Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified)

mRESVIA 50 micrograms

dispersion for injection

First listing

Adopted by the Transparency Committee on 23 October 2024

Summary of opinion

Favourable opinion for reimbursement in active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in accordance with the current HAS recommendations of 27 June and 17 October 2024, i.e. in individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure) liable to decompensate in the event of RSV infection.

Transparency Committee's Conclusions

Clinical Benefit

- In usual care conditions, RSV lower respiratory tract infection is not typically serious. In at-risk populations (elderly people, individuals with comorbidities such as heart diseases [congestive heart failure], pulmonary diseases [COPD, asthma], or immunosuppression [cancer, hematopoietic stem cell transplant, organ transplant]), 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 moderate.
- Therapeutic alternatives are available: ABRYSVO (Respiratory Syncytial Virus (RSV) vaccine (bivalent, recombinant)) and AREXVY (Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)).
- It is a first-line treatment.

➔ Public health benefit

Considering:

- the seriousness, contagiousness and impact on the organisation of care, particularly in the elderly, with individuals with comorbidities having a high risk of serious RSV-associated disease (lower respiratory tract infection or pneumonia, hospitalisation, admission to an intensive care unit, death);
- the medical need partially met by the alternatives available in the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure) liable to decompensate in the event of RSV infection;
- the fact that mRESVIA (Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified)) provides a partial response to the identified need in individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure) liable to decompensate in the event of RSV infection;
- an expected additional impact on morbidity in terms of reduction in RSV-associated LRTD and the lack of evidence of a reduction in severe LRTD;
- but the lack of evidence of an impact on mortality and the organisation of care (reduction in hospitalisations, transfer to critical or intensive care units);

mRESVIA (Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified)) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of mRESVIA (Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified)) is moderate in active immunisation for the prevention of lower respiratory tract disease caused by RSV in accordance with the current HAS recommendations of 27 June and 17 October 2024, i.e. in individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure) liable to decompensate in the event of RSV infection.

The Committee issues a favourable opinion for inclusion of mRESVIA (Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified)) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in active immunisation for the prevention of lower respiratory tract disease caused by RSV in accordance with the current HAS recommendations of 27 June and 17 October 2024, and at the MA dosages, i.e. in individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure) liable to decompensate in the event of RSV infection.

➔ 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 lower respiratory tract disease caused by RSV in individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure);
- **demonstration of a superiority of the mRESVIA vaccine** compared to placebo in 35,088 subjects (P301 study) in terms of reduction in RSV-associated LRTD with ≥ 2 symptoms and RSV-associated LRTD with ≥ 3 symptoms (vaccine efficacy 83.7%, 95% CI 88% [66.0; 92.2]) and 82.4%, CI 96.36% [34.8; 95.3] respectively);
- **an acceptable safety profile of the mRESVIA vaccine**, marked by predominantly grade 1 (mild) or 2 (moderate) adverse effects, such as injection site pain (56.3%), fatigue (31.0%) and headache (27.0%). Serious adverse events considered by the investigator to be causally related to the treatment were reported in the mRNA-1345 group in four subjects (chills, dehydration, facial nerve paralysis (occurring 5 days following injection of mRNA-1345) and superficial venous thrombosis) and in five subjects in the placebo group (seizures, fever, COPB, transient ischaemic attack and myelodysplastic syndrome).

But:

- no evidence of an impact on reduction on severe RSV-associated LRTD and mortality due to RSV infections, as well as on the organisation of care (reduction in conventional hospitalisations and intensive care unit admissions);
- limited data in the populations at highest risk of decompensating following RSV infection (individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure), limiting the transposability of the results in this population;

the Committee deems that, on the basis of currently available data, mRESVIA (Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified)) provides no clinical added value (CAV V) in active immunisation for the prevention of lower respiratory tract disease caused by RSV in individuals 75 years of age and older, and individuals 65 years of age and older with a chronic respiratory disease (in particular COPD) or heart condition (in particular heart failure) liable to decompensate in the event of RSV infection.