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
NIMENRIX solution for injection

Modification of inclusion conditions following updating of the vaccination recommendations
New indication

Key points

Favourable opinion for reimbursement in the active immunisation of individuals from the age of 6 weeks to 12 months against invasive meningococcal disease caused by group A, C, W_{135} and Y strains, **only in the populations recommended by the HAS on 11 March 2021**.

Maintenance of reimbursement in individuals aged 12 months and older **only in the populations recommended following updating of the vaccination recommendations by the HAS on 11 March 2021 incorporating serogroup W meningococcal disease hyperendemic situations.**

What therapeutic improvement?

Therapeutic improvement in the indication extension for the active immunisation of individuals from the age of 6 weeks to 12 months against invasive meningococcal disease caused by group A, C, W_{135} 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_{135} and Y strains and defined the role of the meningococcal group A, C, W_{135} and Yvaccines.

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 NIMENRIX (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_{135} and Y strains in infants from the age of 6 weeks.

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

◗ Modification of inclusion conditions following updating of the vaccination recommendations

The Committee takes note of these modifications incorporating serogroup W meningococcal disease hyperendemic situations.

Considering all these elements, the Committee deems that the clinical benefit of NIMENRIX remains substantial in the active immunisation against invasive meningococcal disease caused by group A, C, W and Y strains, in individuals from the age of 12 months and older, only in the populations recommended by the HAS in March 2021.

The Committee issues a favourable opinion for maintenance of inclusion of NIMENRIX (meningococcal group A, C, W and Y 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 A, C, W and Y strains, in individuals from the age of 12 months and older, only in the populations recommended by the HAS in March 2021, and at the MA dosages.

◗ Paediatric indication extension

◗ 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.*

◗ This medicinal product is a preventive treatment.

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

◗ There is an alternative vaccine against serogroups A, C, W_{135}, Y for adults and children from the age of 2 years and older (MENVEO conjugated tetravalent vaccine) and children from the age of 12 months and older (MENQUADFI conjugated tetravalent vaccine).
In children from the age of 6 weeks to 12 months, no other tetravalent vaccines have an MA.

◗ NIMENRIX (meningococcal group A, C, W_{135}, Y vaccine) can be used in accordance with its MA in the context of current vaccination recommendations.

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 NIMENRIX 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,

NIMENRIX meningococcal groups A, C, W and Y conjugate vaccine is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NIMENRIX is substantial in the active immunisation against invasive meningococcal disease caused by group A, C, W and Y strains, in individuals from the age of 6 weeks to 12 months, only in the populations recommended by the HAS in March 2021.

The Committee issues a favourable opinion for inclusion of NIMENRIX (meningococcal group A, C, W and Y 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 A, C, W and Y strains, in individuals from the age of 6 weeks to 12 months, only in the populations recommended by the HAS in March 2021, and at the MA dosages.

- **Recommended reimbursement rate: 65%**

Clinical Added Value

- **Modification of inclusion conditions following updating of the vaccination recommendations**

The update of the vaccine strategy is not of a nature to modify the clinical added value in individuals from the age of 12 months and older in the populations recommended by the HAS in 2021.

- **Paediatric indication extension**

Considering:

- **the medical need to expand the vaccine offer against invasive meningococcal disease caused by serogroup A, C, W and Y strains, particularly in infants,**
- **the immunogenicity induced by NIMENRIX (meningococcal groups A, C, W and Y conjugate vaccine) against meningococcal serogroup A, C, W and Y strains in children from six weeks of age,**
- **the favourable safety profile,**
- **the fact that NIMENRIX is currently the only conjugated tetravalent meningococcal vaccine with an MA in infants from the age of 6 weeks to 12 months,**

the Transparency Committee considers that NIMENRIX, meningococcal groups A, C, W and Y conjugate vaccine, provides a major clinical added value (CAV I) in the prevention of invasive meningococcal disease caused by group A, C, W and Y strains in children from the age of 6 weeks to 12 months.