SUMMARY

Meningococcal Group A, C, W and Y vaccine conjugated to de Corynebacterium diphteriae CRM197 protein

MENVEO,

powder and solution for solution for injection

Modification of inclusion conditions following updating of the HAS recommendations in 2024

Original French opinion adopted by the Transparency Committee on 3 July 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for maintenance of reimbursement in the active immunisation of individuals against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W-135, and Y, in accordance with the current HAS recommendations of 7 March 2024 and 27 June 2024.

Transparency Committee's conclusions

Clinical Benefit

- Invasive meningococcal disease (IMD) is a serious transmissible infection, primarily manifested in the form of meningitis or meningococcemia, the most severe form being *purpura fulminans.*
- The medicinal product MENVEO Meningococcal Group A, C, W and Y conjugate vaccine is a preventive treatment.
- Its efficacy (immunogenicity)/adverse effects ratio remains high.
- There are alternative vaccines against serogroups A, C, W-135 and Y: MENQUADFI from the age of 12 months and NIMENRIX from the age of 6 weeks.
- **Public health benefit**

Considering:

- a 72% increase in cases of IMD compared to 2022 (560 cases of IMD were reported in 2023), with 44% of these associated with serogroup B (240 cases), 29% with serogroup W (160 cases), 24% with serogroup Y (130 cases) and a very small proportion with serogroup C (< 1% of cases),
- 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 IMD and its complications,
- the medical need to guarantee the vaccine offer against serogroup ACWY IMD,
- an expected impact of the medicinal product MENVEO on reduction of the incidence of IMD ACWY and on the associated morbidity and mortality in view of the available immunogenicity and safety data,
- an expected impact of vaccination on the organisation of care,

MENVEO Meningococcal Group A, C, W and Y conjugate vaccine, like the other conjugated tetravalent meningococcal vaccines, is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that updating of the vaccine strategy in accordance with the current HAS recommendations of 7 March 2024 and 27 June 2024 is not of a nature to modify the clinical benefit, which remains substantial in the active immunisation of individuals from 2 years of age against invasive meningococcal disease caused by *Neisseria meningitidis* groups A, C, W-135 and Y.

The Committee issues a favourable opinion for maintenance of inclusion of MENVEO (Meningococcal Group A, C, W-135 and Y conjugate vaccine) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the active immunisation of individuals against invasive meningococcal disease caused by *Neisseria meningitidis* groups A, C, W-135 and Y, in accordance with the current HAS recommendations of 7 March 2024 and 27 June 2024, and at the MA dosages.

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

Clinical Added Value

Updating of the vaccine strategy in accordance with the current HAS recommendations of 7 March 2024 and 27 June 2024 is not of a nature to modify the clinical added value in the active immunisation of individuals against invasive meningococcal disease caused by *Neisseria meningitidis* groups A, C, W-135 and Y (no clinical added value (CAV V)) in individuals from 2 years of age according to the opinions of 1 December 2010 and 8 January 2014).