Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Entrectinib (Solid Tumours, Histology Independent)

of 18 February 2021

At its session on 18 February 2021 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 amended on DD Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of entrectinib in accordance with the resolution of 18 February 2021:

Entrectinib

Resolution of: 18 February 2021
Entry into force on: 18 February 2021
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 31 July 2020):

Rozlytrek as monotherapy is indicated for the treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC) not previously treated with ROS1 inhibitors.

Rozlytrek as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion,

- who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and
- who have not received a prior NTRK inhibitor
- who have no satisfactory treatment options

Therapeutic indication of the resolution (resolution of 18 February 2021):

Rozlytrek as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion,

- who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and
- who have not received a prior NTRK inhibitor
- who have no satisfactory treatment options

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

Adult and paediatric patients from the age of 12 years with solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion who have a disease that is locally advanced, metastatic, or where surgical resection is likely to result in severe morbidity and who have not received a prior NTRK inhibitor and who have no satisfactory treatment options

Appropriate comparator therapy:

Patient-individual therapy with the selection of

- Best supportive care

  and
- Surgical resection (which is likely to lead to severe morbidity) for which a patient-individual clinical benefit is expected.

Extent and probability of the additional benefit of entrectinib compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

There are no suitable data that would allow for the assessment of the additional benefit.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n.a.	There are no suitable data available.
Morbidity	n.a.	There are no suitable data available.
Health-related quality of life	n.a.	There are no suitable data available.
Side effects	n.a.	There are no suitable data available.
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

approx. 390–770 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 Rozlytrek (active ingredient: entrectinib) at the following publicly accessible link (last access: 11 January 2021):

https://www.ema.europa.eu/en/documents/product-information/rozlytrek-epar-product-information_de.pdf

Treatment with entrectinib should only be initiated and monitored by specialists experienced in the therapy of adult and paediatric patients with solid tumours, specifically in the treatment of the respective tumour entity, and other physicians of other speciality groups participating in the Oncology Agreement.

Before initiating therapy with entrectinib, the presence of NTRK gene fusion in a tumour sample must be confirmed by a validated test.

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

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Entrectinib	€ 74,505.75 – 111,758.62
+ best supportive care	different for each individual patient
Appropriate comparator therapy:	
Best supportive care	different for each individual patient
Surgical resection	different for each individual patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 February 2021

Costs for additionally required SHI services: not applicable.

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 18 February 2021.

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

Berlin, 18 February 2021

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

Prof. Hecken