2023 valid until: unlimited
Entry into force on: 19 October 2023
Federal Gazette, BAnz AT 27 12 2023 B4

**New therapeutic indication (according to the marketing authorisation of 24 March 2023):**

LIBTAYO in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in ≥ 1% of tumour cells), with no EGFR, ALK or ROS1 aberrations, who have:

- locally advanced NSCLC who are not candidates for definitive chemoradiation, or
- metastatic NSCLC.

**Therapeutic indication of the resolution (resolution of 19 October 2023):**

See new therapeutic indication according to marketing authorisation.

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

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

**Appropriate comparator therapy:**

– pembrolizumab as monotherapy

*or*

– atezolizumab as monotherapy

*or*

– cemiplimab as monotherapy

*or*

– nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only for patients with ECOG PS 0-1)

*or*

– pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (only for patients with ECOG PS 0-1 and a squamous NSCLC)

*or*

– pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients without ECOG PS 0-1 and a non-squamous NSCLC)

*or*

– atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG PS 0-1 and a non-squamous NSCLC)

*or*

– atezolizumab in combination with nab-paclitaxel and carboplatin (only for patients with ECOG PS 0-1 and a non-squamous NSCLC)

**Extent and probability of the additional benefit of cemiplimab in combination with platinum-based chemotherapy compared to the appropriate comparator therapy:**

An additional benefit is not proven.

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

**Appropriate comparator therapy:**

– pembrolizumab in combination with pemetrexed and platinum-containing chemotherapy (only for patients without ECOG PS 0-1 and a non-squamous NSCLC)

*or*

– pembrolizumab in combination with carboplatin and either paclitaxel or nab-paclitaxel (only for patients with ECOG PS 0-1 and a squamous NSCLC)

*or*

– atezolizumab as monotherapy (only for patients with PD-L1 expression ≥ 10% in tumour-infiltrating immune cells)

*or*

– atezolizumab in combination with bevacizumab, paclitaxel and carboplatin (only for patients with ECOG PS 0-1 and a non-squamous NSCLC)

*or*

– atezolizumab in combination with nab-paclitaxel and carboplatin (only for patients with ECOG PS 0-1 and a non-squamous NSCLC)

*or*

– nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy (only for patients with ECOG PS 0-1)

*or*

– carboplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG PS 2)

*or*

- carboplatin in combination with nab-paclitaxel (only for patients with ECOG PS 2)

**Extent and probability of the additional benefit of cemiplimab in combination with platinum-based chemotherapy compared to the appropriate comparator therapy:**

An additional benefit is not proven.

**Study results according to endpoints:**[1]

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

No adequate 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. | not assessable |
| Morbidity | n.a. | not assessable |
| Health-related quality of life | n.a. | not assessable |
| Side effects | n.a. | not assessable |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

No adequate 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. | not assessable |
| Morbidity | n.a. | not assessable |
| Health-related quality of life | n.a. | not assessable |
| Side effects | n.a. | not assessable |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-36) unless otherwise indicated.

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

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

Approx. 4,680 to 6,680 patients

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

approx. 4,860 to 6,220 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 Libtayo (active ingredient: cemiplimab) at the following publicly accessible link (last access: 20 July 2023):

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

Treatment with cemiplimab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with non-small cell lung cancer, as well as specialists in internal medicine and pulmonology or specialists in pulmonary medicine and other doctors from specialist groups 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.

Patients are to be selected for treatment with cemiplimab on the basis of PD-L1 tumour expression, confirmed by a validated test.

## 4. Treatment costs

**Annual treatment costs:**

The costs for the first year of treatment are shown for the cost representation in the resolution.

