Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

influenza vaccine, surface antigen, inactivated

INFLUVAC

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 prophylaxis of influenza in adults and children from 6 months of age and in accordance with the current vaccination recommendations (HAS opinion of 12 December 2024).

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 INFLUVAC (influenza vaccine, surface antigen, inactivated) is a preventive medicinal product.
- The efficacy (immunogenicity)/adverse effects ratio is high.
- There are alternative vaccines, namely the other trivalent vaccines.

INFLUVAC (influenza vaccine, surface antigen, inactivated) may be used in accordance with its marketing authorisation within the scope of the 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 in 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,

INFLUVAC (influenza vaccine, surface antigen, 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 INFLUVAC (influenza vaccine, surface antigen, inactivated) is substantial in the prophylaxis of influenza in adults and children from 6 months of age in accordance with the current HAS vaccination recommendations dating from 12 December 2024.

The Committee issues a favourable opinion for inclusion of INFLUVAC (influenza vaccine, surface antigen, inactivated) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the prophylaxis of influenza in adults and children from 6 months of age, in accordance with the current HAS vaccination recommendations dating from 12 December 2024, 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 INFLUVAC (influenza vaccine, surface antigen, 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.