Gemeinsamer Bundesausschuss

Resolution of: 15 August 2019 Valid until: unlimited
Entry into force on: 15 August 2019
Federal Gazette, BAnz AT 16.09.2019 B3

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