HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
6 OCTOBER 2021

The legally binding text is the original French opinion version

Meningococcal groups A, C, W and Y conjugate vaccine
MENQUADFI solution for injection

First assessment

Key points

Favourable opinion for reimbursement in the active immunisation of individuals from the age of 12 months and older against invasive meningococcal disease caused by group A, C, W and Y strains, **only in the populations recommended by the HAS on 11 March 2021**.

What therapeutic improvement?

No clinical added value compared to MENVEO and NIMENRIX for the prevention of invasive meningococcal disease caused by serogroup A, C, W and Y strains.

Role in the care pathway?

In March 2021, the HAS drew up vaccination recommendations for the prevention of invasive meningococcal disease caused by serogroup A, C, W and Y strains: revision of the vaccination strategy and determination of the role of tetravalent meningococcal vaccines.

In France, tetravalent meningococcal vaccines are recommended in the following specific populations:

- individuals with a terminal complement pathway deficiency receiving C5 inhibiting treatment, with a properdin deficiency or with anatomical or functional asplenia and individuals having undergone haematopoietic stem cell transplantation;
- research laboratory personnel working specifically on Meningococcus;
- individuals who have been in contact with an individual with serogroup A, C, Y, or W IMD, in the conditions scheduled by the instruction relative to the prophylaxis of invasive meningococcal disease;
- for IMD W hyperendemic situations.

Role of the medicinal product in the care pathway

The Transparency Committee considers that MENQUADFI meningococcal groups A, C, W and Y conjugate 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 serogroup A, C, W and Y strains in individuals from the age of 12 months.

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.

Special recommendations

The Committee highlights that:

- research laboratory personnel working specifically on Meningococcus can have the costs of their vaccination covered by their employer in accordance with article R4426-6 of French law: “at the suggestion of the occupational health physician, the employer recommends that workers who are not immunised against the biological pathogens to which they are or may be exposed receive the appropriate vaccinations, at the employer’s expense”
- recourse to vaccination in individuals temporarily exposed due to contact with an individual with invasive meningococcal disease caused by serogroup A, W135 or Y strains is a decision that is up to the regional or national authorities and is funded by regional health agencies as part of their epidemic control strategy.

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 meningococcemia, the most severe form being *purpura fulminans.*

◗ The medicinal product MENQUADFI meningococcal groups A, C, W and Y conjugate vaccine is a preventive treatment.

◗ Its efficacy (immunogenicity)/adverse effects ratio is high.

◗ There are alternative vaccines: MENVEO from the age of 2 years and NIMENRIX from the age of 6 weeks.

◗ MENQUADFI meningococcal groups A, C, W and Y conjugate vaccine can be used in accordance with its MA in the context of current vaccine recommendations from the age of 12 months.

Public health impact

Considering:

- the limited number of cases observed in France (459 cases of IMD notified in 2019, i.e. an incidence of 0.76 / 100,000 inhabitants) but due to the seriousness of their prognosis (12% 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 A, C, W and Y IMD,
- an expected impact of the medicinal product MENQUADFI 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,

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

Considering all these elements, the Committee deems that the clinical benefit of MENQUADFI is substantial in the active immunisation of individuals from the age of 12 months and older against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W and Y and only in the populations recommended by the HAS on 11 March 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 of individuals from the age of 12 months and older against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W and Y and only in the populations recommended by the HAS on 11 March 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 A, C, W and Y strains,**
- **the immunogenicity induced by MENQUADFI (meningococcal groups A, C, W and Y conjugate vaccine), which is non-inferior to that of other meningococcal groups A, C, W and Y conjugate vaccines (monovalent and tetravalent),**
- **a similar safety profile to that of other conjugated tetravalent meningococcal vaccines,**

the Committee considers that MENQUADFI meningococcal groups A, C, W and Y conjugate vaccine provides no clinical added value (CAV V) in the prevention of invasive meningococcal disease caused by serogroup A, C, W and Y strains, compared to MENVEO and NIMENRIX (meningococcal groups A, C, W and Y conjugate vaccines).