Selpercatinib (new therapeutic indication: solid tumours, RET fusion-positive)

Resolution of: 7 November 2024 valid until: unlimited
Entry into force on: 7 November 2024
Federal Gazette, BAnz AT 11 12 2024 B4

New therapeutic indication (according to the marketing authorisation of 29 April 2024):

Retsevmo as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted.

Therapeutic indication of the resolution (resolution of 7 November 2024):

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 RET fusion-positive solid tumour, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted

Appropriate comparator therapy:

- Best supportive care

Extent and probability of the additional benefit of selpercatinib as monotherapy compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with advanced RET fusion-positive solid tumour, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted

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		

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

Adults with advanced RET fusion-positive solid tumour, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted

Approx. 51 to 159 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 Retsevmo (active ingredient: selpercatinib) at the following publicly accessible link (last access: 24 September 2024):

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

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-63) unless otherwise indicated.

Treatment with selpercatinib should only be initiated and monitored by specialists experienced in the treatment of patients with solid tumours, specifically in the treatment of the respective tumour entity, and other doctors from specialist groups participating in the Oncology Agreement.

This medicinal product received a conditional marketing authorisation. 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.

RET testing

The selection of patients for treatment of advanced RET fusion-positive solid tumours should be based on a validated test method.

4. Treatment costs

Annual treatment costs:

Adults with advanced RET fusion-positive solid tumour, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Selpercatinib	€ 35,097.21- € 46,715.70
Best supportive care[2]	Different from patient to patient
Appropriate comparator therapy:	
Best supportive care[2]	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2024)

Costs for additionally required SHI services: not applicable

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:

[2] When comparing selpercatinib with best supportive care, the costs of best supportive care must also be additionally considered for the medicinal product to be assessed.

Adults with advanced RET fusion-positive solid tumour, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

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.