Licensure of a Meningococcal Conjugate Vaccine (Menveo) and Guidance for Use --- Advisory Committee on Immunization Practices (ACIP), 2010

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On February 19, 2010, the Food and Drug Administration (FDA) licensed a quadrivalent meningococcal conjugate vaccine, MenACWY-CRM (Menveo, Novartis Vaccines and Diagnostics). MenACWY-CRM is licensed as a single dose for use among persons aged 11--55 years. The Advisory Committee on Immunization Practices (ACIP) reviewed data from prelicensure clinical trials on the safety and immunogenicity of MenACWY-CRM. This report summarizes the approved indications for MenACWY-CRM and provides guidance from ACIP for its use. The following guidance for use of MenACWY-CRM is consistent with licensed indications and ACIP recommendations for meningococcal conjugate vaccines.

MenACWY-CRM consists of two components: 1) 10 μg of lyophilized meningococcal serogroup A capsular polysaccharide conjugated to CRM197 (MenA) and 2) 5 μg each of capsular polysaccharide of serogroup C, Y, and W135 conjugated to CRM197 in 0.5 mL of phosphate buffered saline, which is used to reconstitute the lyophilized MenA component before injection (*1*). The reconstituted vaccine should be used immediately, but may be held at or below 77°F (25°C) for up to 8 hours. MenACWY-CRM is administered as an intramuscular injection, preferably into the deltoid region (*1*).

The capsular polysaccharide serogroups included in MenACWY-CRM are the same as those contained in Sanofi Pasteur's MCV4 (Menactra). In study participants aged 11--18 years, noninferiority of MenACWY-CRM to MCV4 was demonstrated for all four serogroups using the primary endpoint, hSBA seroresponse (serum bactericidal assay using human complement). The proportions of subjects with hSBA seroresponse were statistically higher for serogroups A, W, and Y in the MenACWY-CRM group, compared with the MCV4 group. The clinical relevance of higher postvaccination immune responses is not known (*1*). Safety and reactogenicity profiles were comparable to those observed with MCV4 (*1*).

Guidance for Use of MenACWY-CRM

MenACWY-CRM is licensed by the FDA as a single dose in persons aged 11--55 years (*1*). ACIP recommends quadrivalent meningococcal conjugate vaccine for all persons aged 11--18 years and for persons aged 2--55 years who are at increased risk for meningococcal disease. Persons at increased risk for meningococcal disease include 1) college freshmen living in dormitories, 2) microbiologists who are exposed routinely to isolates of *Neisseria meningitidis*, 3) military recruits, 4) persons who travel to or reside in countries where meningococcal disease is hyperendemic or epidemic, 5) persons who have persistent complement component deficiencies, and 6) persons with anatomic or functional asplenia (*2*). MenACWY-CRM or MCV4 may be used in persons aged 11--55 years, and are preferred to quadrivalent meningococcal polysaccharide vaccine (MPSV4) (*2*). Persons aged 2--10 years who are recommended to receive a meningococcal vaccine should receive MCV4, and persons aged >55 years should receive MPSV4 (*3*).

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of Menveo, any component of this vaccine, or any other CRM197, diphtheria toxoid, or meningococcal-containing vaccine is a contraindication to administration of Menveo. Details regarding the recommended meningococcal vaccination schedule are available at

http://www.cdc.gov/vaccines/recs/schedules/default.htm#child. Adverse events after receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System at http://vaers.hhs.gov.

References