



TRANSPARENCY COMMITTEE SUMMARY 7 JULY 2021

The legally binding text is the original French opinion version

Meningococcal group B vaccine (recombinant, adsorbed)
TRUMENBA suspension for injection in a pre-filled syringe

First assessment

► Key points

Favourable opinion for reimbursement in the active immunisation to prevent invasive meningococcal disease caused by serogroup B strains, **in individuals 10 years and older, only in the populations recommended by the HAS on 3 June 2021.**

► What therapeutic improvement?

No therapeutic improvement compared to BEXSERO in the prevention of invasive meningococcal disease caused by serogroup 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 serogroup 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 TRUMENBA, meningococcal group B vaccine (recombinant, adsorbed) should be used in accordance with its MA and in accordance with current vaccination recommendations for the prevention of invasive meningococcal disease caused by serogroup B strains in high-risk individuals 10 years and older.

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:

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 TRUMENBA meningococcal group B vaccine (recombinant, adsorbed) is a preventive treatment.
- ▶ The efficacy (immunogenicity)/adverse effects ratio is high.
- ▶ There is an alternative vaccine (BEXSERO from the age of 2 months).
- ▶ TRUMENBA meningococcal group B vaccine (recombinant, adsorbed) can be used in accordance with its MA in the context of current vaccine recommendations from the age of 10 years.

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 serogroup B strain IMD,
- an expected impact of the medicinal product TRUMENBA on reduction of the incidence of IMD B 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,
In the same way as BEXSERO (meningococcal group B vaccine), TRUMENBA, meningococcal group B vaccine (recombinant, adsorbed) is likely to have an impact on public health, to prevent invasive meningococcal disease caused by serogroup B strains.

Considering all these elements, the Committee deems that the clinical benefit of TRUMENBA is substantial in the active immunisation against invasive meningococcal disease caused by serogroup B strains, in individuals 10 years and older, in the populations recommended by the HAS on 3 June 2021.

The Committee issues a favourable opinion for inclusion 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 serogroup B strains, in individuals 10 years and older, in the populations recommended by the HAS on 3 June 2021, and at the MA dosages.

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

Clinical Added Value

Considering:

- the medical need to expand the vaccine offer against invasive meningococcal disease caused by serogroup B strains,
- the immunogenicity induced by TRUMENBA, meningococcal group B vaccine (recombinant, adsorbed) against meningococcal serogroup B strains,
- the favourable safety profile,

But,

- the lack of comparative data versus BEXSERO (meningococcal group B vaccine),
- the Committee considers that TRUMENBA, meningococcal group B vaccine (recombinant, adsorbed) provides no clinical added value (CAV V) in the prevention of invasive meningococcal disease caused by serogroup B strains, compared to BEXSERO (meningococcal group B vaccine).