Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive AM-RL): Annex XII – Resolution on the Benefit Assessment of Medicinal Products with New Active Ingredients in Accordance with Section 35a SGB V - Brigatinib

of 4 July 2019

At its session on 4 July 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 shall be amended in alphabetical order to include the active ingredient brigatinib as follows:

Brigatinib

Resolution of: 4 July 2019
Entry into force on: 4 July 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

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

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 4 July 2019.

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

Berlin, 4 July 2019

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

Prof Hecken