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)
Cabotegravir (new therapeutic indication: HIV-1 infection, therapy-experienced adolescents, in combination with rilpivirine)

of 7 August 2025

At their session on 7 August 2025, 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 additional after No. 4 to the information on the benefit assessment of Cabotegravir in accordance with the resolution of 21 October 2021:

Cabotegravir

Resolution of: 7 August 2025
Entry into force on: 7 August 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 13 January 2025):

Vocabria injection is indicated, in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg), who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

Vocabria tablets are indicated in combination with rilpivirine tablets for the short-term treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents (at least 12 years of age and weighing at least 35 kg) who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class for:

- Oral lead-in to assess tolerability of Vocabria and rilpivirine prior to administration of long acting cabotegravir injection plus long acting rilpivirine injection.
- Oral therapy for adults and adolescents who will miss planned dosing with cabotegravir injection plus rilpivirine injection.

Therapeutic indication of the resolution (resolution of 7 August 2025):

Vocabria injection is indicated, in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adolescents (12 to 17 years of age and weighing at least 35 kg), who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

Vocabria tablets are indicated in combination with rilpivirine tablets for the short-term treatment to assess tolerability of Vocabria and rilpivirine prior to administration of long acting cabotegravir injection plus long acting rilpivirine injection. Oral therapy is indicated for adolescents who will miss planned dosing with cabotegravir injection plus rilpivirine injection. The present assessment refers to the entire therapy concept consisting of the oral lead-in phase, the intramuscular maintenance phase and the oral bridging therapy.

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

Adolescents 12 to 17 years of age and weighing at least 35 kg with HIV-1 infection, who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without

present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

Appropriate comparator therapy:

An individualised therapy with selection of approved antiretroviral agents

Extent and probability of the additional benefit of cabotegravir in combination with rilpivirine compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adolescents 12 to 17 years of age and weighing at least 35 kg with HIV-1 infection, who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

No data available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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
∅: No data available.
n.a.: not assessable

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

Adolescents 12 to 17 years of age and weighing at least 35 kg with HIV-1 infection, who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

Approx. 65 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 Vocabria (active ingredient: cabotegravir) at the following publicly accessible link (last access: 3 June 2025):

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

Treatment with cabotegravir should only be initiated and monitored by specialists who are experienced in the treatment of patients with HIV-1.

Prior to starting Vocabria injection, ,healthcare professionals should have carefully selected patients who agree to the required injection schedule and counsel patients about the importance of adherence to scheduled dosing visits to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses. Following discontinuation of Vocabria and rilpivirine injection, it is essential to adopt an alternative, fully suppressive antiretroviral regimen no later than one month after the final injection of Vocabria when dosed monthly and no later than two months after the final injection of Vocabria when dosed every 2 months.

4. Treatment costs

Annual treatment costs:

Adolescents 12 to 17 years of age and weighing at least 35 kg with HIV-1 infection, who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cabotegravir	€ 7,207.86
Rilpivirine	€ 3,121.86
Total:	€ 10,329.72
Appropriate comparator therapy:	
Individualised therapy with selection of approved antiretroviral agents[1]	€ 2,960.48 – € 19,003.94

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2025)

Costs for additionally required SHI services: not applicable

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

5. Designation of 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 the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adolescents 12 to 17 years of age and weighing at least 35 kg with HIV-1 infection, who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the non-nucleoside reverse transcriptase inhibitor (NNRTI) and integrase inhibitor (INI) class.

- No medicinal product with new active ingredients that can be used in a combination therapy and 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.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 7 August 2025.

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

Berlin, 7 August 2025

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

Prof. Hecken