Gemeinsamer Bundesausschuss

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: cutaneous squamous cell carcinoma, following resection and radiotherapy, adjuvant treatment)

From 4 June 2026

At their session on 4 June 2026, 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 last 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 number 5 to the information on the benefit assessment of Cemiplimab in accordance with the resolution of 19 October 2023 for the therapeutic indication: "for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in ≥ 1% tumour cells), with no EGFR, ALK or ROS1 aberrations":**

Cemiplimab

Resolution of: 4 June 2026
Entry into force on: 4 June 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 17 November 2025):

LIBTAYO as monotherapy is indicated for the adjuvant treatment of adult patients with cutaneous squamous cell carcinoma (CSCC) at high risk of recurrence after surgery and radiation.

Therapeutic indication of the resolution (resolution of 4 June 2026):

See new therapeutic indication according to marketing authorisation.

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

Adults with cutaneous squamous cell carcinoma at high risk of recurrence following resection and radiotherapy; adjuvant treatment

Appropriate comparator therapy:

- Monitoring wait-and-see approach

Extent and probability of the additional benefit of cemiplimab as monotherapy compared to monitoring wait-and-see approach:

Indication of non-quantifiable additional benefit

Study results according to endpoints:[1]

Adults with cutaneous squamous cell carcinoma at high risk of recurrence following resection and radiotherapy; adjuvant treatment

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant differences for the benefit assessment
Morbidity	↑	Advantage in the endpoint of failure of the curative therapeutic approach
Health-related quality of life	↔	No relevant differences for the benefit assessment
Side effects	↓↓	Disadvantages in the endpoints of serious adverse events (SAEs), severe AEs (CTCAE grade ≥ 3) and discontinuation due to AEs
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 ∅: No data available. n.a.: not assessable		

- C-POST study[2]:
- Comparison: Cemiplimab versus placebo
- Study design: double-blind, randomised, controlled phase III study
- The results of the data cut-off from 07.04.2025 were used.

[1] Data from the dossier assessment of the IQWiG (A25-155) and from the addendum (A26-44), unless otherwise indicated.

[2] The investigations conducted in the placebo arm of the C-POST study are considered sufficient implementation of the appropriate comparator therapy - monitoring wait-and-see approach.

Mortality

Endpoint	**Cemiplimab**		**Placebo**		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	Hazard ratio [95% CI] p value [a] *Absolute difference (AD) [b]*
Mortality					
Overall survival	209	n.r. 15 (7.2)	206	n.r. 18 (8.7)	0.78 [0.39; 1.56] 0.482

Morbidity

Endpoint	**Cemiplimab**		**Placebo**		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	Hazard ratio [95% CI] p value [a] *Absolute difference (AD) [b]*
Failure of the curative therapeutic approach [c]					
Event rate [d]	209	29 (13.9)	206	68 (33.0)	RR: 0.42 [0.28; 0.62] < 0.001[e] AD: - 19.1%
Locoregional recurrences	209	10 (4.8)	206	36 (17.5)	–
Distant recurrence [f]	209	12 (5.7)	206	28 (13.6)	–
Death	209	7 (3.3)	206	4 (1.9)	–
Disease-free survival	209	n.r. 29 (13.9)	206	n.r. [48.5; n.c.] 68 (33)	0.35 [0.23; 0.55] < 0.001
Failure of the curative therapeutic approach (sensitivity analysis) [g]					
Event rate [d]	209	59 (28.2)	206	100 (48.5)	RR: 0.58 [0.45; 0.75] < 0.001[e] AD: - 20.3%
Recurrence [h]	209	17 (8.1)	206	57 (27.7)	–