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Cemiplimab | € 80,879.55 |
| *+ platinum-based chemotherapy (carboplatin or cisplatin + pemetrexed, carboplatin or cisplatin + paclitaxel):* | |
| *Carboplatin + pemetrexed* | |
| Carboplatin | € 8,718.27 |
| Pemetrexed | € 17,088.19 |
| *Total (pemetrexed + carboplatin)* | € 25,806.46 |
| *Cemiplimab + carboplatin + pemetrexed* | € 106,686.01 |
| Additionally required SHI costs | € 116.92 - € 154.63 |
| *Cisplatin + pemetrexed* | |
| Cisplatin | € 1,984.12 |
| Pemetrexed | € 17,088.19 |
| *Total (pemetrexed + cisplatin)* | € 19,072.31 |
| *Cemiplimab + cisplatin + pemetrexed* | € 99,951.86 |
| Additionally required SHI costs | € 445.50 - € 576.25 |
| *Carboplatin + paclitaxel* | |
| Carboplatin | € 8,718.27 |
| Paclitaxel | € 16,629.01 |
| *Total (carboplatin + paclitaxel)* | € 25,347.28 |
| *Cemiplimab + carboplatin + paclitaxel* | € 106,226.83 |
| Additionally required SHI costs | € 254.58 |
| *Cisplatin + paclitaxel* | |
| Cisplatin | € 2,266.87 |
| Paclitaxel | € 16,629.01 |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| *Total (cisplatin + paclitaxel)* | € 18,895.88 |
| *Cemiplimab + cisplatin + paclitaxel* | € 99,775.43 |
| Additionally required SHI costs | € 583.16 - € 676.20 |
| Appropriate comparator therapy: | |
| *Monotherapies* | |
| Atezolizumab | € 64,877.81 - € 68,557.39 |
| Cemiplimab | € 80,879.55 |
| Pembrolizumab | € 93,515.26 |
| *Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)* | |
| Nivolumab | € 73,035.63 |
| + ipilimumab | € 54,832.10 |
| Total | € 127,867.73 |
| *Carboplatin + paclitaxel* | |
| Carboplatin | € 1,002.10 |
| Paclitaxel | € 1,911.38 |
| Total | € 2,913.48 |
| *Nivolumab + ipilimumab + carboplatin + paclitaxel* | € 130,781.21 |
| Additionally required SHI costs | € 64.01 |
| *Carboplatin + pemetrexed* | |
| Carboplatin | € 1,002.10 |
| Pemetrexed | € 1,964.16 |
| Total | € 2,966.26 |
| *Nivolumab + ipilimumab + carboplatin + pemetrexed* | € 130,833.99 |
| Additionally required SHI costs | € 34.93 - € 41.13 |
| *Cisplatin + pemetrexed* | |
| Cisplatin | € 228.06 |
| Pemetrexed | € 1,964.16 |
| Total | € 2,192.22 |
| *Nivolumab + ipilimumab + cisplatin + pemetrexed* | € 130,059.95 |
| Additionally required SHI costs | € 147.82 - € 164.81 |
| *Atezolizumab + bevacizumab + paclitaxel + carboplatin (only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| *Induction therapy (4 -6 cycles)* | |
| Atezolizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 10,506.88 - € 15,760.32<br>(840 mg; 4 -6 cycles)<br>or<br>€ 14,914.44 - € 22,371.66<br>(1,200 mg; 4 -6 cycles)<br>or<br>€ 21,013.76 - € 31,520.64<br>(1,680 mg; 4 -6 cycles) |
| + bevacizumab<br>(7.5 mg/kg or 15.5 mg/kg) | € 8,486.88 - € 12,730.32<br>(7.5 mg/kg; 4 -6 cycles)<br>or<br>€ 16,858.80 - € 25,288.20<br>(15 mg/kg; 4 -6 cycles) |
| + paclitaxel | € 3,822.76 - € 5,734.14 |
| + carboplatin | € 2,004.20 - € 3,006.30 |
| *Maintenance treatment* | |
| Atezolizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 52,797.07 - € 58,050.51<br>(840 mg; 20.1 -22.1 cycles)<br>or<br>€ 42,506.15 - € 49,963.37<br>(1,200 mg; 11.4 -13.4 cycles)<br>or<br>€ 36,774.08 - € 47,280.96<br>(1,680 mg; 7 -9 cycles) |
| + bevacizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 24,187.61 – € 28,431.05<br>(7.5 mg/kg; 11.4 - 13.4 cycles)<br>or<br>€ 48,047.58 - € 56,476.98<br>(15 mg/kg; 11.4 - 13.4 cycles) |
| *Total*<br>*(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)* | <u>Combination with 7.5 mg/kg bevacizumab:</u><br>€ 111,302.28 - € 114,215.76<br>(4 - 6 induction cycles with 840 mg atezolizumab)<br>or<br>€ 107,622.70 - € 110,536.18<br>(4 - 6 induction cycles with 1,200 mg atezolizumab)<br>or<br>€ 111,039.61 - € 113,953.09<br>(4 - 6 induction cycles with 1,680 mg atezolizumab)<br><br>or<br><br><u>Combination with 15 mg/kg bevacizumab:</u> |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| | € 147,720.13 - € 150,633.61<br>(4 - 6 induction cycles with 840 mg atezolizumab)<br>€ 144,040.55 - € 146,954.03<br>(4 - 6 induction cycles with 1,200 mg atezolizumab)<br>or<br>€ 147,457.46 - € 150,370.94<br>(4 - 6 induction cycles with 1,680 mg atezolizumab) |
| *Additionally required SHI costs* | € 80.20 - € 135.46 |
| *Atezolizumab + carboplatin + nab-paclitaxel*<br>*(only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | |
| *Induction therapy (4 -6 cycles)* | |
| Atezolizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 10,506.88 - € 15,760.32<br>(840 mg; 4 - 6 cycles)<br>or<br>€ 14,914.44 - € 22,371.66<br>(1,200 mg; 4 - 6 cycles)<br>or<br>€ 21,013.76 - € 31,520.64<br>(1,680 mg; 4 - 6 cycles) |
| + carboplatin | € 2,004.20 - € 3,006.30 |
| + nab-paclitaxel | € 9,780.48 - € 14,670.72 |
| *Maintenance treatment* | |
| Atezolizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 52,797.07 - € 58,050.51<br>(840 mg; 20.1 -22.1 cycles)<br>or<br>€ 42,506.15 - € 49,963.37<br>(1,200 mg; 11.4 -13.4 cycles)<br>or<br>€ 36,774.08 - € 47,280.96<br>(1,680 mg; 7 - 9 cycles) |
| *Total*<br>*(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)* | € 80,342.07 - € 86,234.41<br>(4 - 6 induction cycles with 840 mg atezolizumab)<br>or<br>€ 76,662.49 - € 82,554.83<br>(4 - 6 induction cycles with 1,200 mg atezolizumab)<br>or<br>€ 80,079.40 - € 85,971.74<br>(4 - 6 induction cycles with 1,680 mg atezolizumab) |
| *Pembrolizumab + carboplatin + (nab)-paclitaxel* | |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| *(only for patients with ECOG-PS 0-1 and squamous NSCLC)* | |
| *Pembrolizumab + carboplatin + paclitaxel* | |
| Pembrolizumab | € 93,515.26 |
| Carboplatin | € 8,718.27 |
| Paclitaxel | € 16,629.01 |
| *Total* | € 118,862.53 |
| Additionally required SHI costs | € 254.58 |
| *Pembrolizumab + carboplatin + nab-paclitaxel* | |
| Pembrolizumab | € 93,515.26 |
| Carboplatin | € 8,718.27 |
| nab-paclitaxel | € 42,545.09 |
| *Total* | € 144,778.61 |
| *Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)* | |
| *Pembrolizumab + pemetrexed + cisplatin* | |
| Pembrolizumab | € 93,515.26 |
| Pemetrexed | € 17,088.19 |
| Cisplatin | € 1,984.12 |
| *Total* | € 112,587.57 |
| Additionally required SHI costs | € 445.50 - € 576.26 |
| *Pembrolizumab + pemetrexed + carboplatin* | |
| Pembrolizumab | € 93,515.26 |
| Pemetrexed | € 17,088.19 |
| Carboplatin | € 8,718.27 |
| *Total* | € 119,321.72 |
| Additionally required SHI costs | € 116.92 - € 154.64 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2023)

