MENINGOCOCCAL GROUPS A, C, Y, AND W-135 VACCINE

Meningococcal Groups A, C, Y, and W-135 Vaccine

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On August 10, 2026, the White House released an executive order that reaffirms the administration's prior directives regarding childhood vaccines that have been delayed due to litigation over the composition of the Advisory Committee on Immunization Practices (ACIP) and separate updates to the federal vaccine schedule. The order continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) with changes to the historic individual vaccine placement within those categories. For additional information, see [Web] .

Introduction

Meningococcal groups A, C, Y, and W-135 vaccine (MenACWY) is an inactivated (polysaccharide) vaccine that contains antigens extracted from *Neisseria meningitidis* linked to a carrier protein; it is used to stimulate active immunity to meningococcal infection caused by serogroups A, C, Y, and W-135.[1,152]

Uses

Prevention of Meningococcal Infection

Meningococcal groups A, C, Y, and W-135 (MenACWY) is used to stimulate active immunity to active infection caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 in adults and pediatric patients.[1,152] There are currently 2 preparations of the MenACWY vaccine in the US, a polysaccharide tetanus toxoid conjugate vaccine, MenACWY-TT (MenQuadfi®), and an oligosaccharide diphtheria CRM197 conjugate vaccine, MenACWY-CRM (Menveo®).[1,152] MenACWY-TT is indicated for adults and pediatric patients 6 weeks of age and older.[1] MenACWY-CRM is indicated for adults through 55 years of age and pediatric patients 2 months of age and older.[152] Neither vaccine protects against meningococcal serogroup B infections.[1,152] The previous MenACWY polysaccharide vaccine (MPSV4; Menomune®), polysaccharide diphtheria toxoid conjugate vaccine (MenACWY-D; Menactra®), and combination Haemophilus influenzae type b and meningococcal serogroups C and Y conjugate vaccine (Hib-MenCY-TT; MenHibrix®) are no longer commercially available in the US.[5,6,108]

N. meningitis can cause invasive meningococcal disease that usually presents as acute, severe, and potentially life-threatening meningitis and/or meningococcemia with abrupt onset.[105,166,228] Less frequently, *N. meningitidis* infection results in pneumonia and focal disease (e.g., arthritis).[105,166] Based on chemical differences in the antigenic capsular polysaccharide, 12 different serogroups of *N. meningitidis* have been identified.[105,166,228] In the US, serogroups B, C, and Y cause most cases of meningococcal disease; serogroup W and nongroupable strains cause a small percentage of cases.[105,166,237] The proportion of cases caused by each serogroup has changed over time and varies based on geographic location and age group.[105,166,237] Serogroup B causes approximately 60% of cases of meningococcal disease reported in the US in children and young adults <24 years of age.[166] Serogroups C, Y, or W cause approximately 60% of cases of meningococcal disease reported in the US among individuals ≥24 years of age.[166] Although the overall incidence of meningococcal disease in the US has been low during the last 10–15 years,[105,166] the overall case fatality rate for invasive meningococcal disease has remained at 10–15%, even with appropriate anti-infective treatment.[105,166] In addition, meningococcal infection can result in substantial morbidity; long-term sequelae (e.g., hearing loss, neurologic disability, digit or limb amputations) have been reported in 10–20% of patients.[105,166,228]

About 5% of reported cases of meningococcal disease across age groups in the US are due to outbreaks.[166,228] Outbreaks can occur in communities and institutions such as child care centers, schools, colleges, and military recruit camps; multiple outbreaks of serogroup B have occurred on college campuses.[105,166,228]

The incidence of meningococcal disease in the US is highest among infants <1 year of age, followed by children 1–4 years of age.[105,166,228] A second peak of disease incidence is found in young adults 16–23 years of age; incidence also increases again in older adults >85 years of age.[105,166,228] Risk factors of invasive meningococcal disease include travel to or residence in a country where disease is hyperendemic or epidemic, exposure during an outbreak, household crowding, smoking, antecedent viral upper respiratory infection, persistent complement deficiencies (including use of complement component inhibitors such as eculizumab or ravulizumab), functional or anatomic asplenia, and HIV infection.[166,228,237] Microbiologists who routinely work with isolates of *N. meningitidis*, college students, men who have sex with men, and military recruits are also at increased risk of disease.[166,228,237]

Clinical Experience with MenACWY-TT (MenQuadfi®)

