Resolution

Gemeinsamer Bundesausschuss

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 Lenvatinib (evaluation after the withdrawal of orphan drug status)

of 15 August 2019

At its session on 15 August 2019, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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. Annex XII will be amended as follows

1. The information relating to lenvatinib in accordance with the resolution of 17 December 2015 (Federal Gazette, BAnz AT 20 January 2016 B2) is hereby repealed.

2. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of lenvatinib in accordance with the resolution of 22 March 2019:

Lenvatinib

Resolution of: 15 August 2019
Entry into force on: 15 August 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 20 August 2018):

LENVIMA is indicated as monotherapy for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).

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

Adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).

Appropriate comparator therapy:

Sorafenib

Extent and probability of the additional benefit of lenvatinib compared with sorafenib:

An additional benefit is not proven.

Study results according to endpoints:

Adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).

There is no data that would allow for the assessment of the additional benefit.

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

Adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).

approx. 740–770 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 Lenvima® (active ingredient: lenvatinib) at the following publicly accessible link (last access: 9 May 2019):

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

Only specialists in internal medicine, haematology, and oncology with experience treating patients with thyroid cancer, specialists in internal medicine and endocrinology, and other

doctors from other specialisms participating in the oncology agreement after consultation with a specialist in nuclear medicine may initiate and monitor treatment with lenvatinib.

4. Treatment costs

Annual treatment costs:

Adult patients with progressive, locally advanced or metastatic, differentiated (papillary/ follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI).

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Lenvatinib	€ 76,269.67
Appropriate comparator therapy:	
Sorafenib	€ 59,931.04

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2019)

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 15 August 2019.

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

Berlin, 15 August 2019

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

Prof Hecken