Gemeinsamer Bundesausschuss

Brigatinib

Resolution of: 4 July 2019 Valid until: unlimited
Entry into force on: 4 July 2019
Federal Gazette, BAnz AT 23.10.2019 B6

Therapeutic indication (according to the marketing authorisation of 22 November 2018):

Alunbrig is indicated as monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.

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

Appropriate comparator therapy:

Ceritinib or alectinib

Extent and probability of the additional benefit of brigatinib compared with ceritinib:

An additional benefit is not proven.

Study results according to endpoints:

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

approx. 160–1,060 patients

3. Requirements for a quality-assured application

The requirements of 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 Alunbrig® (active ingredient: brigatinib) at the following publicly accessible link (last access: 8 May 2019):
https://www.ema.europa.eu/documents/product-information/alunbrig-epar-product-information_de.pdf

Treatment with brigatinib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in internal medicine and pneumology, specialists in pulmonary medicine, and specialists participating in the Oncology Agreement who are experienced in the treatment of patients with advanced bronchial carcinoma.

ALK verification

The ALK-positive NSCLC status should be known before initiating treatment with Alunbrig.

A validated ALK test is necessary to identify patients with ALK-positive NSCLC (see Section 5.1). The ALK-positive NSCLC status should be determined by laboratories with proven experience in the specific technique required.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Brigatinib 1st year	€89,761.80
Brigatinib from 2nd year	€90,152.26
Appropriate comparator therapy:	
Ceritinib	€66,946.23
Alectinib	€73,479.06

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

Costs for additionally required SHI services: not applicable