Efficacy of MenACWY-TT (MenQuadfi®) is inferred based on the evaluation of immunogenicity using a serogroup-specific serum bactericidal assay with exogenous human complement (hSBA).[1] Serum was collected from patients at baseline and 30 days post-vaccination to measure antibodies with hSBA.[1] The geometric mean titers (GMTs) of the hSBA and the proportion of patients who achieved hSBA seroresponse were evaluated.[1] In all clinical studies, the serogroup response rate was defined as the proportion of participants with an hSBA with a pre-vaccination titer <1:8 who achieved a post-vaccination titer of ≥1:16, or a pre-vaccination titer ≥1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.[1]

Primary Immunization in Infants and Children 2 through 23 Months of Age

A controlled clinical study assessed the immunogenicity of a 4-dose series of MenACWY-TT, based on hSBA, in comparison to a 4-dose series of MenACWY-CRM (Menveo®) in infants 2–18 months of age.[1] Patients received the 4 doses of their assigned vaccine at 2, 4, 6, and 12–15 months of age with concomitant administration of other US-licensed vaccines.[1] The proportions of infants who achieved seroresponse after the 4th dose of MenACWY-TT were 79.4, 97.0, 97.6, and 96.4% for meningococcal serogroups A, C, W, and Y, respectively; the GMTs after the 4th dose were 67, 678, 387, and 296 for serogroups A, C, W, and Y, respectively.[1] The proportions of infants who achieved seroresponse after the 4th dose of MenACWY-CRM were 77.6, 88.2, 96.4, and 92.3% for serogroups A, C, W, and Y, respectively; the GMTs for each serogroup were 57, 91, 175, and 186, respectively.[1] Noninferiority of MenACWY-TT compared to MenACWY-CRM was met for all 4 meningococcal serogroups.[1]

Another controlled clinical study compared the immunogenicity of a 2-dose series of MenACWY-TT with MenACWY-CRM in infants 6–23 months of age.[1] For both vaccines, the first dose was administered at 6–7 months, and the second dose was administered at 12–13 months; both were concomitantly administered with other US-licensed vaccines.[1] For patients who received MenACWY-TT, the seroresponse rates after the second dose were 89.4% for serogroup A, 99.3% for both serogroups C and W, and 98.6% for serogroup Y; the GMTs were 184, 1473, 442, and 423 for serogroups A, C, W, and Y, respectively.[1] For patients who received MenACWY-CRM, the seroresponse rates after the second dose were 82.9% for serogroup A, 97.6% for serogroup C, 92.9% for serogroup W, and 97.7% for serogroup Y; the GMTs were 119, 319, 106, and 133 for serogroups A, C, W, and Y, respectively.[1] Noninferiority of MenACWY-TT compared to MenACWY-CRM was met for all 4 meningococcal serogroups.[1] This study also compared the immunogenicity of MenACWY-TT to MenACWY-CRM following a 2-dose series with the first dose administered to participants at 17–19 months of age and the second dose administered at 20–23 months of age.[1] After the second dose, the seroresponse rates of MenACWY-TT and MenACWY-CRM, respectively, were 72.9 and 46.6% for serogroup A, 100 and 93.2% for serogroup C, 100 and 76.3% for serogroup W, and 100 and 88.1% for serogroup Y.[1]

Primary Immunization in Children 2 through 9 Years of Age

A randomized, controlled, phase 3 clinical study assessed the immunogenicity of a single dose of MenACWY-TT compared to MenACWY-CRM in children 2–9 years of age in the US, including Puerto Rico.[1,311] The seroresponse rates of MenACWY-TT and MenACWY-CRM, respectively, were 55.4 and 47.8% for serogroup A, 95.2 and 47.8% for serogroup C, 78.8 and 64.1% for serogroup W, and 91.5 and 79.3% for serogroup Y.[1,311] The GMTs achieved with MenACWY-TT for serogroups C, W, and Y were higher than those achieved with MenACWY-CRM; for serogroup A, the GMTs for both vaccines were comparable.[1,311] Noninferiority of MenACWY-TT to MenACWY-CRM was met for all 4 serogroups based on seroresponse rates.[1,311]

Primary Immunization in Adolescents 10 through 17 Years of Age

A randomized, controlled, open-label, phase 2 clinical study assessed the immunogenicity of a single dose of MenACWY-TT compared to a single dose of MenACWY-CRM in adolescents 10–17 years of age in the US.[1,312] The proportion of patients who received MenACWY-TT who achieved seroresponse ranged from 70.2–96.1% for each serogroup, and 56–66.8% for each serogroup for patients who received MenACWY-CRM.[1,312] The GMTs achieved with MenACWY-TT for serogroups C, W, and Y were higher than those achieved with MenACWY-CRM; for serogroup A, the GMTs for both vaccines were comparable.[1,312] Noninferiority of MenACWY-TT to MenACWY-CRM was met for all 4 serogroups based on seroresponse rates.[1,312]

