Original French opinion adopted by the Transparency Committee.

The legally binding text is the original French opinion version.

SUMMARY

pneumococcal polysaccharide conjugate vaccine
(21-valent)

CAPVAXIVE 0.5 ml

Solution for injection in pre-filled pen

Inclusion on list

Adopted by the Transparency Committee on 27 August 2025

Summary of opinion

Favourable opinion for reimbursement in active immunisation for the prevention of invasive infections and pneumonia caused by *Streptococcus pneumoniae* in people aged 18 and over, according to the HAS vaccine recommendations of 3 July 2025.

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 CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent) is a preventive treatment.
- The efficacy (immunogenicity)/adverse effects ratio is high.
- There is an alternative vaccine: PREVENAR 20 (pneumococcal conjugate vaccine, 20-valent, adsorbed).
- CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent) may be used according to 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 CAPVAXIVE (VPC 21) on reduction of the incidence of pneumococcal infections and on the associated morbidity and mortality in view of the available immunogenicity and safety data;
- the lack of expected additional impact on the vaccinated subjects' care and/or life pathway;

CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent), is substantial for active immunisation for the prevention of invasive infections and pneumonia caused by *Streptococcus pneumoniae* in people aged 18 and over, according to the HAS guidelines in force dated 3 July 2025.

The Committee issues a favourable opinion for inclusion of CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent), in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in people aged 18 and over, according to the HAS guidelines in force dated 3 July 2025, and the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 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 CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent) compared with PREVENAR 20 (pneumococcal polysaccharide conjugate vaccine, 20-valent, adsorbed) in terms of geometric mean titres of opsonophagocytic activity (GMT OPA) for the 10 shared serotypes covered by both vaccines;
- the superiority of the immune response induced by CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent) over PREVENAR 20 (pneumococcal polysaccharide conjugate vaccine, 20-valent, adsorbed) in terms of geometric mean titres of opsonophagocytic activity (GMT OPA) for 10 of the 11 single serotypes (9N, 15A, 16F, 17F, 20, 23A, 23B, 24F, 31 and 35B) covered by CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent);
- data relative to coadministration with a quadrivalent seasonal influenza vaccine (QIV), showing non-inferiority of concomitant administration of QIV and PCV 21 compared with sequential administration of these same vaccines, in terms of GMT HAI (haemagglutination inhibition) 30 days after vaccination, for three of the four QIV strains except for the A/H3N2 strain;

- a favourable safety profile;

however, in view of:

- a potential additional impact on the reduction of morbidity and mortality as a result of the addition of 11 additional serotypes (9N, 15A, 15C, 16F, 17F, 20A, 23A, 23B, 24F, 31 and 35B) compared with PREVENAR 20, which cannot be assessed in the absence of clinical efficacy data, with a lack of coverage of 10 serotypes currently covered by PREVENAR 20 (4, 6B, 9V, 14, 18C, 19F, 23F, 1, 5, 15B);

the Committee deems that CAPVAXIVE (pneumococcal polysaccharide conjugate vaccine, 21-valent), provides no clinical added value (CAV V) in active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in people aged 18 and over.