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 Larotrectinib (Solid Tumours, Histology Independent)

of 2 April 2020

On 2 April 2020, the Federal Joint Committee (G-BA) resolved by written statement to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 on DD Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient larotrectinib as follows:

Larotrectinib

Resolution of: 2 April 2020
Entry into force on: 2 April 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 19 September 2019):

VITRAKVI as monotherapy is indicated for the treatment of adult and paediatric patients 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 no satisfactory treatment options (see sections 4.4 and 5.1).

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

Adult and paediatric patients 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 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 clinical benefit is expected for individual patients.

Extent and probability of the additional benefit of larotrectinib 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	∅	There are no suitable data for the benefit assessment
Morbidity	∅	There are no suitable data for the benefit assessment
Health-related quality of life	∅	There are no suitable data for the benefit assessment
Side effects	∅	There are no suitable data for the benefit assessment

Explanations:
↑: positive statistically significant and relevant effect with low/unclear reliability of data
↓: negative statistically significant and relevant effect with low/unclear reliability of data
↑↑: positive statistically significant and relevant effect with high reliability of data
↓↓: negative statistically significant and relevant 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 Vitrakvi® (active ingredient: larotrectinib) at the following publicly accessible link (last access: 31 January 2020):
https://www.ema.europa.eu/documents/product-information/vitrakvi-epar-product-information_de.pdf

Treatment with larotrectinib 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 larotrectinib, the presence of NTRK gene fusion in a tumour sample should 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 evaluate new information on this medicinal product at a minimum once per year and update the product information where necessary.

In individual cases, larotrectinib may be a relevant therapy option.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Larotrectinib	€ 76,024.16 – 228,010.03
+ 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: 15 March 2020

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 2 April 2020.

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

Berlin, 2 April 2020

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

Prof. Hecken