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)
Amivantamab (new therapeutic indication: non-small cell lung cancer, EGFR Exon 19 deletions or Exon 21 substitution mutations (L858R), pretreated, combination with carboplatin and pemetrexed)

of 17 July 2025

At their session on 17 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 Amivantamab in accordance with the resolution of 17 July 2025 for the therapeutic indication: "New therapeutic indication: non-small cell lung cancer, EGFR Exon 19 deletions or Exon 21 substitution mutations (L858R), combination with lazertinib".**

Amivantamab

Resolution of: 17 July 2025
Entry into force on: 17 July 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 22 August 2024):

Rybrevant is indicated in combination with carboplatin and pemetrexed for the treatment of adult patients with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI).

Therapeutic indication of the resolution (resolution of 17 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 advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 0-1

Appropriate comparator therapy:

– Atezolizumab in combination with bevacizumab, carboplatin and paclitaxel

Extent and probability of the additional benefit of amivantamab in combination with carboplatin and pemetrexed compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 2

Appropriate comparator therapy:

– 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

or

– carboplatin in combination with nab-paclitaxel

or

– monotherapy with gemcitabine or vinorelbine (only for patients who are ineligible for platinum-based chemotherapy)

Extent and probability of the additional benefit of amivantamab in combination with carboplatin and pemetrexed compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 0-1

There are no assessable data.

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 advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 2

There are no assessable data.

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) (A25-09) unless otherwise indicated.

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

a) Adults with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 0-1

Approx. 760 to 2,350 patients

b) Adults with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 2

Approx. 225 to 695 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 Rybrevant (active ingredient: amivantamab) at the following publicly accessible link (last access: 3 July 2025):

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

Treatment with amivantamab 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.

EGFR mutational status
Prior to a therapy with Rybrevant, the EGFR mutational status must be detected in the tumour tissue or plasma samples using a validated test method.

4. Treatment costs

Annual treatment costs:

The annual treatment costs shown refer to the first year of treatment.

a) Adults with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 0-1

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Amivantamab in combination with carboplatin and pemetrexed	
Amivantamab	€ 162,118.53

Designation of the therapy	Annual treatment costs/ patient
Carboplatin	€ 6,319.68
Pemetrexed	€ 18,621.48
Total (amivantamab + carboplatin + pemetrexed)	€ 187,059.69
Additionally required SHI costs	*€ 288.35 – € 344.93*
Appropriate comparator therapy:	
Atezolizumab in combination with bevacizumab, carboplatin and paclitaxel	
Induction therapy (4 – 6 cycles)	
Atezolizumab	€ 15,579.72 – € 23,369.58
Bevacizumab (7.5 mg/kg or 15.5 mg/kg)	€ 5,067.68 – € 7,601.52 or € 7,601.52 – € 11,402.28
Carboplatin	€ 1,984.16 – € 2,976.24
Paclitaxel	€ 3,823.88 – € 5,735.82
Additionally required SHI costs	*€ 85.12 – € 143.71*
Maintenance treatment	
Atezolizumab	€ 44,402.20 (after 6 cycles of induction therapy) – € 52,192.06 (after 4 cycles of induction therapy)
Bevacizumab (7.5 mg/kg or 15.5 mg/kg)	€ 14,442.89 (after 6 cycles of induction therapy) – € 16,976.73 (after 4 cycles of induction therapy) or € 21,664.33 (after 6 cycles of induction therapy) – € 25,465.09 (after 4 cycles of induction therapy)
Total (cost range taking into account the number of induction cycles and bevacizumab dosage regimens)	<u>Combination with 7.5 mg/kg bevacizumab:</u> € 95,624.23 – € 98,528.25 (4 - 6 induction cycles) or <u>Combination with 15 mg/kg bevacizumab:</u> € 106,646.43 – € 109,550.45 (4 - 6 induction cycles)
Additionally required SHI costs	*€ 85.12 – € 143.71*

