Gemeinsamer Bundesausschuss

Amivantamab (lung cancer, non-small cell, activating EGFR Exon 20 Insertion mutations, after platinum-based chemotherapy)

Resolution of: 7 July 2022 Valid until: unlimited
Entry into force on: 7 July 2022
Federal Gazette, BAnz AT 27 07 2022 B3

Therapeutic indication (according to the marketing authorisation of 9 December 2021):

Rybrevant as monotherapy is indicated for treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based therapy.

Therapeutic indication of the resolution (resolution of 7 July 2022):

See 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 or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom further chemotherapy is indicated

Appropriate comparator therapy:

- Docetaxel

or

- Docetaxel in combination with nintedanib

or

- Pemetrexed

Extent and probability of the additional benefit of amivantamab compared to the appropriate comparator therapy:

An additional benefit is not proven.

b) Adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom no further chemotherapy is indicated

Appropriate comparator therapy:

- Best supportive care

Extent and probability of the additional benefit of amivantamab compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom further chemotherapy is indicated

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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

b) Adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom no further chemotherapy is indicated

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	There are no usable data for the benefit assessment.
Morbidity	∅	There are no usable data for the benefit assessment.
Health-related quality of life	∅	There are no usable data for the benefit assessment.
Side effects	∅	There are no usable data for the benefit assessment.

[1] Data from IQWiG's dossier assessment (A22-05)

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
∅: There are no usable data for the benefit assessment.
n.a.: not assessable

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

a) Adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom further chemotherapy is indicated

approx. 8 - 22 patients

b) Adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom no further chemotherapy is indicated

approx. 1 - 4 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 May 2022):

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.

This medicinal product was authorised under “special conditions”. This means that further evidence of the benefit of the medicinal product is anticipated. The European Medicines Agency will evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

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:

a) Adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom further chemotherapy is indicated

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Amivantamab	€ 136,490.21
Additionally required SHI services	€ 16.84 - € 21.24
Appropriate comparator therapy:	
Docetaxel or docetaxel in combination with nintedanib or pemetrexed	
Docetaxel	€ 13,742.17
Docetaxel in combination with nintedanib	
Docetaxel	€ 13,742.17
Nintedanib	€ 32,010.08
Total	€ 45,752.26
Pemetrexed	€ 8,802.66
Additionally required SHI services	€ 127.87 – € 176.34

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 June 2022)

b) Adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) Exon 20 insertion mutations, after failure of platinum-based chemotherapy, for whom no further chemotherapy is indicated

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Amivantamab	€ 136,490.21
Additionally required SHI services	€ 16.84 - € 21.24
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 2022)

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Amivantamab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	28.1	€ 1,995.1
Docetaxel (mono or combination therapy)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	17.4	€ 1,409.40