Zorginstituut Nederland

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To the Minister of Health, Welfare and Sport
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2025013530

National Health Care Institute
Care
Medicinal Products

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Our reference
2025013530

Date 10 June 2025
Re: GVS advice PCV20 (Prevenar 20®) for the prevention of pneumococcal disease

Dear Mr van Hijum,

The National Health Care Institute advises you about the inclusion in the Medicine Reimbursement System (GVS) of PCV20 (Prevenar 20®) for the prevention of pneumonia and invasive disease caused by Streptococcus pneumoniae in high-risk groups. This advice was prompted by your request in the letter of 17 March 2025 (CIBG-25-08008).
The National Health Care Institute advises you to include the pneumococcal vaccine PCV20 for the registered indication in List 1B of the GVS, with the further conditions for reimbursement specified below.

Pneumonia is an inflammation of the lungs. In invasive disease, the bacterium has also penetrated the bloodstream or other tissues, making the person seriously ill. Streptococcus pneumoniae are bacteria that can cause pneumococcal disease. High-risk patients have a disease or are receiving treatment that reduces their immune response. For example, people who are receiving a stem cell transplant or people who do not have a spleen. This makes them more susceptible to infectious diseases, such as pneumonia or shingles. The consequences of an infectious disease can be very serious. The PCV20 vaccine is designed to protect against 20 different types of pneumococcal bacteria. Pneumococci can lead to life-threatening complications such as meningitis, blood poisoning (sepsis) and severe pneumonia. The previously developed vaccine PCV13 protects 37.5% and 75% of vaccinated people against pneumonia and invasive disease, respectively.

Therapeutic indications
PCV20 is indicated for:
- Active immunisation for the prevention of invasive diseases, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants, children and adolescents aged 6 weeks to 18 years.
- Active immunisation for the prevention of invasive diseases and pneumonia caused by *Streptococcus pneumoniae* in people aged 18 years and older.

PCV20 (Prevenar 20®) is available in 0.5 mL suspension in a pre-filled syringe. The dose depends on the age of the patient. An adjusted dose is available for infants and children under the age of two years, see the Summary of Product Characteristics. For children aged 2 years and older and adults, the dosage of PCV20 is a single dose (0.5 mL).

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Claim by the marketing authorisation holder
PCV20 for active immunisation to prevent invasive disease and pneumonia caused by *S. pneumoniae* in high-risk groups as defined in the RIVM-LCI guideline has a value comparable to PCV13 and PCV15.

The marketing authorisation holder requests the inclusion in List 1A of the Health Insurance Regulation for the registered indication.

The National Health Care Institute advises you to include PCV20 (Prevenar 20®) in List 1B of the GVS for the registered indication. Inclusion is likely to be associated with savings for the pharmaceutical budget.

In addition, we advise you to apply the additional conditions applicable to the current pneumococcal vaccines also to PCV20.

We explain the preparation of this advice below.

Assessment outcome

Assessment of interchangeability
The GVS currently includes 3 pneumococcal vaccines. PCV13 and PCV15 are clustered in List 1A. PPV23 is also included in List 1A of the Health Insurance Regulation in a (ghost) cluster. Based on the criteria for interchangeability, the National Health Care Institute concluded that PCV20 is *not* interchangeable with the other pneumococcal vaccinations, PCV13, PCV15, and PPV23, included in the GVS. There is a clinically relevant difference in properties. PCV20 differs from PCV13 and PCV15 because its broader protection does not require it to be given in sequential combination with PPV23, unlike PCV13 and PCV15. PCV20 is also not interchangeable with PPV23, because PCV20 is a conjugate vaccine and has a different protection mechanism than the PPV23 polysaccharide vaccine. For these reasons, PCV20 is not interchangeable with other vaccines in the GVS.
On this basis, PCV20 cannot be placed on List 1A. The National Health Care Institute has therefore assessed whether PCV20 can be included in List 1B.

Therapeutic value
In Dutch medical practice, people who are categorised as a high-risk group, regardless of their age, are vaccinated with PCV13 or PCV15 combined with PPV23. The National Health Care Institute concludes that PCV20 for the above indication is equivalent to standard treatment with PCV13 or PCV15, both combined with PPV23.

PCV20 has been compared with PCV13 (followed by PPV23 in adults ≥60 years) in the general population in two randomised studies (RCTs). In these studies, the immunogenicity of PCV20 was not inferior to PCV13. Nor was PCV20 inferior to PCV13 followed by PPV23 in adults ≥60 years. Since PCV13 and PCV15 are clustered and considered interchangeable, the National Health Care Institute concludes that PCV20 is also indirectly not inferior to PCV15 in combination with PPV23.

The National Health Care Institute has concluded that the value of PCV20 for the above indication is comparable to standard treatment with PCV13 or PCV15, both

combined with PPV23. PCV20 can be placed on List 1B.

Budget impact analysis
Given the comparable value of PCV20 to standard treatment. inclusion in List 1B should not incur additional costs for the pharmacy budget. To estimate this, the National Health Care Institute carried out a budget impact analysis. The GIP database provides insight into the number of individuals who are vaccinated annually with a pneumococcal vaccine. Because vaccination with PCV13 or PCV15, like vaccination with PCV20, is a single vaccine, the data for PCV13 and PCV15 are used as a basis for estimating the budget impact. The publicly available part of the GIP database shows that the total number of persons vaccinated with these two types of vaccinations has increased from 1148 in 2021 to 6519 in 2023. The National Health Care Institute also has access to the restricted part of the GIP database. This includes more recent quarterly data on the number of users of these vaccines. These figures indicate that the number of vaccinated people appears to be stabilising. In the first half of 2024, there was even a slight decrease in the number of vaccinations. The marketing authorisation holder of PCV20 assumes that approximately 7,000 individuals will be vaccinated with this new vaccine on an annual basis. The National Health Care Institute agrees with this estimate.

The pharmacy purchase price of PCV20 is €76.10. This amount is slightly higher than for PCV13 and PCV15, which both cost €68.56. However, PCV13 and PCV15 must be combined with PPV23 (at €23.81), which should be repeated every five years. On average, patients have to pay an additional contribution of €12.95 for PPV23. However, PCV20 does not need to be combined with PPV23. When the costs of either PCV13 or PCV15 are added to the costs of PPV23, the total amount is €92.37. As this amount is higher than the cost of PCV20 (€76.10), it can be inferred that administering this new vaccine is likely to result in savings. In any event, the introduction of PCV20 should not lead to additional costs compared to the combined use of PCV13 or PCV15 with PPV23.

Cost-effectiveness
As there is a comparable value of PCV20 to standard treatment, an assessment of the cost-effectiveness of PCV20 (Prevenar 20®) is not required.

<u>List 2 conditions</u>
The current additional conditions (List 2 conditions) for pneumococcal vaccines are as follows:
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%).

Since pneumococcal vaccination for persons who have suffered lung damage due

to COVID-19 is now included in guidelines, the additional conditions can be adjusted accordingly:
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.

Should you need any further information, please do not hesitate to contact us. The assessment report is attached (marginal test).

Yours sincerely,

K.C. Timm-van Ruitenburg
Acting Chairperson of the Executive Board

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