Another randomized controlled trial compared the immunogenicity of a single dose of MenACWY-TT to MenACWY-D (Menactra®; no longer available in the US) in adolescents 10–17 years of age in the US.[1,313] Noninferiority of MenACWY-TT to MenACWY-D was demonstrated for all serogroups based on seroresponse rates.[1,313]

Primary Immunization in Adults 18 through 55 Years of Age

A randomized, controlled, blinded, phase 3 clinical study assessed the immunogenicity of a single dose of MenACWY-TT as compared to a single dose of MenACWY-D (Menactra®; no longer available in the US) in adults 18–55 years of age in the US.[1,313] The proportion of patients who received MenACWY-TT who achieved seroresponse ranged from 73.5–88.1% for each serogroup, and 42.3–60.8% for each serogroup for patients who received MenACWY-D.[1,313] The GMTs achieved with MenACWY-TT ranged from 76–234, compared to a range of 33–55 with MenACWY-D.[1,313] Noninferiority of MenACWY-TT to MenACWY-D was demonstrated for all serogroups based on seroresponse rates.[1,313]

Primary Immunization in Adults 56 Years of Age or Older

A randomized, controlled, blinded, phase 3 clinical study assessed and compared the immunogenicity of a single dose of MenACWY-TT to a single dose of the polysaccharide meningococcal vaccine (MPSV4 [Menomune®]; no longer available in the US) in adults ≥56 years of age in the US, including Puerto Rico.[1,314] The seroresponse rates 30 days after immunization with MenACWY-TT and MPSV4, respectively, were 58.2 and 42.5% for serogroup A, 77.1 and 49.7% for serogroup C, 62.6 and 44.8% for serogroup W, and 74.4 and 43.4% for serogroup Y.[1,314] The GMTs achieved with MenACWY-TT for all serogroups were higher than those achieved with MPSV4.[1,314] Based on seroresponse rates, noninferiority of MenACWY-TT to MPSV4 was met for all 4 serogroups.[1,314]

Booster Immunization in Adolescents and Adults 13 Years of Age or Older

A randomized controlled study of adolescents and adults ≥15 years of age in the US, including Puerto Rico, compared the immunogenicity of a single booster dose of MenACWY-TT to a booster dose of MenACWY-D (Menactra®; no longer available in the US).[1,315] Patients enrolled in this study received a dose of either MenACWY-D or MenACWY-CRM (Menveo®) 4–10 years previously.[1,315] The seroresponse rates 30 days after the booster dose of MenACWY-TT and MenACWY-D, respectively, were 92.2 and 87.1% for serogroup A, 97.1 and 91.8% for serogroup C, 98.2 and 90.7% for serogroup W, and 97.4 and 95.6% for serogroup Y.[1,315] The GMTs achieved with MenACWY-TT ranged from 497–2618, compared to a range of 296–811 with MenACWY-D.[1,315] Noninferiority of MenACWY-TT to MenACWY-D was demonstrated for all 4 serogroups based on seroresponse rates.[1,315]

Another randomized controlled study enrolled adolescents and adults 13–26 years of age to assess the immunogenicity of a single booster dose of MenACWY-TT.[1,316] To be eligible, patients had to have received a primary dose of MenACWY-TT or MenACWY-CRM 3–6 years previously in prior clinical studies of MenACWY-TT.[1,316] The seroresponse rates 30 days after the booster dose of MenACWY-TT in patients who previously received a primary dose of MenACWY-TT were 94.8, 97.1, 97.7, and 98.9% for serogroups A, C, W, and Y, respectively.[1,316] The seroresponse rates 30 days after the booster dose of MenACWY-TT in patients who previously received a primary dose of MenACWY-CRM were 93.2, 98.9, 98.9, and 100% for serogroups A, C, W, and Y, respectively.[1,316] The GMTs for serogroups A, W, and Y 30 days after the booster dose were comparable for patients who previously received a primary dose of MenACWY-TT or MenACWY-CRM; patients who previously received a primary dose of MenACWY-TT had a higher GMT for serogroup C than those who previously received MenACWY-CRM.[1,316]