Other SHI services:

| Designation of the therapy | Type of service | Costs/ unit | Number / cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| **Medicinal product to be assessed** | | | | | |
| *Cemiplimab + platinum-based chemotherapy* | | | | | |
| Cemiplimab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| + carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| + cisplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| + pemetrexed | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| + paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| **Appropriate comparator therapy** | | | | | |
| *Monotherapies* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 26.1 | € 2,610 |
| | | | | or | |
| | | | | 17.4 | € 1,740 |
| | | | | or | |
| | | | | 13.0 | € 1,300 |
| Cemiplimab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |

| | | | | | |
|---|---|---|---|---|---|
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 8.7 | € 870 |
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| *Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)* | | | | | |
| Nivolumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| Ipilimumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 8.7 | € 870 |
| Cisplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Pemetrexed | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| *Atezolizumab + bevacizumab + paclitaxel + carboplatin (only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | | | | | |
| *Induction therapy* | | | | | |
| Atezolizumab | Surcharge for the preparation of a | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |

| | | | | | |
|---|---|---|---|---|---|
| | parenteral solution containing monoclonal antibodies | | | | |
| Bevacizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| Paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| *Maintenance treatment* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 20.1 - 22.1 | € 2,010 - € 2,210 |
| | | | | or | |
| | | | | 11.4 - 13.4 | € 1,140 - € 1,340 |
| | | | | or | |
| | | | | 7.0 - 9.0 | € 700 - € 900 |
| Bevacizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 11.4 - 13.4 | € 1,140 - € 1,340 |
| *Atezolizumab + carboplatin + nab-paclitaxel*<br>*(only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | | | | | |
| *Induction therapy* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| nab-paclitaxel | Surcharge for production of a parenteral | € 100 | 3 | 4.0 - 6.0 | € 1,200 - € 1,800 |

| | | | | | |
|---|---|---|---|---|---|
| | preparation containing cytostatic agents | | | | |
| *Maintenance treatment* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 20.1 - 22.1 | € 2,010 - € 2,210 |
| | | | | or | |
| | | | | 11.4 - 13.4 | € 1,140 - € 1,340 |
| | | | | or | |
| | | | | 7.0 - 9.0 | € 700 - € 900 |
| *Pembrolizumab + carboplatin + (nab)-paclitaxel (only for patients with ECOG-PS 0-1 and squamous NSCLC)* | | | | | |
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| | | | | or | |
| | | | | 8.7 | € 870 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| nab-paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 3 | 17.4 | € 5,220 |
| *Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)* | | | | | |
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| | | | | or | |
| | | | | 8.7 | € 870 |
| Pemetrexed | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Cisplatin | Surcharge for production of a parenteral | € 100 | 1 | 17.4 | € 1,740 |

