HAUTE AUTORITÉ DE SANTÉ

INFECTIOLOGY
Inclusion on list of reimbursable products for supply by pharmacists
June 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

MENVEO and NIMENRIX, meningococcal group A, C, W_{135} and Y conjugate vaccines

Inclusion on the list of reimbursable products for supply by pharmacists for individuals expected to benefit from long-lasting protection extended to include a larger number of meningococcal serogroups

Main points

- MENVEO and NIMENRIX, tetravalent conjugate vaccines, have Marketing Authorisation in active immunisation against invasive meningococcal infections caused by serogroups A, C, W_{135} and Y from the age of 1 year (NIMENRIX) or 2 years (MENVEO).
- The need for vaccination against serogroups A, W_{135} and Y is confined to particular populations: primarily certain research laboratory workers, certain individuals with risk factors for invasive meningococcal infections and individuals travelling to endemic areas, especially pilgrims travelling to Mecca.
- These vaccines have been available in hospitals and at vaccination centres since 2010 and are now reimbursable for supply by pharmacists only for individuals with risk factors for invasive meningococcal infections who are expected to benefit from long-lasting protection extended to include serogroups A, C, W_{135} and Y.

Therapeutic use

According to the French High Council for Public Health (HCSP), immunisation with the tetravalent meningococcal vaccine is recommended in situations where extension of vaccination to serogroups other than C (A, Y and W_{135}) is necessary, i.e. for the following populations:

- research laboratory personnel working on meningococcus,
- individuals temporarily exposed to meningococcus A, Y or W_{135}:
  - through contact with a patient with invasive meningococcal infection (vaccination not later than 10 days after contact),
  - through travel to an endemic area or pilgrimage to Mecca (vaccination at least 10 days before departure),
- individuals expected to benefit from long-lasting protection extended to include a larger number of meningococcal serogroups, i.e. individuals with terminal complement component deficiency or who are receiving anti-C5A treatment, individuals with properdin deficiency and individuals with anatomical or functional asplenia or who have undergone haematopoietic stem cell transplantation.

Reimbursement of MENVEO and NIMENRIX by pharmacists is intended to facilitate implementation of the recommended vaccination strategy.

Clinical data

- The conclusions of the earlier Transparency Committee Opinions on the efficacy and safety of MENVEO and NIMENRIX in active immunisation against invasive meningococcal infection caused by serogroups A, C, W_{135} and Y are unchanged by the new data that are available.

Benefit of the medicinal product

- The actual benefit* of MENVEO and NIMENRIX is substantial.

- Recommends inclusion on the list of reimbursable products for supply by pharmacists only for the population expected to benefit from long-lasting protection extended to include a larger number of meningococcal serogroups (individuals with terminal complement component deficiency or who are receiving anti-C5A treatment, individuals with properdin deficiency and individuals with anatomical or functional asplenia or who have undergone haematopoietic stem cell transplantation).

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This document was created on the basis of the Transparency Committee Opinion of 03 June 2015
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* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".