Another randomized controlled trial enrolled adults ≥59 years of age to assess the immunogenicity of a single booster dose of MenACWY-TT.[1,317] Patients in this study received a single primary dose of MenACWY-TT or MPSV4 (Menomune®; no longer available in the US) at least 3 years previously in prior clinical studies of MenACWY-TT.[1,317] The seroresponse rates 30 days after the booster dose of MenACWY-TT in patients who previously received a primary dose of MenACWY-TT were 79.3, 93.1, 90.3, and 92.4% for serogroups A, C, W, and Y, respectively.[1,317] The seroresponse rates 30 days after the booster dose of MenACWY-TT in patients who previously received a primary dose of MPSV4 were 60.8, 55, 49.2, and 49.2% for serogroups A, C, W, and Y, respectively.[1,317] The GMTs 30 days after booster vaccination with MenACWY-TT achieved for those who previously received primary vaccination with MenACWY-TT ranged from 162–638, compared to a range of 31–57 for those who received primary vaccination with MPSV4.[1] Another controlled trial assessed immunogenicity of a single booster dose of MenACWY-TT 5 years after primary vaccination with MenACWY-TT or MPSV4 in adults ≥56 years of age.[318] The seroresponse rates for all 4 serogroups 30 days after the booster dose in patients who previously received MenACWY-TT ranged from 90–100%, compared to a range of 25–62.5% in patients who previously received MPSV4.[318]

Clinical Experience with MenACWY-CRM (Menveo®)

Efficacy of MenACWY-CRM (Menveo®) is inferred based on the evaluation of immunogenicity from the measurement of serogroup-specific anticapsular antibodies with bactericidal activity using pooled human serum that lacked bactericidal activity as the source of exogenous human complement (hSBA).[152] The efficacy of MenACWY-CRM in patients 2–55 years was assessed by comparing the hSBA responses after immunization with MenACWY-CRM to the responses following immunization with MenACWY-D (Menactra®; no longer available in the US).[152] The main efficacy endpoint that was used in most of the clinical studies of MenACWY-CRM was hSBA seroresponse to each serogroup 28 days after immunization.[152] Seroresponse was defined as a post-vaccination hSBA ≥1:8 for participants with a baseline hSBA <1:4, or titers at least 4-fold higher than baseline for participants with a pre-vaccination hSBA ≥1:4.[152]

Primary Immunization in Infants 2 through 12 Months of Age

Due to the absence of an FDA-approved comparator vaccine for use in infants during the time of clinical development, the pre-specified endpoint for effectiveness of MenACWY-CRM in infants in the US, who received a 4-dose series at 2, 4, 6, and 12 months of age, was the proportion of patients who achieved an hSBA ≥1:8, with the lower limit of the 2-sided 95% confidence interval (CI) for the point estimate being ≥80% of vaccinees for serogroup A, and ≥85% of vaccinees for serogroups C, W, and Y 1 month after the final dose.[152] In a clinical trial in infants 2–12 months of age who were given a 4-dose series of MenACWY-CRM (given at 2, 4, 6, and 12 months of age), the pre-defined immunogenicity criteria were met for all 4 serogroups (A, C, W, and Y) at 1 month following completion of the series.[152] The percentages of patients with hSBA ≥1:8 at 1 month after the last dose were 89, 95, 97, and 96% for serogroups A, C, W, and Y, respectively.[152] In another clinical trial, the efficacy of MenACWY-CRM was assessed in infants; a 2-dose series was administered at 7–9 months and 12 months of age.[152] The percentages of patients with hSBA ≥1:8 in this study were 88, 100, 98, and 96% for serogroups A, C, W, and Y, respectively.[152]

Primary Immunization in Children 2 through 10 Years of Age

A randomized, controlled, phase 3 clinical study assessed the immunogenicity of a single dose of MenACWY-CRM compared to a single dose of MenACWY-D (Menactra®; no longer available in the US) in children 2–10 years of age in the US and Canada.[152,319] In children 2–5 years of age, the seroresponse rates 28 days after a single dose of MenACWY-TT and MenACWY-D, respectively, were 72 and 77% for serogroup A, 60 and 56% for serogroup C, 72 and 58% for serogroup W, and 66 and 45% for serogroup Y.[152,319] Noninferiority was met for this age group for serogroups C, W, and Y; however, noninferiority was not met for serogroup A.[152,319] In children 6–10 years of age, the seroresponse rates 28 days after a single dose of MenACWY-TT and MenACWY-D, respectively, were 77 and 83% for serogroup A, 63 and 57% for serogroup C, 57 and 44% for serogroup W, and 58 and 39% for serogroup Y.[152,319] For this age group, noninferiority was met for serogroups C, W, and Y; however, noninferiority was not met for serogroup A.[152,319]