| | | | | | |
|---|---|---|---|---|---|
| | preparation containing cytostatic agents | | | | |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1- (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Cemiplimab | € 80,879.55 |
| *+ platinum-based chemotherapy (carboplatin or cisplatin + pemetrexed, carboplatin or cisplatin + paclitaxel):* | |
| *Carboplatin + pemetrexed* | |
| Carboplatin | € 8,718.27 |
| Pemetrexed | € 17,088.19 |
| *Total (pemetrexed + carboplatin)* | € 25,806.46 |
| *Cemiplimab + carboplatin + pemetrexed* | € 106,686.01 |
| Additionally required SHI costs | € 116.92 - € 154.63 |
| *Cisplatin + pemetrexed* | |
| Cisplatin | € 1,984.12 |
| Pemetrexed | € 17,088.19 |
| *Total (pemetrexed + cisplatin)* | € 19,072.31 |
| *Cemiplimab + cisplatin + pemetrexed* | € 99,951.86 |
| Additionally required SHI costs | € 445.50 - € 576.25 |
| *Carboplatin + paclitaxel* | |
| Carboplatin | € 8,718.27 |
| Paclitaxel | € 16,629.01 |
| *Total (carboplatin + paclitaxel)* | € 25,347.28 |
| *Cemiplimab + carboplatin + paclitaxel* | € 106,226.83 |
| Additionally required SHI costs | € 254.58 |
| *Cisplatin + paclitaxel* | |
| Cisplatin | € 2,266.87 |
| Paclitaxel | € 16,629.01 |
| *Total (cisplatin + paclitaxel)* | € 18,895.88 |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| *Cemiplimab + cisplatin + paclitaxel* | € 99,775.43 |
| Additionally required SHI costs | € 583.16 - € 676.20 |
| Appropriate comparator therapy: | |
| *Monotherapies* | |
| Atezolizumab | € 64,877.81 - € 68,557.39 |
| *Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)* | |
| Nivolumab | € 73,035.63 |
| + ipilimumab | € 54,832.10 |
| Total | € 127,867.73 |
| *Carboplatin + paclitaxel* | |
| Carboplatin | € 1,002.10 |
| Paclitaxel | € 1,911.38 |
| Total | € 2,913.48 |
| *Nivolumab + ipilimumab + carboplatin + paclitaxel* | € 130,781.21 |
| Additionally required SHI costs | € 64.01 |
| *Carboplatin + pemetrexed* | |
| Carboplatin | € 1,002.10 |
| Pemetrexed | € 1,964.16 |
| Total | € 2,966.26 |
| *Nivolumab + ipilimumab + carboplatin + pemetrexed* | € 130,833.99 |
| Additionally required SHI costs | € 34.93 - € 41.13 |
| *Cisplatin + pemetrexed* | |
| Cisplatin | € 228.06 |
| Pemetrexed | € 1,964.16 |
| Total | € 2,192.22 |
| *Nivolumab + ipilimumab + cisplatin + pemetrexed* | € 130,059.95 |
| Additionally required SHI costs | € 147.82 - € 164.81 |
| *Atezolizumab + bevacizumab + paclitaxel + carboplatin (only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | |
| *Induction therapy (4 -6 cycles)* | |
| Atezolizumab (840 mg or 1,200 mg or 1,680 mg) | € 10,506.88 - € 15,760.32 (840 mg; 4 - 6 cycles) or € 14,914.44 - € 22,371.66 (1,200 mg; 4 - 6 cycles) or |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| | € 21,013.76 - € 31,520.64<br>(1,680 mg; 4 - 6 cycles) |
| + bevacizumab<br>(7.5 mg/kg or 15.5 mg/kg) | € 8,486.88 - € 12,730.32<br>(7.5 mg/kg; 4 - 6 cycles)<br>or<br>€ 16,858.80 - € 25,288.20<br>(15 mg/kg; 4 - 6 cycles) |
| + paclitaxel | € 3,822.76 - € 5,734.14 |
| + carboplatin | € 2,004.20 - € 3,006.30 |
| *Maintenance treatment* | |
| Atezolizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 52,797.07 - € 58,050.51<br>(840 mg; 20.1 - 22.1 cycles)<br>or<br>€ 42,506.15 - € 49,963.37<br>(1,200 mg; 11.4 - 13.4 cycles)<br>or<br>€ 36,774.08 - € 47,280.96<br>(1,680 mg; 7 - 9 cycles) |
| + bevacizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 24,187.61 - € 28,431.05<br>(7.5 mg/kg; 11.4 - 13.4 cycles)<br>or<br>€ 48,047.58 - € 56,476.98<br>(15 mg/kg; 11.4 - 13.4 cycles) |
