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
Doravirine/ Lamivudine/ Tenofovir Disoproxil (new therapeutic indication: HIV infection, 12 to < 18 years)

of 20 October 2022

At its session on 20 October 2022, 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 (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 Doravirine/ Lamivudine/ Tenofovir Disoproxil in accordance with the resolution of 4 July 2019 last modified on 26 May 2020:

Doravirine/ lamivudine/ tenofovir disoproxil

Resolution of: 20 October 2022
Entry into force on: 20 October 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 28 March 2022):

Delstrigo is also indicated for the treatment of adolescents aged 12 years and older weighing at least 35 kg who are infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil.

Therapeutic indication of the resolution (resolution of 20 October 2022):

Delstrigo is indicated for the treatment of adolescents aged 12 to < 18 years weighing at least 35 kg who are infected with HIV-1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir and who have experienced toxicities which preclude the use of other regimens that do not contain tenofovir disoproxil.

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

Therapy experienced adolescents with HIV-1 infection aged 12 to < 18 years without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir disoproxil

Appropriate comparator therapy for doravirine/ lamivudine/ tenofovir disoproxil:

- a patient-individual antiretroviral therapy using a selection of approved active ingredients; taking into account the previous therapy/ therapies 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 doravirine/ lamivudine/ tenofovir disoproxil compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Therapy experienced adolescents with HIV-1 infection aged 12 to < 18 years without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir disoproxil

No suitable data versus the appropriate comparator therapy were presented.

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	∅	No data available.
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

Therapy experienced adolescents with HIV-1 infection aged 12 to < 18 years without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir disoproxil

approx. 10 – 20 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 Delstrigo (active ingredient: doravirine/ lamivudine/ tenofovir disoproxil) at the following publicly accessible link (last access: 1 October 2022):

https://www.ema.europa.eu/en/documents/product-information/delstrigo-epar-product-information_en.pdf

Treatment with doravirine/ lamivudine/ tenofovir disoproxil should only be initiated and monitored by specialists who are experienced in the treatment of patients with HIV-1.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-49) unless otherwise indicated.

4. Treatment costs

Annual treatment costs:

Therapy experienced adolescents with HIV-1 infection aged 12 to < 18 years without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir disoproxil

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Doravirine/ lamivudine/ tenofovir disoproxil	€ 9,313.18
Appropriate comparator therapy:	
Individual antiretroviral therapy[2]	€ 2,281.43 - € 34,630.02

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 October 2022)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 October 2022.

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

Berlin, 20 October 2022

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

Prof. Hecken

[2] Because of the different combination possibilities in individual therapy, not all possible variants of combination therapies are presented and considered but the cost range from a cost-effective (nevirapine + emtricitabine/ tenofovir disoproxil) to a cost-intensive therapy (enfuvirtide + abacavir + emtricitabine) is specified as an example.