

SUMMARY

Meningococcal group B Vaccine (rDNA, component, adsorbed)

BEXSERO

suspension for injection in pre-filled syringe

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 for active immunisation of individuals from 2 months of age and older against invasive meningococcal disease caused by *Neisseria meningitidis* group B, in accordance with the HAS vaccine 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 meningococemia, the most severe form being *purpura fulminans*.
- The medicinal product BEXSERO, meningococcal group B vaccine, is a preventive treatment.
- Its efficacy (immunogenicity)/adverse effects ratio remains high.
- There is an alternative vaccine against serogroups B in children from 10 years: TRUMENBA.

→ 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 B strain IMD,

- an expected impact of the medicinal product BEXSERO in terms of reducing the incidence of IMD B and the associated morbidity and mortality in view of the available immunogenicity and safety data,
- an expected impact of vaccination on the organisation of care,

BEXSERO, meningococcal group B vaccine 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 months of age and older against invasive meningococcal disease caused by *Neisseria meningitidis* group B.

The Committee issues a favourable opinion for maintenance of inclusion of BEXSERO (meningococcal group B 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 from the age of 2 months and older against invasive meningococcal disease caused by *Neisseria meningitidis* group B, 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

The vaccine strategy update 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 from 2 months of age and older against invasive meningococcal disease caused by *Neisseria meningitidis* group B (important clinical added value (CAV II) in individuals from the age of 2 months and older according to the opinion of 25 June 2014).

BEXSERO 3 July 2024

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