| *Total*<br>*(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)* | <u>Combination with 7.5 mg/kg bevacizumab:</u><br>€ 111,302.28 - € 114,215.76<br>(4 - 6 induction cycles with 840 mg atezolizumab)<br>or<br>€ 107,622.70 - € 110,536.18<br>(4 - 6 induction cycles with 1,200 mg atezolizumab)<br>or<br>€ 111,039.61 - € 113,953.09<br>(4 - 6 induction cycles with 1,680 mg atezolizumab)<br><br>or<br><br><u>Combination with 15 mg/kg bevacizumab:</u><br>€ 147,720.13 - € 150,633.61<br>(4 - 6 induction cycles with 840 mg atezolizumab)<br>€ 144,040.55 - € 146,954.03<br>(4 - 6 induction cycles with 1,200 mg atezolizumab)<br>or |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| | € 147,457.46 - € 150,370.94<br>(4 - 6 induction cycles with 1,680 mg atezolizumab) |
| *Additionally required SHI costs* | € 80.20 - € 135.46 |
| *Atezolizumab + carboplatin + nab-paclitaxel*<br>*(only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | |
| *Induction therapy (4 -6 cycles)* | |
| Atezolizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 10,506.88 - € 15,760.32<br>(840 mg; 4 -6 cycles)<br>or<br>€ 14,914.44 - € 22,371.66<br>(1,200 mg; 4 - 6 cycles)<br>or<br>€ 21,013.76 - € 31,520.64<br>(1,680 mg; 4 - 6 cycles) |
| + carboplatin | € 2,004.20 - € 3,006.30 |
| + nab-paclitaxel | € 9,780.48 - € 14,670.72 |
| *Maintenance treatment* | |
| Atezolizumab<br>(840 mg or 1,200 mg or 1,680 mg) | € 52,797.07 - € 58,050.51<br>(840 mg; 20.1 -22.1 cycles)<br>or<br>€ 42,506.15 - € 49,963.37<br>(1,200 mg; 11.4 - 13.4 cycles)<br>or<br>€ 36,774.08 - € 47,280.96<br>(1,680 mg; 7 - 9 cycles) |
| *Total*<br>*(Cost range taking into account the number of induction cycles and atezolizumab as well as bevacizumab dosing regimens)* | € 80,342.07 - € 86,234.41<br>(4 - 6 induction cycles with 840 mg atezolizumab)<br>or<br>€ 76,662.49 - € 82,554.83<br>(4 - 6 induction cycles with 1,200 mg atezolizumab)<br>or<br>€ 80,079.40 - € 85,971.74<br>(4 - 6 induction cycles with 1,680 mg atezolizumab) |
| *Pembrolizumab + carboplatin + (nab)-paclitaxel*<br>*(only for patients with ECOG-PS 0-1 and squamous NSCLC)* | |
| *Pembrolizumab + carboplatin + paclitaxel* | |
| Pembrolizumab | € 93,515.26 |
| Carboplatin | € 8,718.27 |
| Paclitaxel | € 16,629.01 |
| *Total* | € 118,862.53 |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Additionally required SHI costs | € 254.58 |
| *Pembrolizumab + carboplatin + nab-paclitaxel* | |
| Pembrolizumab | € 93,515.26 |
| Carboplatin | € 8,718.27 |
| nab-paclitaxel | € 42,545.09 |
| *Total* | € 144,778.61 |
| *Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)* | |
| *Pembrolizumab + pemetrexed + cisplatin* | |
| Pembrolizumab | € 93,515.26 |
| Pemetrexed | € 17,088.19 |
| Cisplatin | € 1,984.12 |
| *Total* | € 112,587.57 |
| Additionally required SHI costs | € 445.50 - € 576.26 |
| *Pembrolizumab + pemetrexed + carboplatin* | |
| Pembrolizumab | € 93,515.26 |
| Pemetrexed | € 17,088.19 |
| Carboplatin | € 8,718.27 |
| *Total* | € 119,321.72 |
| Additionally required SHI costs | € 116.92 - € 154.64 |
| *Carboplatin + nab-paclitaxel (only for patients with ECOG-PS 2)* | |
| Carboplatin | € 8,718.27 |
| nab-paclitaxel | € 42,545.09 |
| *Total* | € 51,263.36 |
| *Carboplatin + third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG-PS 2)* | |
| *Carboplatin + vinorelbine* | |
| Carboplatin | € 8,718.27 |
| Vinorelbine | € 4,717.11 - € 5,686.60 |
| *Total* | € 13,435.38 - € 14,404.87 |
| *Carboplatin + gemcitabine* | |
| Carboplatin | € 8,718.27 |
| Gemcitabine | € 8,056.20 |
| *Total* | € 16,774.47 |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| *Carboplatin + docetaxel* | |
| Carboplatin | € 8,718.27 |
| Docetaxel | € 8,523.22 |
| *Total* | € 17,241.49 |
| *Carboplatin + paclitaxel* | |
| Carboplatin | € 8,718.27 |
| Paclitaxel | € 16,629.01 |
| *Total* | € 25,347.28 |
| Additionally required SHI costs | € 254.58 |
| *Carboplatin + pemetrexed* | |
| Carboplatin | € 8,718.27 |
| Pemetrexed | € 17,088.19 |
| *Total* | € 25,806.46 |
| Additionally required SHI costs | € 116.92 - € 154.64 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2023)

