SUMMARY

respiratory syncytial virus vaccine (bivalent, recombinant)

ABRYSVO

powder and solvent for solution for injection

First listing

Original French opinion adopted by the Transparency Committee on 10 July 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy in accordance with the current HAS vaccine recommendations of 6 June 2024.

Transparency Committee's conclusions

Clinical Benefit

- In usual care conditions, RSV lower respiratory tract infection is not usually serious. In at-risk populations, these infections can cause respiratory distress, which may require hospitalisation, oxygen therapy and mechanical ventilation in the most severe forms, with a risk of sequelae and mortality.
- This is a preventive medicinal product.
- The efficacy (immunogenicity)/adverse effects ratio is modest.
- Therapeutic alternatives are available: SYNAGIS (palivizumab) in infants with risk factors and BEYFORTUS (nirsevimab) in infants with or without risk factors.
- This is a first-line treatment with regard to the available therapies.

Public health benefit

Considering:

- the seriousness, contagiousness and impact on the organisation of care, particularly in new-borns and infants with risk factors (consultations, emergency department visits, hospitalisations and critical or intensive care unit admissions);

- the inadequately met medical need in the prevention of RSV lower respiratory tract disease in infants from birth during their first RSV season;
- the fact that ABRYSVO (respiratory syncytial virus vaccine (bivalent, recombinant)) provides a partial response to the identified need in infants from birth through 6 months of age following maternal immunisation during pregnancy, due to:
  - a demonstrated additional impact on morbidity in terms of reduction in severe RSV LRTI within 180 days following birth, but no demonstrated additional impact on mortality,
  - a demonstrated additional impact on the organisation of care (reduction in RSV LRTI hospitalisations within 180 days following administration), but no demonstrated additional impact on the length of hospital stay, intensive care unit admissions and reduction in the requirement for supplemental oxygen,

ABRYSVO (respiratory syncytial virus vaccine (bivalent, recombinant)) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ABRYSVO (respiratory syncytial virus vaccine (bivalent, recombinant)) is moderate in the passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy at 32 to 36 weeks of gestation only, in accordance with the current HAS recommendations of 6 June 2024.

The Committee issues a favourable opinion for inclusion of ABRYSVO (respiratory syncytial virus vaccine (bivalent, recombinant)) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy at 32 to 36 weeks of gestation only, in accordance with the current HAS recommendations of 6 June 2024 and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 30%**

Clinical Added Value

Considering:

- the inadequately met medical need in the prevention of RSV lower respiratory tract disease in newborns and infants during their first RSV season;
- **demonstration of the superiority of the ABRYSVO vaccine** versus placebo in 6,975 infants born to individuals vaccinated during pregnancy in terms of reduction in severe RSV LRTI cases up to D180 (0.5% in the ABRYSVO group versus 1.8% in the placebo group), i.e. a vaccine efficacy of 69.4% [44.3; 84.1];
- **an acceptable safety profile** of the ABRYSVO vaccine, marked by predominantly grade 1 (mild) or 2 (moderate) adverse effects, such as pain at the vaccination site (41%), headaches (31%) and myalgia (27%). However, pharmacovigilance follow-up is necessary due to a potential excess risk of premature births (not significant for this vaccine, but having led to the development of a concurrent vaccine being stopped);

But:

- a non-significant reduction in the incidence of RSV LRTI cases (co-primary endpoint): 0.7% in the ABRYSVO group versus 1.6% in the placebo group, i.e. a vaccine efficacy (VE) of 57.1% [14.7; 79.8]; deemed to be non-significant because the lower limit of the CI is below 20% in the 90 days following birth:
  - a reduction in hospitalisations (secondary endpoint): VE of 67.7%, $CI_{99.17\%}$ = [15.9; 89.5] reported at D90 after birth before decreasing over time, to values of 59.5% [8.3; 83.7], 56.4% [5.2; 81.5], 56.8% [10.1; 80.7], 33.3% [-17.6; 62.9] at D120, 150, 180 and 360 after birth, respectively;
  - no evidence of an impact on reduction in the length of hospital stay, transfer to critical or intensive care units and mortality due to RSV infections;
  - the lack of comparative data enabling robust differentiation between maternal vaccination during pregnancy compared to the alternative strategy of passive immunisation from birth using monoclonal antibodies;

The Committee deems that ABRYSVO (respiratory syncytial virus vaccine (bivalent, recombinant)) provides a clinical added value (CAV IV) in the passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy at 32 to 36 weeks of gestation only.