



TRANSPARENCY COMMITTEE SUMMARY

The legally binding text is the original French opinion version

7 JULY 2021

***Meningococcal group B Vaccine (rDNA, component, adsorbed)
BEXSERO suspension for injection in a pre-filled syringe***

Modification of inclusion conditions following updating of the SPC and of vaccination recommendations

► Key points

Favourable opinion for reimbursement in the active immunisation against invasive meningococcal disease caused by group B strains, **in individuals from 2 months of age and older, only in the populations recommended by the HAS on 3 June 2021.**

► What therapeutic improvement?

Therapeutic improvement in the prevention of invasive meningococcal disease caused by group B strains.

► Role in the care pathway?

In June 2021, the HAS drew up vaccine recommendations for the prevention of invasive meningococcal disease caused by group B strains and defined the role of the meningococcal group B vaccines: BEXSERO and TRUMENBA in the preventive strategy.

In France, for the prevention of invasive meningococcal disease, it is now recommended to perform vaccination using:

- BEXSERO and TRUMENBA in individuals at increased risk of meningococcal disease and for targeted populations in the context of specific situations;
- BEXSERO in all infants from 2 months of age and older.

Role of the medicinal product in the care pathway

The Committee considers that BEXSERO (meningococcal group B vaccine) should be used in accordance with its MA and in accordance with current vaccination recommendations for the prevention of invasive meningococcal disease caused by group B strains in all infants and high-risk individuals.

The Committee highlights the fact that vaccination is the most effective tool for the prevention of meningococcal infection and associated complications (*purpura fulminans*). Good vaccination coverage of infants and high-risk populations is essential.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers that the MA amendments and updating of the vaccination strategy do not modify its previous 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 proprietary medicinal product BEXSERO is a preventive treatment.
- ▶ Its efficacy (immunogenicity)/adverse effects ratio remains high.
- ▶ There is an alternative vaccine in children from the age of 10 years (TRUMENBA, meningococcal group B vaccine). In children under the age of 10 years, there is no alternative vaccine offering broad protection against the multiple meningococcal group B strains.
- ▶ BEXSERO (meningococcal group B vaccine) can be used in accordance with its MA in the context of current vaccine recommendations.

Public health impact

Considering:

- the limited number of cases observed in France (240 cases of IMD B in 2019) but due to the seriousness of their prognosis (7% fatality rate in 2019) and their contagious nature,
- 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 expand the vaccine offer against group B strain IMD,
- an expected impact of the proprietary medicinal product BEXSERO on reduction of the incidence of IMD B and on the associated morbidity and mortality in view of the available immunogenicity, efficacy 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 to prevent invasive meningococcal disease caused by group B strains.

Considering all these elements, the Committee deems that the clinical benefit of BEXSERO remains substantial in the active immunisation against invasive meningococcal disease caused by group B strains, in individuals from 2 months of age and older, only in the populations recommended by the HAS on 3 June 2021.

The Committee issues a favourable opinion for maintenance of inclusion of BEXSERO (meningococcal group B vaccine) in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the active immunisation against invasive meningococcal disease caused by group B strains, in individuals from 2 months of age and older, only in the populations recommended by the HAS on 3 June 2021, and at the MA dosages.

- ▶ **Recommended reimbursement rate: 65%**

Clinical Added Value

The MA amendments and updating of the vaccine strategy do not modify the clinical added value, which remains important (CAV II) in the prevention of invasive meningococcal disease caused by group B strains, in the populations recommended by the HAS in 2021.