

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health,
Welfare and Sport
PO Box 20350
2500 EJ THE HAGUE

2023020384

Date 2 June 2023
Re: GVS advice hepatitis B vaccine (PreHevbri®)

Dear Mr Kuipers,

In your letter of 1 May 2023 (CIBG-23-05421), you asked the National Health Care Institute to assess whether the hepatitis B vaccine PreHevbri® can be included in the Medicine Reimbursement System (GVS). You have asked us to deal with this request by means of a marginal review. The National Health Care Institute has completed this substantive assessment. The outcome of this can be found in the enclosed GVS report.

PreHevbri® is available as a suspension for intramuscular injection; each dose (1 ml) contains 10 micrograms of hepatitis B surface antigens. This medicinal product is indicated for active immunisation against infections caused by all known subtypes of the hepatitis B virus in adults.

The primary vaccination consists of three doses within 6 months, to be administered at t=0, 1 and 6 months. The need for a booster dose has not been established.

According to the marketing authorisation holder, PreHevbri® is interchangeable with the hepatitis B vaccines Engerix-B® and HBVAXPRO®; therefore, PreHevbri® can be placed on List 1A of the Health Insurance Regulation (Rzv).

The outcome of the assessment

Based on the criteria for interchangeability, the National Health Care Institute has concluded that the hepatitis B vaccine PreHevbri® is interchangeable with the vaccines included in the GVS cluster 0J07BCAP V, namely Engerix-B® and HBVAXPRO 10®.

The World Health Organization (WHO) has not established a DDD for hepatitis B vaccines. The standard dose for PreHevbri® can be set at 1 dose (1 ml) per day, similar to the other hepatitis B vaccines.

National Health Care Institute

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M.J.S. de Vries

Case number

2023018338

Our reference

2023020384

Your reference

CIBG-23-05421

Your letter of

1 May 2023

Advice

The National Health Care Institute advises you to include the hepatitis B vaccine PreHevbri® on the Rzv's List 1A in cluster 0J07BCAP V. The standard dose can be set at 1 dose (1 ml) per day.

Furthermore, the List 2 reimbursement conditions applicable to hepatitis vaccines also apply to PreHevbri®.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

**National Health Care
Institute**
Care
Medicinal Products

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