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Our reference
2021006845

Date 03 March 2021
Subject 13-valent pneumococcal conjugate vaccine (Prevenar13®) for medical high-risk groups

Dear Ms van Ark,

In your letter of 12 January 2021 (CIBG-21-01333), you requested National Health Care Institute to assess whether 13-valent pneumococcal conjugate vaccine (PVC13; Prevenar13®) is interchangeable with a product that is included in the medication reimbursement system (GVS). The National Health Care Institute has now completed the substantive assessment. The considerations are included in the GVS report attached to this letter, with the pharmaco-therapeutic report and the budget impact analysis.

PCV13 is registered for the following indications:
- Active immunization for the prevention of invasive diseases, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents aged 6 weeks to 17 years.
- Active immunization for the prevention of invasive diseases and pneumonia caused by *Streptococcus pneumoniae* in adults ≥ 18 years and older people.

The marketing authorisation holder has requested inclusion in List 1B of the Health Insurance Act for persons belonging to the medical risk groups for which the National Coordination Centre for Communicable Disease Control (LCI) of the National Institute for Public Health and the Environment (RIVM) in its recent guideline "Pneumococcal disease" (last update 2020) recommends vaccination with PCV13 in sequential combination with the 23-valent polysaccharide vaccine (PPV23; Pneumovax®) and for which PPV23 is already included in the Medicine Reimbursement System (GVS).

Assessment outcome
Assessment of interchangeability
There is no medicinal product in the GVS that is interchangeable with PCV13 (Prevenar13®). Based on this, PCV13 (Prevenar13®) cannot be placed on List 1A. Next, the National Health Care Institute assessed whether PCV13 (Prevenar13®) is eligible for inclusion on List 1B and was advised on this matter by the Scientific Advisory Board (WAR).

Therapeutic value
The National Health Care Institute has come to the final conclusion that for active

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immunization to prevent pneumonia and invasive diseases caused by *S. pneumoniae* in medical high-risk groups with an increased risk of invasive pneumococcal infection, a more serious course of the disease and an increased risk of death of invasive infection, PCV13 in sequential combination with PPV23 has added value compared to PPV23 immunization alone.

Budget impact analysis
Taking into account the number of persons belonging to medical high-risk groups who are now vaccinated against pneumococci, the proposed vaccination schedule and the price of PCV13, inclusion of PVC13 on the GVS List 1B for active immunization for the prevention of pneumonia and invasive diseases caused by *S. pneumoniae* in medical high-risk groups prior to immunization with the 23-valent pneumococcal polysaccharide vaccine (PPV23) will be accompanied by additional costs of €0.2 to €0.5 million, charged to the pharmacy budget. There is uncertainty about the number of persons belonging to medical high-risk groups who will be vaccinated with pneumococcal vaccines in the coming years.

Cost-effectiveness
In view of the budget impact of €0.2 to €0.5 million, the product has been exempted from pharmaco-economic analysis.

Advice on inclusion in the GVS
The National Health Care Institute recommends removing PCV13 (Prevenar13®) from List 3B and including it for the active immunization for the prevention of pneumonia and invasive diseases caused by *S. pneumoniae* in medical high-risk groups in List 1B and List 2 of the Health Insurance Act, and setting the following conditions. This means an adaptation of the current further condition regarding pneumococcal vaccine. Inclusion in List 1B will lead to additional costs.

Pneumococcal vaccine conditions
only for insured persons:
a. that fall into a medical high-risk group and have been designated 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