Other SHI services:

| Designation of the therapy | Type of service | Costs/ unit | Number / cycle | Number/ patient/ year | Costs/ patient/ year |
|---|---|---|---|---|---|
| **Medicinal product to be assessed** | | | | | |
| *Cemiplimab + platinum-based chemotherapy* | | | | | |
| Cemiplimab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| + carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| + cisplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| + pemetrexed | Surcharge for production of a parenteral | € 100 | 1 | 17.4 | € 1,740 |

| | | | | | |
|---|---|---|---|---|---|
| | preparation containing cytostatic agents | | | | |
| + paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| **Appropriate comparator therapy** | | | | | |
| *Monotherapy* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 26.1 | € 2,610 |
| | | | | or | |
| | | | | 17.4 | € 1,740 |
| | | | | or | |
| | | | | 13.0 | € 1,300 |
| *Nivolumab + ipilimumab + 2 cycles of platinum-based chemotherapy (only for patients with ECOG-PS 0-1)* | | | | | |
| Nivolumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| Ipilimumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 8.7 | € 870 |
| Cisplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Pemetrexed | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |
| Paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 2.0 | € 200 |

| | | | | | |
|---|---|---|---|---|---|
| *Atezolizumab + bevacizumab + paclitaxel + carboplatin*<br>*(only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | | | | | |
| *Induction therapy* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| Bevacizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| Paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| *Maintenance treatment* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 20.1 - 22.1 | € 2,010 - € 2,210 |
| | | | | or | |
| | | | | 11.4 - 13.4 | € 1,140 - € 1,340 |
| | | | | or | |
| | | | | 7.0 - 9.0 | € 700 - € 900 |
| Bevacizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 11.4 - 13.4 | € 1,140 - € 1,340 |
| *Atezolizumab + carboplatin + nab-paclitaxel*<br>*(only for patients with ECOG PS 0-1 and non-squamous NSCLC)* | | | | | |
| *Induction therapy* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |

| | | | | | |
|---|---|---|---|---|---|
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 4.0 - 6.0 | € 400 - € 600 |
| nab-paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 3 | 4.0 - 6.0 | € 1,200 - € 1,800 |
| *Maintenance treatment* | | | | | |
| Atezolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 20.1 - 22.1 | € 2,010 - € 2,210 |
| | | | | or | |
| | | | | 11.4 - 13.4 | € 1,140 - € 1,340 |
| | | | | or | |
| | | | | 7.0 - 9.0 | € 700 - € 900 |
| *Pembrolizumab + carboplatin + (nab)-paclitaxel (only for patients with ECOG-PS 0-1 and squamous NSCLC)* | | | | | |
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| | | | | or | |
| | | | | 8.7 | € 870 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| nab-paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 3 | 17.4 | € 5,220 |
| *Pembrolizumab + pemetrexed + platinum-containing chemotherapy (only for patients with ECOG-PS 0-1 and non-squamous NSCLC)* | | | | | |
| Pembrolizumab | Surcharge for the preparation of a parenteral solution containing monoclonal antibodies | € 100 | 1 | 17.4 | € 1,740 |
| | | | | or | |
| | | | | 8.7 | € 870 |

| | | | | | |
|---|---|---|---|---|---|
| Pemetrexed | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Cisplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| *Carboplatin + nab-paclitaxel (only for patients with ECOG-PS 2)* | | | | | |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| nab-paclitaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 3 | 17.4 | € 5,220 |
| *Carboplatin + third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed) cf. Annex VI to Section K of the Pharmaceuticals Directive (only for patients with ECOG-PS 2)* | | | | | |
| Carboplatin | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Vinorelbine | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 2 | 17.4 | € 3,480 |
| Gemcitabine | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 2 | 17.4 | € 3,480 |
| Docetaxel | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |
| Paclitaxel | Surcharge for production of a parenteral | € 100 | 1 | 17.4 | € 1,740 |

| | | | | | |
|---|---|---|---|---|---|
| | preparation containing cytostatic agents | | | | |
| Pemetrexed | Surcharge for production of a parenteral preparation containing cytostatic agents | € 100 | 1 | 17.4 | € 1,740 |

**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:

a) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Adults with locally advanced or metastatic NSCLC expressing PD-L1 (in ≥ 1% to < 50% of tumour cells), with no EGFR, ALK or ROS1 aberrations; first-line therapy

- No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

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.