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To the Minister of Health, Welfare and Sport
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2023003206

**National Health Care
Institute**

Care
Medicinal Products

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Date 25 January 2023
Subject GVS advice PCV15 (Vaxneuvance®)

Our reference
2023003206

Dear Mr Kuipers,

In your letter of 31 October 2022 (CIBG-22-04609), you asked the National Health Care Institute to assess whether the 15-valent pneumococcal polysaccharide conjugate vaccine (PCV15, Vaxneuvance®) is interchangeable with another vaccine that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has now completed this assessment. The considerations are included in the GVS report attached to this letter.

PCV15 is a 15-valent pneumococcal conjugate vaccine (PCV15) directed against 15 different types of *Streptococcus pneumoniae*. One dose of PCV15 (0.5 ml) contains 2.0 µg pneumococcal polysaccharide of serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F, and 4.0 µg of serotype 6B.

PCV15 is indicated for

- Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *S. pneumoniae* in infants, children and adolescents from 6 weeks to less than 18 years of age,
- Active immunisation for the prevention of invasive disease and pneumonia caused by *S. pneumoniae* in individuals aged 18 and older.

The current assessment is related to the active immunisation to prevent pneumonia and invasive disease caused by *S. pneumoniae* in individuals with an increased risk of infection.

The outcome of the assessment

The National Health Care Institute has concluded that PCV15 meets the established medical science and medical practice for active immunisation to prevent pneumonia and invasive disease caused by *S. pneumoniae* in individuals with an increased risk of infection, in sequential combination with PPV23, as defined in the RIVM-LCI guideline. On the basis of the data, the National Health Care Institute concludes that the value of PCV15 is comparable with that of PCV13.

Assessment of interchangeability

On the basis of the criteria of interchangeability, the National Health Care Institute concluded that the 15-valent pneumococcal polysaccharide conjugate vaccine is interchangeable with the 13-valent pneumococcal polysaccharide conjugate vaccine (Prevenar13®).

Advice

The National Health Care Institute advises you to place 15-valent pneumococcal polysaccharide conjugate vaccine (PCV15, Vaxneuvance®) on List 1A of the Health Insurance Regulation (Rzv) in a new cluster with the 13-valent pneumococcal polysaccharide conjugate vaccine (Prevenar13®). The standard dose of PCV15 and of PCV13 can be determined for both at a single dose (0.5 ml).

We also recommend that the existing List 2 condition applicable to pneumococcal vaccines also be applied to PCV15:

Condition:

only for insured persons:

- a. that fall into a medical high-risk group and have been designated to vaccination in accordance with the (international) guidelines accepted in the Netherlands by the relevant professional groups.
- b. who, as a result of COVID-19, have been hospitalised, and
 1. whose thorax CT shows residual abnormalities (fibrosis, and/or bronchial disorders, and/or persistent infiltrative abnormalities/atelectasis), and
 2. who show abnormalities in lung function (FVC < 70% and/ or Z score < 2.00, or FEV1/FVC Z ratio score < -1.64 and FEV1 < 50% of predicted, or DLCOc < 60%).

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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