Gemeinsamer Bundesausschuss

Selpercatinib (new therapeutic indication: medullary thyroid cancer, RET-mutant, monotherapy, 12 years and older)

Resolution of: 16 March 2023 valid until: 1 June 2025
Entry into force on: 16 March 2023
Federal Gazette, BAnz AT 19 05 2023

New therapeutic indication (according to the marketing authorisation of 2 September 2022):

Retsevmo as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC).

Therapeutic indication of the resolution (resolution of 16 March 2023):
Retsevmo as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC), first-line therapy.

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

Adults and adolescents 12 years and older with advanced medullary RET receptor tyrosine kinase (rearranged during transfection - RET)-mutant thyroid cancer; first-line therapy

Appropriate comparator therapy:

– Vandetanib

or

– Cabozantinib

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 and adolescents 12 years and older with advanced medullary RET receptor tyrosine kinase (rearranged during transfection - RET)-mutant thyroid cancer; first-line therapy

No adequate data are available to allow an assessment of the additional benefit.

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-106) unless otherwise indicated.

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

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

Adults and adolescents 12 years and older with advanced medullary RET receptor tyrosine kinase (rearranged during transfection - RET)-mutant thyroid cancer; first-line therapy

approx. 40 - 170 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: 1 February 2023):

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

Treatment with selpercatinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology experienced in the treatment of adults with thyroid cancer, and specialists in internal medicine, endocrinology and diabetology, as well as other specialists participating in the Oncology Agreement.

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.

RET testing

The presence of an RET gene fusion (NSCLC and non-medullary thyroid cancer) or mutation (MTC) should be confirmed by a validated test prior to starting treatment with Retsevmo.

4. Treatment costs

Annual treatment costs:

Adults and adolescents 12 years and older with advanced medullary RET receptor tyrosine kinase (rearranged during transfection - RET)-mutant thyroid cancer; first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Selpercatinib	€ 36,432.37 - € 48,495.86
Appropriate comparator therapy:	
Cabozantinib[2]	€ 64,751.91
Vandetanib	First year of treatment: € 50,631.29 - € 52,379.82 Subsequent year: € 52,276.03 - € 52,952.50

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 March 2023)

Costs for additionally required SHI services: not applicable

5. 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 Selpercatinib

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients, which, on the basis of the marketing authorisation under Medicinal Products Act, can be used in a combination therapy with selpercatinib for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC), first-line therapy:

Adults and adolescents 12 years and older with advanced medullary RET receptor tyrosine kinase (rearranged during transfection - RET)-mutant thyroid cancer; first-line therapy

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

[2] Patients ≥ 18 years.

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.