SUMMARY

Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)

AREXVY

powder and suspension for suspension for injection

First listing

Adopted by the Transparency Committee on 28 August 2024

Summary of opinion

Favourable opinion for reimbursement in active immunisation for the prevention of lower respiratory tract disease caused by RSV in accordance with the current HAS recommendations of 27 June 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 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 moderate.
- There is a therapeutic alternative: ABRYSVO (Respiratory Syncytial Virus (RSV) vaccine (bivalent, recombinant)).
- This 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 inadequately met medical need 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 AREXVY (Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)) 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;
  - 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);

AREXVY (Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of AREXVY (Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)) 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 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 AREXVY (Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)) 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 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.

➔ **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 AREXVY vaccine** compared to placebo in 24,966 subjects (study (RSV OA=ADJ-006) in terms of reduction in RSV-associated LRTD confirmed by RT-PCR (vaccine efficacy of 82.6%, $CI_{96.95\%}$ = [57.9; 94.1], p< 0.0001, 15 days after administration of a single dose of vaccine, primary endpoint) and in terms of reduction in severe RSV-associated LRTD (vaccine efficacy of 94.1%, $CI_{95\%}$ = [62.4; 99.9], secondary endpoint),

- **an acceptable safety profile** of the AREXVY vaccine, marked by predominantly grade 1 (mild) or 2 (moderate) adverse effects, such as pain (60.9%), fatigue (33.6%) and myalgia (28.9%). One case of Guillain-Barré syndrome having occurred 9 days following administration of AREXVY was assessed by the investigator as being potentially related to the vaccine administered.

But:

- no evidence of an impact on reduction on mortality due to RSV infections, or 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, AREXVY (Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)) provides no clinical added value (CAV V) in active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (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.

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