Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive: Annex XII - Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V:

Fostemsavir (multidrug resistant HIV-1 infection)

of 16 September 2021

At its session on 16 September 2021, 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 by the publication of the resolution of D. month YYYY (BAnz AT TT.MM.JJJJ BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient fostemsavir as follows:

Fostemsavir

Resolution of: 16 September 2021
Entry into force on: 16 September 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 4 February 2021):

Rukobia, in combination with other antiretrovirals, is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.

Therapeutic indication of the resolution (resolution of 16 September 2021):

"see therapeutic indication according to marketing authorisation."

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

Adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regime

Appropriate comparator therapy for fostemsavir in combination with other antiretrovirals:

A patient-individual antiretroviral therapy using a selection of approved active ingredients; taking into account the previous therapy(ies) and the reason for the change of therapy, in particular, therapy failure because of virological failure and the possible associated development of resistance or because of side effects.

Extent and probability of the additional benefit of fostemsavir compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regime

There are no suitable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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

Adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regime

approx. 80 – 240 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 Rukobia (active ingredient: fostemsavir) at the following publicly accessible link (last access: 2 July 2021):
https://www.ema.europa.eu/en/documents/product-information/rukobia-epar-product-information_en.pdf

Treatment with fostemsavir should only be initiated and monitored by doctors experienced in treating patients with HIV infection.

4. Treatment costs

Annual treatment costs:

Adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regime

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Fostemsavir	€ 45,044.97
Individual antiretroviral therapy[1]	€ 2,066.02 - € 131,291.83
Appropriate comparator therapy:	
Individual antiretroviral therapy[1]	€ 2,066.02 - € 131,291.83

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 September 2021

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Ibalizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	26.1	€ 1,853.10

[1]Because of the different combination possibilities in individual therapy, not all possible combination therapies are presented but a cost-effective (nevirapine + lamivudine / tenofovirdisoproxil) and a cost-intensive therapy (ibalizumab + abacavir + emtricitabine) as examples.

II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 16 September 2021.**

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

Berlin, 16 September 2021

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

Prof. Hecken