

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
Cemiplimab (new therapeutic indication: non-small cell lung
cancer, first-line)

of 20 January 2022

At its session on 20 January 2022, the Federal Joint Committee (G-BA) resolved to amend 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 amended by the publication of the
resolution of D. month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

- I. In Annex XII, the following information shall be added after No. 4 to the information on
the benefit assessment of Cemiplimab in accordance with the resolution of 6 February
2020:**

Cemiplimab

Resolution of: 20 January 2022

Entry into force on: 20 January 2022

Federal Gazette, BAuz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 21 June 2021):

LIBTAYO as monotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in $\geq 50\%$ 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 20 January 2022):

see new therapeutic indication according to marketing authorisation

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

Adults with locally advanced NSCLC, who are not candidates for definitive chemoradiation or have metastatic NSCLC, expressing PD-L1 in $\geq 50\%$ of tumour cells with no EGFR, ALK or ROS1 aberrations; first-line treatment

Appropriate comparator therapy:

Pembrolizumab

Extent and probability of the additional benefit of Cemiplimab compared to pembrolizumab:

An additional benefit is not proven.

Study results according to endpoints:¹

Adults with locally advanced NSCLC, who are not candidates for definitive chemoradiation or have metastatic NSCLC, expressing PD-L1 in $\geq 50\%$ of tumour cells with no EGFR, ALK or ROS1 aberrations; first-line treatment

No suitable data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

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

Adults with locally advanced NSCLC, who are not candidates for definitive chemoradiation or have metastatic NSCLC, expressing PD-L1 in $\geq 50\%$ of tumour cells with no EGFR, ALK or ROS1 aberrations; first-line treatment

approx. 4,130 - 5,110 patients

¹ Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-98) unless otherwise indicated.

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: 25 November 2021):

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

Treatment with cemiplimab may only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of adult 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.

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

According to the requirements for risk minimisation activities in the EPAR (European Public Assessment Report), the pharmaceutical company must provide the following information material on cemiplimab:

- information brochure for patients
- patient pass

The training material contains, in particular, instructions on the management of immune-mediated side effects potentially occurring with cemiplimab as well as on infusion-related reactions.

This medicinal product was approved under "special conditions". This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

4. Treatment costs

Annual treatment costs:

Adults with locally advanced NSCLC, who are not candidates for definitive chemoradiation or have metastatic NSCLC, expressing PD-L1 in $\geq 50\%$ of tumour cells with no EGFR, ALK or ROS1 aberrations; first-line treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cemiplimab	€ 74,660.27
Appropriate comparator therapy:	
Pembrolizumab	€ 99,714.53

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

Costs for additionally required SHI services: not applicable

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	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	8.7 - 17.4	€ 617.70 - € 1,235.40

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 January 2022.

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

Berlin, 20 January 2022

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

Prof. Hecken