SUMMARY

Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)

APEXXNAR

suspension for injection in pre-filled syringe

First assessment

Original French opinion adopted by the Transparency Committee on 18 October 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Invasive pneumococcal infections can be life-threatening in some patients, irrespective of their age, particularly immunocompromised individuals.
- The proprietary medicinal product APEXXNAR (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)) is a preventive treatment.
- The efficacy (immunogenicity)/adverse effect ratio is high.
- There is no alternative vaccine insofar as APEXXNAR (VPC20) is intended to replace PREVENAR 13 (VPC13) and PNEUMOVAX (VPP23). The HAS no longer recommends the use of the VPC13 and VPP23 vaccines in adults.
- APEXXNAR (VPC20) may be used in accordance with its marketing authorisation within the scope of the vaccination guidelines in force.

Public health benefit

Considering:

- the high frequency of pneumococcal infections (including sepsis, bacteraemia, meningitis and pneumonia), 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 impact of APEXXNAR (VPC20) 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,
  - an expected additional impact on the care and life pathway of vaccinated subjects (simplification of the vaccination regimen, switching from the use of two different vaccines to a single vaccine);

APEXXNAR (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of APEXXNAR (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)), is substantial in the active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older, in accordance with the current HAS recommendations issued on 27 July 2023.

The Committee issues a favourable opinion for inclusion of APEXXNAR (pneumococcal polysaccharide conjugate vaccine (20-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 and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older, 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 APEXXNAR (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) or VPC20) compared to PREVENAR 13 (pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed) or VPC13) in terms of geometric mean titres of opsonophagocytic activity (GMT OPA) for the 13 shared serotypes covered by PREVENAR 13 (VPC13);
- the non-inferiority of the immune response induced by APEXXNAR (VPC20) compared to the sequential PREVENAR 13 (VPC13) - PNEUMOVAX (23-valent pneumococcal polysaccharide non-conjugate vaccine or VPP23) regimen in terms of GMT OPA for six of the seven additional serotypes;
- interchangeability data having demonstrated an increase in the immune response induced by APEXXNAR (VPC20) in terms of GMT OPA in subjects aged 65 years and over having received a dose of VPP23 at least 5 years before inclusion or a dose of VPC13 or having received a sequential VPC13 - VPP23 regimen;

- data relative to coadministration with an inactivated, adjuvanted quadrivalent, seasonal influenza vaccine (FLUAD TETRA) having demonstrated a non-inferiority of APEXXNAR (VPC20) in terms of GMT OPA compared to deferred administration (influenza vaccination at D0 then VPC20 at D30) for the 20 serotypes covered by VPC20;
- data relative to coadministration with a COVID-19 mRNA vaccine (COMIRNATY, BNT162b2) having demonstrated a comparable immune response of APEXXNAR (VPC20) in terms of GMT OPA compared to administration of VPC20 or BNT162b2 alone for the 20 serotypes covered by VPC20;
- a favourable safety profile;

but:

- a potential additional impact on the reduction of morbidity and mortality as a result of the addition of seven serotypes (8, 10A, 11A, 12F, 15B/C, 22F and 33F) that cannot be assessed in the absence of clinical efficacy data and the absence of demonstration of non-inferiority against serotype 8 compared to a VPC13 - VPP23 regimen. It should be noted that in 2020 and 2021, serotypes 8 and 3 were the most frequently isolated serotypes in invasive pneumococcal infection in adults. In 2020, in adults aged 65 years and over, the main serotypes observed were serotypes 8 (not included in the VPC13 vaccine, included in VPC20 and VPP23) and 3 (included in all three vaccines), representing, respectively, 15.38% and 11.37% of bacteraemia cases and 10.24% and 9.45% of meningitis cases;

the Committee deems that APEXXNAR (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)) provides no clinical added value (CAV V) in the active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older.