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)
Osimertinib (new therapeutic indication: non-small cell lung cancer, EGFR mutations, following platinum-based chemoradiation therapy)

of 3 July 2025

At their session on 3 July 2025, 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 No. 5 to the information on the benefit assessment of Osimertinib in accordance with the resolution of 6 February 2025:

Osimertinib

Resolution of: 3 July 2025
Entry into force on: 3 July 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 19 December 2024):

Tagrisso as monotherapy is indicated for the treatment of adult patients with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy.

Therapeutic indication of the resolution (resolution of 3 July 2025):

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, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in ≥ 1% of tumour cells

Appropriate comparator therapy:

- Durvalumab

Extent and probability of the additional benefit of osimertinib as monotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in < 1% of tumour cells

Appropriate comparator therapy:

- Best supportive care

Extent and probability of the additional benefit of osimertinib as monotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in ≥ 1% of tumour cells

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 ∅: No data available. n. a.: not assessable		

b) Adults with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in < 1% of tumour cells

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 ∅: No data available. n. a.: not assessable		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-03) unless otherwise indicated.

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

a) Adults with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in ≥ 1% of tumour cells

Approx. 80 – 150 patients

b) Adults with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in < 1% of tumour cells

Approx. 80 – 140 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 Tagrisso (active ingredient: osimertinib) at the following publicly accessible link (last access: 28 May 2025):

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

Treatment with osimertinib may 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 doctors from other specialist groups participating in the Oncology Agreement.

If the use of osimertinib is considered, EGFR mutational status must be determined using a validated assay.

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, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in ≥ 1% of tumour cells

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Osimertinib	€ 66,097.97
Appropriate comparator therapy:	
Durvalumab	€ 77,472.72 - € 89,742.12

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 June 2025)

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
Durvalumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13	€ 1,300
				26	€ 2,600

b) Adults with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in < 1% of tumour cells

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Osimertinib	€ 66,097.97
Best supportive care	Different from patient to patient
Appropriate comparator therapy:	
Best supportive care	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 June 2025)

Costs for additionally required SHI services: not applicable

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, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in ≥ 1% of tumour cells

- 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 authorised in monotherapy.

b) Adults with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, whose disease has not progressed during or following platinum-based chemoradiation therapy and whose tumours express PD-L1 in < 1% of tumour cells

- 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 authorised in 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. The resolution will enter into force on the day of its publication on the website of the G-BA on 3 July 2025.

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

Berlin, 3 July 2025

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

Prof. Hecken