Gemeinsamer Bundesausschuss

Resolution

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

Selpercatinib (thyroid cancer, RET fusion-positive, after prior therapy with sorafenib and/or lenvatinib)

of 2 September 2021

At its session on 2 September 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 last 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 selpercatinib in accordance with the resolution of 2 September 2021:

Selpercatinib

Resolution of: 02.09.2021
Entry into force on:02.09.2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 11 February 2021):

Retsevmo as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib.

Retsevmo as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer (MTC) who require systemic therapy following prior treatment with cabozantinib and/or vandetanib.

Retsevmo as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive non-small cell lung cancer (NSCLC) who require systemic therapy following prior treatment with immunotherapy and/or platinum-based chemotherapy.

Therapeutic indication of the resolution (resolution of 2 September 2021):

Retsevmo as monotherapy is indicated for the treatment of adults with advanced RET fusion-positive thyroid cancer who require systemic therapy following prior treatment with sorafenib and/or lenvatinib.

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

Adults with advanced thyroid cancer; with existing fusion of rearranged during transfection (RET) receptor tyrosine kinase who require systemic therapy following prior treatment with sorafenib and/or lenvatinib

Appropriate comparator therapy:

Patient-individual therapy under the selection of

- sorafenib,
- lenvatinib and
- best supportive care

taking into account histology, previous 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:[1]

There are no suitable 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 ∅: 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. 2 – 16 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: 29 July 2021):

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

Treatment with selpercatinib should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with thyroid cancer, as well as specialists in internal medicine and specialists in endocrinology and diabetes, as well as doctors from other specialist groups participating in the Oncology Agreement.

This medicinal product has been authorised under a so-called “conditional approval” scheme. 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 least annually and update the product information for healthcare professionals as necessary.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-29) unless otherwise indicated.

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

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Selpercatinib	€ 169,382.39
Best supportive care	patient-individual
Appropriate comparator therapy:	
Best supportive care	patient-individual
Sorafenib	€ 59,931.83
Lenvatinib	€ 61,230.82

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2021)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 2 September 2021.

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

Berlin, 2 September 2021

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

Prof. Hecken