Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Selpercatinib (new therapeutic indication: thyroid cancer, RET fusion-positive, refractory to radioactive iodine, first-line or after prior systemic therapy, ≥ 12 years)

of 7 November 2024

At its session on 7 November 2024, 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 last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. **In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Selpercatinib in accordance with the resolution of 16 March 2023:**

Selpercatinib

Resolution of: 7 November 2024
Entry into force on: 7 November 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

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

Retsevmo as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with:

– advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory (if radioactive iodine is appropriate)

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

Retsevmo as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory (if radioactive iodine is appropriate); first-line therapy.

Retsevmo as monotherapy is indicated for the treatment of adolescents 12 years and older with advanced RET fusion-positive thyroid cancer; after previous therapy with a protein kinase inhibitor.

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

a) <u>Adults and adolescents 12 years and older with advanced RET fusion-positive, radioactive iodine-refractory thyroid cancer, first-line therapy</u>

Appropriate comparator therapy:

- Sorafenib

or

- lenvatinib (for adults only)

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

An additional benefit is not proven.

b) Adolescents 12 years and older with advanced RET fusion-positive thyroid cancer, after previous therapy with a protein kinase inhibitor

Appropriate comparator therapy:

Patient-individual therapy with selection of:

- sorafenib,
- lenvatinib and
- best supportive care

taking into account prior therapy and general condition.

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

An additional benefit is not proven.

Study results according to endpoints:[1]

a) Adults and adolescents 12 years and older with advanced RET fusion-positive, radioactive iodine-refractory thyroid cancer, first-line therapy

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		

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-62) unless otherwise indicated.

b) Adolescents 12 years and older with advanced RET fusion-positive thyroid cancer, after previous therapy with a protein kinase inhibitor

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No 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
∅: No data available.
n.a.: not assessable

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

a) Adults and adolescents 12 years and older with advanced RET fusion-positive, radioactive iodine-refractory thyroid cancer, first-line therapy

Approx. 5 to 35 patients

b) Adolescents 12 years and older with advanced RET fusion-positive thyroid cancer, after previous therapy with a protein kinase inhibitor

approx. 1 patient

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: 15 October 2024):

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, specialists in internal medicine, endocrinology, and diabetology and specialists in paediatrics and adolescent medicine with a focus on paediatric haematology and oncology, all of whom are experienced in the treatment of patients with thyroid cancer, as well as 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 presence of an RET gene mutation (MTC) or RET fusion (all other tumour types) should be confirmed by a validated test prior to treatment with Retsevmo.

4. Treatment costs[2]

Annual treatment costs:

a) Adults and adolescents 12 years and older with advanced RET fusion-positive, radioactive iodine-refractory thyroid cancer, first-line therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Selpercatinib	€ 35,097.21- € 46,715.70
Appropriate comparator therapy:	
Sorafenib	€ 4,590.92
Lenvatinib (Lenvima)	€ 49,243.61

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

Costs for additionally required SHI services: not applicable

[2] Only the costs for the first year of treatment are presented.

b) Adolescents 12 years and older with advanced RET fusion-positive thyroid cancer, after previous therapy with a protein kinase inhibitor

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Selpercatinib	€ 35,097.21- € 46,715.70
Best supportive care[3]	Different from patient to patient
Appropriate comparator therapy:	
Sorafenib	€ 4,590.92
Lenvatinib (Kisplyx, Lenvima)	€ 30,517.89 - € 44,208.80
Best supportive care[3]	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:

a) Adults and adolescents 12 years and older with advanced RET fusion-positive, radioactive iodine-refractory 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.

b) Adolescents 12 years and older with advanced RET fusion-positive thyroid cancer, after previous therapy with a protein kinase inhibitor

- 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

[3] 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.

medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 7 November 2024.

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

Berlin, 7 November 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken