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 Cobicistat (New Therapeutic Indication: HIV Infection, Combination with Atazanavir or Darunavir, 12 to < 18 years)

of 1 October 2020

At its session on 1 October 2020 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 on DD Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of cobicistat in accordance with the resolution of 18 September 2014:

Cobicistat

Resolution of: 1 October 2020
Entry into force on: 1 October 2020
Federal Gazette, BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 9 March 2020):

Tybost® is indicated as a pharmacokinetic enhancer of atazanavir 300 mg once daily or darunavir 800 mg once daily as part of antiretroviral combination therapy in human immunodeficiency virus-1 (HIV-1) infected adults and adolescents aged 12 years and older weighing at least 35 kg co-administered with atazanavir or weighing at least 40 kg co-administered with darunavir. (See sections 4.2, 4.4, 5.1, and 5.2.)

This resolution relates exclusively to the newly approved therapeutic indication of (i.e. adolescents from 12 to < 18 years with HIV-1 infection.

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

Adolescent patients aged 12 to < 18 years with HIV-1 infection:

Appropriate comparator therapy:

Ritonavir in combination with atazanavir or darunavir

Extent and probability of the additional benefit of cobicistat in combination with atazanavir or darunavir compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

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

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	∅	There are no usable data for the benefit assessment.
Morbidity	∅	There are no usable data for the benefit assessment.
Health-related quality of life	∅	There are no usable data for the benefit assessment.
Side effects	∅	There are no usable data for the benefit assessment.

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. 130 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 Tybost® (active ingredient: cobicistat) at the following publicly accessible link (last access: 1 July 2020):
https://www.ema.europa.eu/documents/product-information/tybost-epar-product-information_de.pdf

Treatment with cobicistat should only be initiated and monitored by specialists who are experienced in the treatment of patients with HIV infection.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Cobicistat	€ 496.52
Cobicistat + atazanavir	€ 5,001.84
Cobicistat + darunavir	€ 4,802.06
Appropriate comparator therapy:	
Ritonavir	€ 478.19
Ritonavir + atazanavir	€ 4,983.51
Ritonavir + darunavir	€ 4,783.73

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2020

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 1 October 2020.

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

Berlin, 1 October 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken