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
Vandetanib (reassessment after the deadline (medullary thyroid cancer))

of 18 March 2022

At its session on 18 March 2022, 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. Annex XII is amended as follows:

1. The information on Vandetanib in the version of the resolution of 6 July 2017 (BAnz AT 09.08.2017 B3) is repealed.

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

Vandetanib

Resolution of: 18 March 2022
Entry into force on: 18 March 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 February 2012):

Caprelsa is indicated for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease.

Therapeutic indication of the resolution (resolution of 18 March 2022):

Adults with aggressive and symptomatic medullary thyroid cancer (MTC) and unresectable locally advanced or metastatic disease

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

Adults with aggressive and symptomatic medullary thyroid cancer (MTC) and unresectable locally advanced or metastatic disease

Appropriate comparator therapy:

- Cabozantinib

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

An additional benefit is not proven.

Study results according to endpoints:[1]

No data available.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-127) unless otherwise indicated.

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
∅: 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. 50 - 670 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 Caprelsa (active ingredient: vandetanib) at the following publicly accessible link (last access: 17 January 2022):

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

Treatment with vandetanib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in internal medicine and endocrinology, and other specialists participating in the Oncology Agreement, experienced in the therapy of patients with medullary thyroid cancer.

In accordance with the European Medicines Agency (EMA) requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material and a patient pass. The training material for medical professionals includes, among others, instructions on how to manage the risks of QTc prolongations, Torsades de Pointes and posterior reversible encephalopathy syndrome associated with vandetanib.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Vandetanib	€ 54,612.15
Appropriate comparator therapy:	
Cabozantinib	€ 69,836.91

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 March 2022)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 18 March 2022.

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

Berlin, 18 March 2022

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

Prof. Hecken