SUMMARY

Pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)

VAXNEUVANCE

suspension for injection in pre-filled syringe

First assessment

Original French opinion adopted by the Transparency Committee on 20 September 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- The very high frequency of pneumococcal infections (including sepsis, bacteraemia, meningitis, pneumonia and acute otitis media), which can be a source of serious complications or even be life-threatening in some patients, irrespective of their age, particularly immunocompromised individuals.
- The proprietary medicinal product VAXNEUVANCE (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)) is a preventive treatment.
- The efficacy (immunogenicity)/adverse effects ratio is significant.
- There is an alternative vaccine: PREVENAR 13 (VPC13). It should be noted that PNEUMOVAX (VPP23) cannot be considered to be an alternative based on the current vaccination schedule.
- VAXNEUVANCE (VPC15) may be used in accordance with its marketing authorisation within the scope of the vaccination guidelines in force.

Public health benefit

Considering:

- the very high frequency of pneumococcal infections (including sepsis, bacteraemia, meningitis, pneumonia and acute otitis media), which can be a source of serious complications or even be life-threatening;
- the public health objective of lowering morbidity and mortality from this infection;

- the fact that vaccination is the most effective prevention tool against pneumococcal infections and their complications;
- the medical need to expand the range of pneumococcal vaccines available;
- the partial response to the identified need:
  - an expected additional impact of VAXNEUVANCE (VPC15) on reduction of the incidence of pneumococcal infections and on the associated morbidity and mortality in view of the available immunogenicity and safety data,
  - an expected additional impact of vaccination on the organisation of care;

VAXNEUVANCE (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of VAXNEUVANCE (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)), is substantial in the active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by pneumococcal infections in infants, children and adolescents from 6 weeks to less than 18 years of age, in accordance with the current HAS recommendations issued on 27 July 2023.

The Committee issues a favourable opinion for inclusion of VAXNEUVANCE (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)), in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by pneumococcal infections in infants, children and adolescents from 6 weeks to less than 18 years of age, in accordance with the current HAS recommendations issued on 27 July 2023.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%**

Clinical Added Value

Considering:

- the medical need to expand the range of pneumococcal vaccines available based on the evolution of the epidemiological situation for infections caused by *Streptococcus pneumoniae*, in particular due to the emergence of new non-vaccine serotypes;
- the non-inferiority of the immune response induced by VAXNEUVANCE (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed) or VPC15) compared to PREVENAR 13 (pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) or VPC13) in terms of serologic response rate and geometric mean titres of antibodies for the 13 shared serotypes covered by PREVENAR 13 (VPC13) on D30 after the last dose;
- the superiority of the immune response induced by VAXNEUVANCE (VPC15) compared to PREVENAR 13 (VPC13) in terms of serologic response rate and geometric mean titres of antibodies for the two additional serotypes (22F and 33F) on D30 after the last dose;
- data relative to coadministration with paediatric vaccines (INFANRIX HEXA, ROTARIX, RECOMBIVAX HB, ROTATEQ, PENTACEL, VAQTA, HIBERIX, MMRII and VARIVAX) having

demonstrated a non-inferiority of VAXNEUVANCE (VPC15) compared to PREVENAR 13 (VPC13) in terms of immunogenicity with respect to the antigens contained in these vaccines;

- a favourable safety profile, despite being marked by a higher incidence of irritability in the VAXNEUVANCE (VPC15) group compared to the PREVENAR 13 (VPC13) group;

but,

- a potential additional impact on the reduction of morbidity and mortality as a result of the addition of two serotypes (22F and 33F) that cannot be assessed in the absence of clinical efficacy data and given the low representation of these circulating serotypes in France (22F and 33F respectively responsible for 5.13% and 1.71% of cases of bacteraemia, and 0% and 5.88% of cases of pneumococcal meningitis in 2020). It should be noted that the serotypes most frequently isolated in invasive pneumococcal infection in children under 15 years of age in 2020 were serotypes 24F, 10A and 23B, not included in anti-pneumococcal vaccines. Respectively, they account for 16.24%, 10.26% and 10.26% of cases of bacteraemia and 11.76%, 13.73% and 5.88% of meningitis;
- heterogeneous results concerning the immune response against vaccine serotype 6A on D30 after the third dose (non-inferiority endpoint not reached in the PNEU-PED study and weaker immune response in the VAXNEUVANCE group (VPC15) in the PNEU-LINK study);

the Committee deems that VAXNEUVANCE (pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)) provides no clinical added value (CAV V) in the active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by pneumococcal infections in infants, children and adolescents from 6 weeks to less than 18 years of age.