Death	209	7 (3.3)	206	4 (1.9)	–
New primary tumours	209	35 (16.7)	206	39 (18.9)	–
Disease-free survival	209	53.9 (51.5; n.c.) 59 (28.2)	206	25.7 (16.0; 39.2); 100 (48.5)	0.46 [0.33; 0.64] < 0.001 AD: + 28.2 months
Symptomatology					
EORTC QLQ-C30 (time to first deterioration) [i]					
Fatigue	n.d. [j]	5.65 [5.55; 8.31] 136 (65.1)	n.d. [j]	8.31 [5.72; 8.61] 111 (53.9)	1.12 [0.87; 1.45] 0.351
Nausea and vomiting	n.d. [j]	n.r. [40.31; n.c.] 61 (29.2)	n.d. [j]	48.82 [30.75; n.c.] 53 (25.7)	0.91 [0.63; 1.32] 0.625
Pain	n.d. [j]	10.64 [8.34; 13.67] 121 (57.9)	n.d. [j]	13.93 [9.72; 29.57] 97 (47.1)	1.24 [0.94; 1.62] 0.121
Dyspnoea	n.d. [j]	25.86 [21.22; 33.91] 86 (41.1)	n.d. [j]	33.61 [18.20; n.c.] 66 (32.0)	1.08 [0.78; 1.50] 0.644
Insomnia	n.d. [j]	14.98 [10.64; n.c.] 91 (43.5)	n.d. [j]	21.72 [14.55; 38.70] 79 (38.3)	1.06 [0.78; 1.44] 0.699
Appetite loss	n.d. [j]	n.r. [24.08; n.c.] 70 (33.5)	n.d. [j]	n.r. [45.83; n.c.] 47 (22.8)	1.28 [0.88; 1.86] 0.193
Constipation	n.d. [j]	43.96 [25.13; n.c.] 71 (34.0)	n.d. [j]	30.69 [22.34; 58.68] 68 (33.0)	0.86 [0.62; 1.21] 0.397
Diarrhoea	n.d. [j]	62.26 [41.46; n.c.] 60 (28.7)	n.d. [j]	n.r. [29.73; n.c.] 52 (25.2)	0.95 [0.65; 1.38] 0.793

Health status					
EQ-5D VAS (time to first deterioration) [k]					
	n.d. [j]	28.85 [17.87; 37.06] 84 (40.2)	n.d. [j]	38.90 [22.21; n.c.] 62 (30.1)	1.30 [0.93; 1.81] 0.116

Health-related quality of life

Endpoint	**Cemiplimab**		**Placebo**		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	Hazard ratio [95% CI] p value [a] *Absolute difference (AD)* [b]
EORTC QLQ-C30 (time to first deterioration) [l]					
Global health status	n.d. [j]	14.59 [10.64; 29.31] 105 (50.2)	n.d. [j]	22.21 [8.61; 45.83] 87 (42.2)	1.11 [0.83; 1.48] 0.469
Physical functioning	n.d. [j]	21.68 [17.58; 39.82] 89 (42.6)	n.d. [j]	34.83 [14.85; n.c.] 72 (35.0)	1.03 [0.76; 1.42] 0.834
Role functioning	n.d. [j]	10.84 [8.34; 14.75] 118 (56.5)	n.d. [j]	14.39 [9.69; 25.69] 89 (43.2)	1.17 [0.89; 1.55] 0.264
Emotional functioning	n.d. [j]	25.63 [14.98; n.c.] 87 (41.6)	n.d. [j]	22.47 [13.54; 48.82] 80 (38.8)	0.96 [0.70; 1.30] 0.785
Cognitive functioning	n.d. [j]	13.90 [10.78; 18.40] 107 (51.2)	n.d. [j]	13.93 [10.18; 22.21] 94 (45.6)	0.94 [0.71; 1.25] 0.699
Social functioning	n.d. [j]	15.38 [10.81; 25.63] 105 (50.2)	n.d. [j]	17.77 [10.68; 45.83] 84 (40.8)	1.04 [0.78; 1.38] 0.802

Side effects

Endpoint	Cemiplimab		Placebo		Intervention vs control
	N	Median in months [95% CI] *Patients with event n (%)*	N	Median in months [95% CI] *Patients with event n (%)*	Relative risk [95% CI] p value [m] *Absolute difference (AD) [b]*
Total adverse events (presented additionally)					
	205	191 (93.2)	204	185 (90.7)	–
Serious adverse events (SAEs)					
	205	38 (18.5)	204	21 (10.3)	1.78 [1.08; 2.92] 0.024 AD: + 8.2%
Severe adverse events (CTCAE grade ≥ 3)					
	205	52 (25.4)	204	33 (16.2)	1.50 [1.02; 2.22] 0.042 AD: + 9.2%
Therapy discontinuation due to adverse events					
	205	20 (9.8)	204	4 (2.0)	4.93 [1.70; 14.25] 0.003 AD: + 7.8%
Specific adverse events					
Immune-mediated SAEs	205	11 (5.4)	204	1 (0.5)	10.95 [1.43; 84.01] 0.004 [n]
Immune-mediated severe AEs [o]	205	19 (9.3)	204	1 (0.5)	18.91 [2.55; 139.92] < 0.001[n]
Hypothyroidism (PT, AEs) [p]	205	28 (13.7)	204	9 (4.4)	3.07 [1.48; 6.35] 0.003