Primary Immunization in Adolescents 11 through 18 Years of Age

A randomized, controlled, phase 3 clinical study assessed the immunogenicity of a single dose of MenACWY-CRM compared to a single dose of MenACWY-D (Menactra®; no longer available in the US) in adolescents 11–18 years of age in the US.[152,320] The seroresponse rates 28 days after a single dose of MenACWY-TT and MenACWY-D, respectively, were 75 and 66% for serogroup A, 76 and 73% for serogroup C, 75 and 63% for serogroup W, and 68 and 41% for serogroup Y.[152] Based on seroresponse rates, noninferiority was demonstrated for all 4 serogroups.[152]

Primary Immunization in Adults 19 through 55 Years of Age

A randomized, controlled, phase 3 clinical study assessed immunogenicity of a single dose of MenACWY-CRM compared to a single dose of MenACWY-D (Menactra®; no longer available in the US) in adults 19–55 years of age in the US.[152,321] The seroresponse rates 28 days after a single dose of MenACWY-TT and MenACWY-D, respectively, were 67 and 68% for serogroup A, 67 and 58% for serogroup C, 50 and 41% for serogroup W, and 56 and 40% for serogroup Y.[321] Based on seroresponse rates, noninferiority was demonstrated for all 4 serogroups.[152,321]

Immunization with One-Vial Presentation in Adolescents and Adults 10 through 40 Years of Age

A randomized, controlled, phase 2 clinical study compared the immunogenicity of the 1-vial presentation of MenACWY-CRM to its 2-vial presentation in adolescents and adults 15–55 years of age in Brazil, Estonia, Finland, France, Mexico, Russia, South Africa, Spain, and Turkey.[152,322] The 1-vial presentation was found to be noninferior to the 2-vial presentation based on the hSBA GMT against serogroup A.[152,322] Immune responses against serogroups C, W, and Y were also comparable between these vial presentations based on hSBA GMTs.[152,322]

Booster Immunization in Adolescents and Adults 15 through 55 Years of Age

A randomized controlled study of adolescents and adults 15–55 years of age in the US, including Puerto Rico, compared the immunogenicity of a single booster dose of MenACWY-CRM with a booster dose of MenACWY-D (Menactra®; no longer available in the US).[152,323] Patients enrolled in this study previously received a dose of either MenACWY-CRM or MenACWY-D 4–6 years earlier at an age of at least 11 years.[323] Seroresponse rate was defined in this study as a post-vaccination hSBA ≥1:16 for patients with a baseline hSBA <1:4 or at least 4-fold higher than baseline titers for subjects with a pre-vaccination hSBA ≥1:4.[152,323] The seroresponse rates 28 days after the booster dose of MenACWY-CRM and MenACWY-D, respectively, were 97 and 96% for serogroup A, 95 and 96% for serogroup C, 96 and 93% for serogroup W, and 97 and 94% for serogroup Y.[323]

Clinical Perspective

The American Academy of Pediatrics (AAP) and other organizations provide recommendations for the prevention of meningococcal disease caused by *N. meningitidis* serogroups A, C, W, and Y.[199,200,310] The Centers for Disease Control and Prevention (CDC) recommend the meningococcal groups A, C, Y, and W-135 vaccine for children at high risk of serious illness or after shared clinical decision-making with a healthcare provider.[199] Primary immunization against meningococcal serogroups A, C, Y, and W infection is recommended in adolescents as a 2-dose series, with the first dose administered at 11–12 years of age and the second dose administered at 16 years of age.[199,200,310] Catch-up vaccination is recommended in adolescents not previously vaccinated against meningococcal serogroups A, C, Y, and W.[199,310] For patients 13–15 years of age who have not

been previously vaccinated, 1 dose of MenACWY vaccine should be administered immediately, and a booster should be administered between 16–18 years of age, with a minimum interval of 8 weeks in between the 2 doses.[199,310] For patients 16–18 years of age who have not been previously vaccinated, 1 dose of MenACWY vaccine should be administered.[199,310] Either MenACWY-CRM (Menveo®) or MenACWY-TT (MenQuadfi®) can be used for this patient population.[199,310]

The CDC Advisory Committee on Immunization Practices (ACIP) and AAP recommend meningococcal serogroups A, C, W, and Y vaccination in specific high-risk groups and populations in children as young as 2 months of age and in adults ≥19 years of age.[199,200,310] For adults and pediatric patients with anatomic or functional asplenia (including sickle cell disease), HIV infection, consistent complement component deficiency, or complement inhibitor (e.g., eculizumab, ravulizumab) use, vaccination with either MenACWY-CRM (Menveo®) or MenACWY-TT (MenQuadfi®) is recommended.[199,200,310] For use of MenACWY-CRM in pediatric patients, a 4-dose series should be used if dose 1 is given at 2 months of age, a 3- or 4-dose series should be used if dose 1 is given at 3−6 months of age, and a 2-dose series should be used if dose 1 is given at 7 months of age or older.[199,310] For use of MenACWY-TT in pediatric patients, dose 1 should be given at 24 months of age or older with a 2-dose series at least 8 weeks apart.[199,310] In adults, a 2-dose primary series of either MenACWY-CRM or MenACWY-TT at least 8 weeks apart is recommended; patients should also receive 1 booster dose 5 years after primary vaccination and every 5 years if risk remains.[200]

