Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) or VPC20

PREVENAR 20

suspension for injection in pre-filled syringe

Modification of inclusion conditions following updating of the HAS recommendations in 2024

Adopted by the Transparency Committee on 9 April 2025

Summary of opinion

Favourable opinion for maintenance of reimbursement in active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults ≥ 18 years of age, in accordance with the HAS vaccination recommendations of 19 December 2024

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 PREVENAR 20 (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)) is a preventive treatment.
- The efficacy (immunogenicity)/adverse effects ratio is high.
- There is no alternative vaccine insofar as PREVENAR 20 is intended to replace PREVENAR 13 (13-valent pneumococcal polysaccharide conjugate vaccine, VPC13) and PNEUMOVAX (23-valent pneumococcal polysaccharide non-conjugate vaccine, VPP23). The HAS no longer recommends the use of the VPC13 and VPP23 vaccines in adults.
- PREVENAR 20 (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)) can be used in accordance with its MA in the context of current vaccine recommendations.

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 PREVENAR 20 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);

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

Considering all of these elements, the Committee deems that the clinical benefit of PREVENAR 20 (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)) remains substantial in the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults ≥ 18 years of age, in accordance with the current HAS recommendations issued on 19 December 2024.

The Committee issues a favourable opinion for maintenance of inclusion of PREVENAR 20 (pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)) in both the list of drugs covered for outpatients and in the list of drugs covered for inpatients approved for use in the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults ≥ 18 years of age, in accordance with the current HAS recommendations issued on 19 December 2024, and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Updating of the vaccine strategy in accordance with the current HAS recommendations of 19 December 2024 does not modify the clinical added value level (**CAV V** according to the opinion of 18/10/2023) in the active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in adults ≥ 18 years of age.