

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 Cemiplimab

of 6 February 2020

At its session on 6 February 2020, the Federal Joint Committee (G-BA) resolved 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 Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

- I. Annex XII shall be amended in alphabetical order to include the active ingredient cemiplimab as follows:**

Cemiplimab

Resolution of: 6 February 2020

Entry into force on: 6 February 2020

Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 28 June 2019):

LIBTAYO as monotherapy is indicated for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation.

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

- a) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; who have not yet received any previous medicinal therapy

Appropriate comparator therapy:

A systemic antineoplastic therapy according to the doctor's instructions

Extent and probability of the additional benefit of cemiplimab compared with the appropriate comparator therapy:

An additional benefit is not proven.

- b) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; whose cancer has progressed after prior medicinal therapy

Appropriate comparator therapy:

Best supportive care

Extent and probability of the additional benefit of cemiplimab compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

- a) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; who have not yet received any previous medicinal therapy

There is no data that would allow for the assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Effect direction/ Risk of bias	Summary
Mortality	n.r.	No data suitable for the benefit assessment.
Morbidity	n.r.	No data suitable for the benefit assessment.
Health-related quality of life	n.r.	No data suitable for the benefit assessment.
Side effects	n.r.	No data suitable for the benefit assessment.
Explanations: ↑, ↓: statistically significant and relevant positive or negative effect with high or unclear risk of bias ↑↑, ↓↓: statistically significant and relevant positive or negative effect with low risk of bias ↔: no relevant difference ∅: no data available n.r.: not rateable		

- b) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; whose cancer has progressed after prior medicinal therapy

There is no data that would allow for the assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Effect direction/ Risk of bias	Summary
Mortality	∅	No data were submitted.
Morbidity	∅	No data were submitted.
Health-related quality of life	∅	No data were submitted.
Side effects	∅	No data were submitted.
Explanations: ↑, ↓: statistically significant and relevant positive or negative effect with high or unclear risk of bias ↑↑, ↓↓: statistically significant and relevant positive or negative effect with low risk of bias ↔: no relevant difference ∅: no data available n.r.: not rateable		

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

- a) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; who have not yet received any previous medicinal therapy

approx. 300 to 920 patients

- b) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; whose cancer has progressed after prior medicinal therapy

approx. 150 to 480 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: 4 November 2019):

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

Treatment with cemiplimab should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in skin and venereal diseases, and specialists participating in the Oncology Agreement who are experienced in the treatment of patients with cutaneous squamous cell carcinoma.

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

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 (EMA) 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:

- a) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; who have not yet received any previous medicinal therapy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Cemiplimab	€ 122,220.82
Appropriate comparator therapy:	
A systemic antineoplastic therapy according to the doctor's instructions	No specification possible

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

- b) Adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation; whose cancer has progressed after prior medicinal therapy

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Cemiplimab	€ 122,220.82
Best supportive care	different for each individual patient
Appropriate comparator therapy:	
Best supportive care	different for each individual patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 January 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
Cemiplimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	17	17	€ 1,207

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 6 February 2020.

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

Berlin, 6 February 2020

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

Prof. Hecken