ACIP and AAP also recommend meningococcal serogroups A, C, W, and Y vaccination in persons who are traveling to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj.[199,200,310] In pediatric patients <24 months of age, MenACWY-CRM should be administered.[199,310] A 4-dose series should be used if the first dose is given at 2 months of age, a 3- or 4-dose series should be given if dose 1 is given at 3–6 months of age, and a 2-dose series should be given if the first dose is given at 7–23 months of age.[199,310] In pediatric patients ≥2 years of age, 1 dose of either MenACWY-CRM or MenACWY-TT should be used.[199,310] In adults, 1 dose of either MenACWY-CRM or MenACWY-TT should be used; 1 booster dose should be administered 5 years after the primary series and every 5 years thereafter if risk remains.[200]

ACIP also recommends meningococcal serogroups A, C, W, and Y vaccination in persons who are microbiologists routinely exposed to *N. meningitidis*.[200] If indicated, patients should receive 1 dose of either MenACWY-CRM or MenACWY-TT with 1 booster dose 5 years after the primary series and every 5 years if risk remains.[200]

ACIP and AAP also recommend meningococcal serogroups A, C, W, and Y vaccination for first-year college students who live in residential housing (if not previously vaccinated at ≥16 years of age) or military recruits; 1 dose of either MenACWY-CRM or MenACWY-TT is recommended.[199,200,310]

ACIP and AAP also provide recommendations for adolescent vaccination of children who received MenACWY vaccination prior to 10 years of age.[199,310] In children for whom boosters are recommended because of an ongoing risk of meningococcal disease (e.g., complement component deficiency, HIV, or asplenia), the booster schedule for persons at increased risk should be followed.[199,310] Boosters are not recommended in children who are not at continued increased risk (i.e., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic); MenACWY vaccine should be administered according to the recommended adolescent schedule with dose 1 at 11−12 years of age and dose 2 at 16 years of age.[199,310]

ACIP recommends meningococcal serogroups A, C, W, and Y vaccination in response to outbreaks among persons 2 months of age and older who are at increased risk of disease (e.g., in community or organizational settings or among men who have sex with men).[200,310] For pediatric patients 2−23 months of age, use of a 4-, 3-, or 2-dose series of MenACWY-CRM is recommended, dependent on the age of the patient's first dose.[228] For pediatric patients 2−9 years of age who are unvaccinated, 1 dose of either MenACWY-CRM or MenACWY-TT is recommended.[228] For pediatric patients 2−9 years of age who are previously vaccinated and are identified as being at increased risk, a single dose is recommend if the patient is <7 years of age and it has been ≥3 years since vaccination; a single dose is also recommended if the patient is ≥7 years of age and it has been ≥5 years since vaccination.[228] For adults and pediatric patients ≥10 years of age, 1 dose of either MenACWY-CRM or MenACWY-TT is recommended if previously unvaccinated.[228] If previously vaccinated, a single booster dose is recommended if it has been ≥5 years since vaccination.[228]

Dosage and Administration

General

Dispensing and Administration Precautions

- Appropriate medical treatment used to manage immediate allergic reactions must be available in the event an acute anaphylactic reaction occurs following vaccination.[1,152]
- Ensure procedures are in place to avoid injury from syncope following vaccination.[1,134,152]

Administration

There are 2 different vaccines commercially available in the US for active immunization for prevention of invasive meningococcal disease caused by serogroups A, C, Y, and W-135: meningococcal (groups A, C, Y and W-135) oligosaccharide diphtheria CRM197 conjugate vaccine (MenACWY-CRM; Menveo®), and meningococcal (groups A, C, Y and W-135) polysaccharide tetanus toxoid conjugate vaccine (MenACWY-TT; MenQuadfi®).[1,152] These vaccines are administered only by IM injection.[1,152]

MenACWY vaccines usually can be given concurrently with other age-appropriate vaccines.[228] When multiple vaccines are administered during a single health-care visit, each parenteral vaccine should be given using separates syringes and different injection sites.[134,228] Injection sites should be separated by ≥1 inch if possible.[307]

Depending on patient age, IM injections should be made into the anterolateral muscles of the thigh or deltoid muscle of the arm.[134]

