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
Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir alafenamide
(New therapeutic indication: HIV infection, 2 to < 6 years)

of 20 April 2023

At its session on 20 April 2023, 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 Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir alafenamide in accordance with the resolution of 5 July 2018:**

**Elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide**

Resolution of: 20 April 2023
Entry into force on: 20 April 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

**New therapeutic indication (according to the marketing authorisation of 03 October 2022):**

Genvoya is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in adults and paediatric patients aged from 2 years and with body weight at least 14 kg.

**Therapeutic indication of the resolution (resolution of 20 April 2023):**

Genvoya is indicated for the treatment of infection with HIV-1 without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir in children aged 2 to < 6 years and weighing at least 14 kg.

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

a) Therapy-naive children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

**Appropriate comparator therapy:**

Abacavir + lamivudine or abacavir + emtricitabine, in each case in combination with

- dolutegravir or
- lopinavir/ ritonavir or
- raltegravir or
- nevirapine or
- atazanavir/ ritonavir or
- darunavir/ ritonavir

**Extent and probability of the additional benefit of elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide compared to the active ingredient of the appropriate comparator therapy:**

An additional benefit is not proven.

b) Therapy-experienced children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

**Appropriate comparator therapy:**

- 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 the possible associated development of resistance or because of side effects

**Extent and probability of the additional benefit of elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide compared to the active ingredient of the appropriate comparator therapy:**

An additional benefit is not proven.

**Study results according to endpoints[1]:**

a) Therapy-naive children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

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:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: No data available.<br>n.a.: not assessable | | |

[1] Data from the dossier evaluation of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-116) unless otherwise indicated.

b) Therapy-experienced children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

No suitable data versus the appropriate comparator therapy were presented.

**Summary of results for relevant clinical endpoints**

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## 2. Number of patients or demarcation of patient groups eligible for treatment

a) Therapy-naive children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

approx. 3 patients

b) Therapy-experienced children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

approx. 13 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 Genvoya (combination of active ingredients: elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide) at the following publicly accessible link (last access: 14 December 2022):

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

Treatment with elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide should only be initiated and monitored by doctors experienced in treating patients with HIV-1.

## 4. Treatment costs

**Annual treatment costs:**

a) Therapy-naive children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Elvitegravir/ cobicistat/<br>Emtricitabine/ tenofovir alafenamide | € 9,945.11 |
| Appropriate comparator therapy: | |
| Abacavir + emtricitabine + atazanavir/ ritonavir | € 11,460.39 - € 14,966.22 |
| Abacavir + emtricitabine + darunavir/ ritonavir | € 11,952.48 - € 13,664.70 |
| Abacavir + emtricitabine + dolutegravir | € 7,802.18 - € 10,354.32 |
| Abacavir + emtricitabine + lopinavir/ ritonavir | € 6,064.24 - € 9,358.97 |
| Abacavir + emtricitabine + nevirapine | € 6,772.58 - € 10,069.80 |
| Abacavir + emtricitabine + raltegravir | € 6,121.17 - € 9,262.24 |
| Abacavir + lamivudine + atazanavir/ ritonavir | € 11,438.43 - € 15,022.34 |
| Abacavir + lamivudine + darunavir/ ritonavir | € 11,930.52 - € 13,720.82 |
| Abacavir + lamivudine + dolutegravir | € 7,780.22 - € 10,410.44 |
| Abacavir + lamivudine + lopinavir/ ritonavir | € 6,042.28 - € 9,415.09 |
| Abacavir + lamivudine + nevirapine | € 6,750.61 - € 10,125.92 |
| Abacavir + lamivudine + raltegravir | € 6,099.21 - € 9,318.36 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 01 April 2023

Costs for additionally required SHI services: not applicable

b) Therapy-experienced children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Elvitegravir/ cobicistat/ Emtricitabine/ tenofovir alafenamide | € 9,945.11 |
| Appropriate comparator therapy: | |
| Individual antiretroviral therapy[2] | € 6,042.28 - € 15,022.34 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 01 April 2023

Costs for additionally required SHI services: not applicable

## 5. Medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir alafenamide

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide for the treatment of infection with HIV-1 in children aged 2 to < 6 years and weighing at least 14 kg on the basis of the marketing authorisation granted under Medicinal Products Act:

a) Therapy-naive children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

- No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

b) Therapy-experienced children with HIV-1 infection aged 2 to < 6 years without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir

- No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

[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 (abacavir + lamivudine + lopinavir/ ritonavir) to a cost-intensive therapy (abacavir + lamivudine + atazanavir + ritonavir) is specified as an example.

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 April 2023.**

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

Berlin, 20 April 2023

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

Prof. Hecken