Original French opinion adopted by the Transparency Committee on [Date]

The legally binding text is the original French opinion version.

SUMMARY

trivalent influenza vaccine (split virion, inactivated)

VAXIGRIP

suspension for injection in pre-filled syringe

Inclusion on list

Adopted by the Transparency Committee on 12 February 2025

Summary of opinion

Favourable opinion for reimbursement in the prevention of influenza in adults and childre- from 6 months of age and in accordance with the current vaccination recommendations (HAS opinion of 6 February 2025).

Transparency Committee's Conclusions

Clinical Benefit

- Influenza is a highly contagious acute viral illness. Sometimes serious complications develop more readily in subjects already weakened by underlying diseases and/or over 65 years of age.
- The proprietary medicinal product VAXIGRIP (trivalent influenza vaccine (split virion, inactivated)) is a preventive medicinal product.
- The efficacy (immunogenicity)/adverse effects ratio is high.
- There are alternative vaccines, namely the other trivalent vaccines.
- VAXIGRIP (trivalent influenza vaccine (split virion, inactivated)) may be used in accordance with its marketing authorisation within the scope of the current vaccination recommendations in force.

- **Public health benefit**

Considering:

- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications, particularly in individuals with specific risk factors (almost 3,000 serious cases admitted to intensive care units during the 2017-2018 season),
- the public health objective, aimed at reducing the morbidity and mortality of this infection,
- the fact that vaccination is the most effective tool to prevent influenza and its complications,
- the objective of improving vaccination coverage to reach a minimum of 75% in the populations targeted by vaccination,
- the medical need to meet WHO recommendations supported by the HAS in order to be able to guarantee seasonal vaccination of all recommended populations in subsequent influenza seasons,
- the expected impact of vaccination on the organisation of care,

VAXIGRIP (trivalent influenza vaccine (split virion, inactivated)) is likely to have an additional impact on public health in the same way as the other trivalent vaccines available in subjects from 6 months of age. However, this impact remains dependent, firstly, on achievement of an adequate vaccination coverage rate in the targeted populations and, secondly, on the protection provided by the seasonal vaccine against the viral strains circulating.

Considering all of these elements, the change from tetravalent to trivalent is not of a nature to modify the clinical added value. The Committee considers that the clinical benefit of VAXIGRIP (trivalent influenza vaccine (split virion, inactivated)) is substantial in the prevention of influenza in adults and children from 6 months of age in accordance with the current HAS vaccination recommendations dating from 6 February 2025.

The Committee issues a favourable opinion for inclusion of VAXIGRIP (trivalent influenza vaccine (split virion, inactivated)) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the prevention of influenza in adults and children from 6 months of age, in accordance with the current HAS vaccination recommendations dating from 6 February 2025, and at the MA dosages.

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

Clinical Added Value

The change from tetravalent to trivalent is not of a nature to modify the clinical added value. The Committee considers that VAXIGRIP (trivalent influenza vaccine (split virion, inactivated)) provides no clinical added value (CAV V), in adults and children from 6 months of age for whom vaccination is recommended, compared to the other vaccines recommended in the prevention of seasonal influenza.