In infants younger than 12 months of age, IM injections should preferably be made into the anterolateral thigh.[134] In certain circumstances (e.g., physical obstruction at other sites and no reasonable indication to defer the vaccine dose), IM injections can be made into the gluteal muscle using care to identify anatomical landmarks prior to injection.[134]

In infants and children 1 through 2 years of age, the anterolateral thigh is the preferred site for IM injections; alternatively, IM injections can be made into the deltoid muscle if muscle mass is adequate.[134]

In adults, adolescents, and children 3 years of age or older, IM injections should preferably be made into the deltoid muscle; alternatively, IM injections can be made into the anterolateral thigh.[134]

To ensure delivery into muscle, IM injections should be made at a 90° angle to the skin using a needle length appropriate for the individual's age and body mass, thickness of adipose tissue and muscle at the injection site, and injection technique.[134,308]

Improper storage or handling of vaccines may reduce vaccine potency resulting in reduced or inadequate immune response in vaccinees.[134] All vaccines should be inspected upon delivery and monitored during storage to ensure that the appropriate temperature is maintained.[134] Meningococcal vaccine that has been mishandled or has not been stored at the recommended temperature should not be administered.[134] If there are concerns about mishandling, the manufacturer or state or local immunization or health departments should be contacted for guidance on whether the vaccine is usable.[134]

Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine (MenACWY-CRM; Menveo®)

MenACWY-CRM is supplied by the manufacturer as 2 presentations: a 2-vial presentation for use in individuals 2 months through 55 years of age, and a 1-vial presentation for use in individuals 10–55 years of age.[152]

The 2-vial presentation includes the following components that must be combined prior to administration: a single-dose vial containing the meningococcal A conjugate component (MenA) in lyophilized form and a single-dose vial containing the meningococcal C, Y, and W-135 conjugate component (MenCYW-135) as a liquid.[152] The entire contents of the vial containing the MenCYW-135 liquid component should be withdrawn into a syringe and injected into the vial containing the lyophilized MenA component.[152] The vial should be inverted and shaken well until the vaccine is completely dissolved.[152] MenACWY-CRM should be administered immediately after reconstitution.[152] To administer, withdraw 0.5 mL from the vial containing the reconstituted vaccine.[152] Refer to the full prescribing information for complete reconstitution instructions for the 2-vial presentation.[152]

The 1-vial presentation is supplied as a single-dose vial containing the vaccine and does not require reconstitution before use.[152] To administer, withdraw 0.5 mL from the vial.[152]

MenACWY-CRM (either presentation) should be a clear, colorless solution and should not be used if it contains particulate matter or appears discolored.[152]

MenACWY-CRM (either presentation) should be stored in the refrigerator, away from the freezer compartment, at 2–8°C.[152] Do not freeze; frozen or previously frozen vaccine components should be discarded.[152] The vaccine components should be protected from light.[152] MenACWY-CRM must be maintained at 2–8°C during transport.[152]

MenACWY-CRM or its individual components should not be mixed with any other vaccine or diluent in the same syringe or vial.[152]

MenACWY-CRM does not contain preservative or adjuvant.[152]

Meningococcal (Groups A, C, Y and W-135) Polysaccharide Tetanus Toxoid Conjugate Vaccine (MenACWY-TT; MenQuadfi®)

MenACWY-TT is supplied by the manufacturer as single-dose vials.[1] MenACWY-TT is administered IM undiluted.[1]

MenACWY-TT should appear as a clear, colorless solution; do not use if it contains particulate matter or appears discolored.[1]

MenACWY-TT should be stored in the refrigerator at 2–8°C.[1] Do not freeze; do not use vaccine that has been frozen.[1]

MenACWY-TT does not contain any preservative.[1]

■ Dosage

The dosage schedule (i.e., number and timing of doses for primary immunization) and specific MenACWY vaccine administered (MenACWY-CRM, MenACWY-TT) depend on the individual's age, immunization status, and risk factors.[1,152,228] The interval for the booster dose varies by age at time of previous vaccination.[1,152,228] The age-appropriate recommendations for the specific preparation used should be followed.[1,152,228] Consult the US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) vaccination schedules for specific dosage information, including detailed recommendations for certain scenarios (e.g., catch-up vaccination) and high-risk conditions.[199,200,228]

The CDC and ACIP state that MenACWY-CRM and MenACWY-TT can be used interchangeably; however, the same vaccine is recommended (but not required) for all doses.[228]

MenACWY-TT and MenACWY-CRM are administered IM in 0.5-mL doses.[1,152]

Primary Immunization

Although FDA approved in patients <11 years of age, MenACWY vaccination in children <11 years of age is only recommended in those at increased risk; routine use is not recommended by ACIP.[1,152,228]

> Children at Increased Risk for Meningococcal Disease.