[a] HR and CI from the Cox proportional hazards model, p value from log-rank test, stratified in each case by high-risk tumour (HN vs non-HN) and geographical region (North America vs Australia / New Zealand vs rest of the world)
[b] Data on absolute difference (AD) only in the case of statistically significant difference; own calculation
[c] New-onset primary tumours were not included in the operationalisation.
[d] Percentage of patients, individual components are shown in the rows below.
[e] Logistic regression model, stratified by high-risk tumour (HN vs non-HN) and geographical region (North America vs Australia / New Zealand vs rest of the world)
[f] Number of qualifying events for the endpoint of disease-free survival. Patients with multiple recurrences are counted only once. 6 patients experienced both locoregional and distant recurrences (1 in the intervention arm and 5 in the comparator arm) and are shown only under distant recurrences.

[g] Sensitivity analysis that includes new-onset primary tumours in the operationalisation
[h] No information is available on the percentage of locoregional or distant recurrences.
[i] An increase in the score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
[j] According to the pharmaceutical company, all randomised patients were included in the analysis. At the same time, it is stated in PRO-SAP that patients with no baseline value or no value in the course of the study were censored on day 1. For example, depending on the scale, no surveys were available for 8% to 11% of patients at the start of the study. Thus, de facto no times of these patients were included in the evaluation. It is not possible to specify the exact number of these patients.
[k] A decrease in the score by ≥ 15 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
[l] A decrease in the score by ≥ 10 points compared to the start of the study is considered as clinically relevant deterioration (scale range: 0 to 100).
[m] Unless otherwise stated, logistic regression model, stratified by high-risk tumour (HN vs non-HN) and geographical region (North America vs Australia / New Zealand vs rest of the world)
[n] Own calculation of RR, CI (asymptotic) and p value (unconditional exact test, CSZ method according to Martín Andrés et al., Computat Stat Data Anal 1994)
[o] Operationalised as CTCAE grade ≥ 3
[p] The PT hypothyroidism includes both symptomatic (CTCAE grade ≥ 2) and asymptomatic events. The data from the study documents show that the majority of hypothyroidism events were symptomatic (82% in the intervention arm and 89% in the comparator arm).

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; EORTC QLQ-C30 = European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30; HN = head and neck; HR = hazard ratio; n.d. = no data available; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PRO-SAP = Patient-Reported Outcome Statistical Analysis Plan; RR = relative risk; VAS = visual analogue scale; vs = versus

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

Adults with advanced cutaneous squamous cell carcinoma at high risk of recurrence following resection and radiotherapy; adjuvant treatment

Approx. 690 to 1,420 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: 27 May 2026):

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

Therapy 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 cutaneous squamous cell carcinoma, specialists in skin and sexually transmitted diseases, as well as other doctors from other 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.

4. Treatment costs

Annual treatment costs:

Adults with advanced cutaneous squamous cell carcinoma at high risk of recurrence following resection and radiotherapy; adjuvant treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cemiplimab	€ 65,218.56
Appropriate comparator therapy:	
Monitoring wait-and-see approach	Not calculable

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 April 2026)

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
Cemiplimab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	16	€ 1,600

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:

Adults with advanced cutaneous squamous cell carcinoma at high risk of recurrence following resection and radiotherapy; adjuvant treatment

– No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient approved as monotherapy.

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.

II. Entry into force

1st The resolution will enter into force on the day of its publication on the Federal Joint Committee's website on 4 June 2026.

2nd The period of validity of the resolution is limited to 1 November 2028.

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

Berlin, 4 June 2026

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

Prof. Hecken