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**National Health Care
Institute**

Care II
Infectious Diseases, Blood &
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Date 14 June 2021
Subject GVS advice Shingrix®

Our reference
2021021907

Dear Ms van Ark,

In your letter of 16 March 2021 (CIBG-21-01601), you requested the National Health Care Institute to carry out a substantive review of whether the recombinant herpes zoster vaccine with adjuvant (RZV, Shingrix®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed its substantive assessment. The considerations are included in the GVS report attached to this letter.

RZV (Shingrix®) is indicated for the prevention of herpes zoster (shingles) and related post-herpetic neuralgia (secondary prevention of Varicella zoster infection) in:

- adults \geq 50 years old;
- adult \geq 18 years old with increased risk of herpes zoster.

The marketing authorisation holder (MAH) requests inclusion in List 1B of the Health Insurance Regulation for the vaccination of part of the group of adults with an increased risk of herpes zoster.

The outcome of the assessment

Assessment of interchangeability

None of the medicinal products included in the Medicine Reimbursement System are interchangeable with RZV (Shingrix®). Based on this, RZV (Shingrix®) cannot be placed on List 1A. Next, the National Health Care Institute assessed whether RZV (Shingrix®) is eligible for inclusion on List 1B. In this matter, it was advised by the Scientific Advisory Board (WAR).

Therapeutic value

The National Health Care Institute has concluded that for the vaccination of adults aged 18 years or over with an increased risk of herpes zoster and belonging to the following medical risk groups:

- persons who have recently undergone a stem cell transplant (allogenic or autologous); or a stem cell transplant is planned;
- persons with a solid tumour or haematological cancer who are treated with an immune suppressive treatment, in which vaccination must be administered before, during or after treatment;

- persons who have recently undergone an organ transplant; or for whom an organ transplant is planned; and
 - persons infected with the Human Immune-deficiency Virus (HIV),
- the recombinant herpes zoster vaccine (with adjuvant) has added value compared to no vaccination.

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Budget impact analysis

Taking into account the different assumptions with regard to patient numbers and vaccination rate, the inclusion of RZV on List 1B of the GVS for the vaccination of patients with an increased risk of herpes zoster will be accompanied by additional costs charged to the pharmaceutical budget of €5.5 to €10.9 million, depending on the vaccination rate. After the first three years, if all prevalent HIV, stem cell and organ transplantation patients have been vaccinated, the additional costs charged to the pharmaceutical budget will range between €3.2 million and €6.3 million, depending on the vaccination rate.

Cost-effectiveness

A PE exemption has been granted because the budget impact is less than €10 million.

Advice on inclusion in the GVS

The National Health Care Institute recommends including the recombinant herpes zoster vaccine with adjuvant (Shingrix®) in List 1B and List 2 of the Health Insurance Regulation, and imposing the conditions stated below. Inclusion in List 1B will lead to additional costs.

Conditions for the recombinant herpes zoster vaccine with adjuvant

Only for insured persons aged 18 years or older:

- who have recently undergone a stem cell transplant (allogenic or autologous), or for whom a stem cell transplant is planned;
- with a solid tumour or haematological cancer, who are being treated with an immunosuppressive treatment;
- who have recently undergone an organ transplant; or for whom an organ transplant is planned;
- who are infected with the Human Immunodeficiency Virus (HIV).

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board