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 July 2025)

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					
Amivantamab in combination with carboplatin and pemetrexed					
Amivantamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	19.4	€ 1,940
Carboplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Pemetrexed	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					
Atezolizumab + bevacizumab + paclitaxel + carboplatin					
Induction therapy					
Bevacizumab	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 solution containing cytostatic agents	€ 100	1	4.0 – 6.0	€ 400 - € 600
Paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	4.0 – 6.0	€ 400 - € 600
Maintenance treatment					
Bevacizumab	Surcharge for the preparation of a	€ 100	1	11.4 –	€ 1,140 –

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing monoclonal antibodies			13.4	€ 1,340

b) Adults with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 2

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Amivantamab in combination with carboplatin and pemetrexed	
Amivantamab	€ 162,118.53
Carboplatin	€ 6,319.68
Pemetrexed	€ 18,621.48
Amivantamab + carboplatin + pemetrexed	
Total (amivantamab + carboplatin + pemetrexed)	€ 187,059.69
Additionally required SHI costs	*€ 288.35 – € 344.93*
Appropriate comparator therapy:	
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	
Carboplatin + docetaxel	
Carboplatin	€ 8,631.10
Docetaxel	€ 8,527.22
Total (carboplatin + docetaxel)	€ 17,158.32
Carboplatin + gemcitabine	
Carboplatin	€ 8,631.10
Gemcitabine	€ 8,088.22
Total (carboplatin + gemcitabine)	€ 16,719.32
Carboplatin + paclitaxel	
Carboplatin	€ 8,631.10
Paclitaxel	€ 16,633.88
Total (carboplatin + paclitaxel)	€ 25,264.98
Additionally required SHI costs	*€ 271.07*

Designation of the therapy	Annual treatment costs/ patient
Carboplatin + pemetrexed	
Carboplatin	€ 8,631.10
Pemetrexed	€ 18,621.48
Total (carboplatin + pemetrexed)	€ 27,252.58
Additionally required SHI costs	*€ 134.39 – € 188.19*
Carboplatin + vinorelbine	
Carboplatin	€ 8,631.10
Vinorelbine	€ 5,016.77 – € 6,263.31
Total (carboplatin + vinorelbine)	€ 13,647.87 – € 14,894.41
Carboplatin in combination with nab-paclitaxel	
Carboplatin	€ 8,631.10
nab-paclitaxel	€ 42,569.10
Total (carboplatin + nab-paclitaxel)	€ 51,200.20
Monotherapy with gemcitabine or vinorelbine (only for patients who are ineligible for platinum-based chemotherapy)	
Gemcitabine	€ 7,016.88
Vinorelbine	€ 7,510.74 – € 9,376.96

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 July 2025)

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					
Amivantamab in combination with carboplatin and pemetrexed					
Amivantamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	19.4	€ 1,940
Carboplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pemetrexed	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					
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					
Carboplatin	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Docetaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Gemcitabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
Paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Pemetrexed	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	17.4	€ 1,740
Vinorelbine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	2	34.8	€ 3,480
Carboplatin in combination with nab-paclitaxel					
Carboplatin	Surcharge for production of a	€ 100	1	17.4	€ 1,740

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral solution containing cytostatic agents				
nab-paclitaxel	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	52.2	€ 5,220
Monotherapy with gemcitabine or vinorelbine (only for patients who are ineligible for platinum-based chemotherapy)					
Gemcitabine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	3	39.0	€ 3,900
Vinorelbine	Surcharge for production of a parenteral solution containing cytostatic agents	€ 100	1	52.1	€ 5,210

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 advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 0-1

- 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.

b) Adults with advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations after failure of prior therapy including an EGFR tyrosine kinase inhibitor (TKI); ECOG-PS 2

- 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.

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 17 July 2025.

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

Berlin, 17 July 2025

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

Prof. Hecken