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 20 insertion mutation, first-line, 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), pretreated, combination with carboplatin and pemetrexed".**

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 27 June 2024):

Rybrevant is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations.

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

Adults with advanced NSCLC and with activating EGFR Exon 20 insertion mutations; first-line therapy

Appropriate comparator therapy:

- Cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)

  or

- 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

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]

Adults with advanced NSCLC and with activating EGFR Exon 20 insertion mutations; first-line therapy

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

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

Adults with advanced NSCLC and with activating EGFR Exon 20 insertion mutations; first-line therapy

Approx. 70 – 215 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: 14 April 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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-10) unless otherwise indicated.

specialists in pulmonary medicine and other doctors from specialist groups participating in the Oncology Agreement.

EGFR Exon 20 insertion mutation testing
Prior to a therapy with Rybrevant, positive EGFR Exon 20 insertion mutational status must be detected using a validated test method.

4. Treatment costs

Annual treatment costs:

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

Adults with advanced NSCLC and with activating EGFR Exon 20 insertion mutations; first-line therapy

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:	
Cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)	
Cisplatin + docetaxel	
Cisplatin	€ 2,017.18
Docetaxel	€ 8,527.22
Total (cisplatin + docetaxel)	€ 10,544.40
Additionally required SHI costs	*€ 271.70 – € 341.48*
Cisplatin + gemcitabine	
Cisplatin	€ 2,017.18 – € 2,495.86
Gemcitabine	€ 8,088.22
Total (cisplatin + gemcitabine)	€ 10,105.40 – € 10,584.08
Additionally required SHI costs	*€ 271.70 – € 341.48*
Cisplatin + paclitaxel	

Designation of the therapy	Annual treatment costs/ patient
Cisplatin	€ 2,286.18
Paclitaxel	€ 16,633.88
Total (cisplatin + paclitaxel)	€ 18,920.06
Additionally required SHI costs	*€ 542.77 – € 612.55*
Cisplatin + pemetrexed	
Cisplatin	€ 2,017.18
Pemetrexed	€ 18,621.48
Total (cisplatin + pemetrexed)	€ 20,638.66
Additionally required SHI costs	*€ 406.09 – € 529.67*
Cisplatin + vinorelbine	
Cisplatin	€ 2,017.18 – € 2,495.86
Vinorelbine	€ 5,016.77 – € 6,263.31
Total (cisplatin + vinorelbine)	€ 7,033.95 – € 8,759.17
Additionally required SHI costs	*€ 271.70 – € 341.48*
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*
Carboplatin + pemetrexed	
Carboplatin	€ 8,631.10
Pemetrexed	€ 18,621.48

Designation of the therapy	Annual treatment costs/ patient
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

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 preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Appropriate comparator therapy					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Cisplatin in combination with a third-generation cytostatic (vinorelbine or gemcitabine or docetaxel or paclitaxel or pemetrexed)					
Cisplatin	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 preparation containing cytostatic agents	€ 100	2	34.8	€ 3,480
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	€ 100	1	17.4	€ 1,740

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	preparation containing cytostatic agents				
Docetaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	34.8	€ 3,480
Paclitaxel	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
Vinorelbine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	34.8	€ 3,480
Carboplatin in combination with nab-paclitaxel					
Carboplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	17.4	€ 1,740
nab-paclitaxel	Surcharge for production of a	€ 100	3	52.2	€ 5,220

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	parenteral preparation containing cytostatic agents				

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 NSCLC and with activating EGFR Exon 20 insertion mutations; first-line therapy

– 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. Entry into force

1. The resolution will enter into force on the day of its publication on the internet on the website of the Federal Joint Committee on 17 July 2025.

2. The period of validity of the resolution is limited to 1 July 2026.

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