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 Ibalizumab (Multidrug Resistant HIV-1 Infection)

of 18 February 2021

At its session on 18 February 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 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 ibalizumab as follows:

Ibalizumab

Resolution of: 18 February 2021
Entry into force on: 18 February 2021
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 26 September 2019):

Trogarzo, in combination with other antiretroviral(s), is indicated for the treatment of adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.

Therapeutic indication of the resolution (resolution of 18 February 2021):

See therapeutic indication according to marketing authorisation

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

Adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen

Appropriate comparator therapy:

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 possible associated development of resistance or because of side effects.

Extent and probability of the additional benefit of ibalizumab compared with the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen

No suitable data were submitted for the benefit assessment.

Summary of results for relevant clinical endpoints

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

Adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen

approx. 50–110 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 Trogarzo (active ingredient: ibalizumab) at the following publicly accessible link (last access: 10 December 2020):

https://www.ema.europa.eu/en/documents/product-information/trogarzo-epar-product-information_de.pdf

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

4. Treatment costs

Annual treatment costs:

Adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Ibalizumab	€ 123,557.92
Individual antiretroviral therapy[1]	€ 2,066.02 – 33,887.74
Appropriate comparator therapy:	
Individual antiretroviral therapy	€ 2,066.02 – 33,887.74

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

Costs for additionally required SHI services: not applicable

Other services covered by SHI funds:

Designation of the 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 options in individual therapy, not all possible combination therapies are presented; however, one low-cost therapy (nevirapine + lamivudine/tenofovir disoproxil) and one high-cost therapy (enfurvitide + abacavir + emtricitabine) are presented as an example.

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 18 February 2021.

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

Berlin, 18 February 2021

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

Prof. Hecken