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 (HIV-1 infection, combination with rilpivirine)

of 21 October 2021

At its session on 21 October 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 by the publication of the resolution of 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 cabotegravir as follows:

Cabotegravir

Resolution of: 21 October 2021
Entry into force on: 21 October 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 December 2020):

Vocabria injection is indicated, in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults 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 NNRTI and 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 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 NNRTI and INI class for:

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

Therapeutic indication of the resolution (resolution of 21 October 2021):

Vocabria injection is indicated, in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults 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 NNRTI and 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 adults 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

Adults 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 NNRTI and INI class.

Appropriate comparator therapy for cabotegravir in combination with rilpivirine:

a patient-individual antiretroviral therapy using a selection of approved active ingredients; taking into account the previous therapy(ies) and, if applicable, side effects

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:

Adults 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 NNRTI and INI class.

No adequate data are available to allow an assessment of the additional benefit.

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 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 NNRTI and INI class.

approx. 59,900 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: 12 July 2021):
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 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:

Adults 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 NNRTI and INI class.

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cabotegravir + rilpivirine	
Cabotegravir	€ 7,974.00
Rilpivirine	€ 4,430.40
Total:	€ 12,404.40
Appropriate comparator therapy:	
Individual antiretroviral therapy[1]	€ 2,066.02 - 20,052.53

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

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 21 October 2021.

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

Berlin, 21 October 2021

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

Prof. Hecken

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