FDA Dosage: *See Table 1 for the primary vaccination dosing schedule of MenACWY-TT and MenACWY-CRM as recommended by the manufacturers.*[1,152,]

Table 1. Manufacturer's Recommended Dosing Schedule for MenACWY Primary Vaccination in Children[1,152,]

AGE	VACCINE SCHEDULE
MenACWY-TT (MenQuadfi®)	
2 months of age at first dose	4-dose series at 2, 4, 6, and 12 through 18 months of age; first dose may be given as early as 6 weeks
6—11 months of age at first dose	2-dose series with the second dose administered in the second year of life and ≥3 months after the first dose
12—23 months of age at first dose	2-dose series with the second dose administered ≥3 months after the first dose
≥2 years of age	Single dose
MenACWY-CRM (Menveo®) 2-vial presentation	
2 months of age	4-dose series at 2, 4, 6, and 12 months of age
7—23 months of age	2-dose series with the second dose administered in the second year of life and ≥3 months after the first dose
2—10 years of age	1 dose; for children 2—5 years of age at continued high risk of meningococcal disease, a second dose may be administered 2 months after the first dose
≥11 years of age	1 dose
MenACWY-CRM (Menveo®) 1-vial presentation	
≥10 years of age	1 dose

The manufacturer of MenACWY-TT states that a single booster dose may be administered to individuals ≥13 years of age who are at continued risk for meningococcal disease if ≥3 years have elapsed since a prior dose of a MenACWY conjugate vaccine.[1,] *A single dose of MenACWY-TT may be administered if ≥3 years have elapsed since a prior dose of meningococcal polysaccharide vaccine (no longer available in the US).*[1,]

The manufacturer of MenACWY-CRM states that a single booster dose using either the 2-vial presentation or 1-vial presentation may be administered to individuals ≥15 years of age who are at continued risk for meningococcal disease if ≥4 years have elapsed since a prior dose of a MenACWY conjugate vaccine.[152,]

Expert Dosage: *ACIP recommends routine MenACWY vaccination of individuals ≥2 months of age at increased risk for meningococcal disease.*[228,] *Those at increased risk of meningococcal disease include: a) individuals with certain medical conditions such as anatomic or functional asplenia, complement component deficiencies (e.g., C3, C5-C9, properdin, factor H, or factor D), complement inhibitor (e.g., eculizumab, ravulizumab) use, or human immunodeficiency virus (HIV) infection; b) microbiologists with routine exposure to Neisseria meningitidis isolates; c) persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men); d) individuals who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic; e) unvaccinated or under-vaccinated first-year college students living in residence halls; and f) military recruits.*[228,] *Booster doses are recommended for previously vaccinated individuals who remain at increased risk.*[228,] *The American Academy of Pediatrics (AAP) has similar recommendations.*[310,]

See Table 2 for ACIP and AAP's recommended dosing schedule for MenACWY vaccination in children ≥2 months of age at increased risk.[199,228,310,] *Refer to the ACIP guideline for specific vaccination recommendations in an outbreak setting.*[199,228,]

In children who remain at increased risk, follow ACIP's booster schedule for specific groups; booster dose timing varies based on age and indication.[228,] *Generally, a single booster dose is recommended 3 years after completion of the primary series and every 5 years thereafter in children <7 years of age at increased risk, and a single booster dose is recommended 5 years after completion of the primary series and every 5 years thereafter in children ≥7 years of age at increased risk.*[228,]

Table 2. ACIP and AAP's Recommended Dosing Schedule for MenACWY Vaccination in Children ≥2 Months of Age at Increased Risk[199,228,310,]

VACCINE	DOSAGE RECOMMENDATION
Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use	
MenACWY-CRM (Menveo®)	Dose 1 at 2 months of age: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
	Dose 1 at 3–6 months of age: 3-dose or 4-dose series (dose 2 [and dose 3 if applicable] ≥8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose ≥12 weeks later and after age 12 months)
	Dose 1 at 7–23 months of age: 2-dose series (dose 2 ≥12 weeks after dose 1 and after age 12 months)
	Dose 1 at 24 months of age or older: 2-dose series ≥8 weeks apart
MenACWY-TT (MenQuadfi®)	Dose 1 at 24 months of age or older: 2-dose series ≥8 weeks apart
Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj	
MenACWY-CRM (Menveo®): children <24 months of age (i.e., 2–23 months)	Dose 1 at 2 months of age: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
	Dose 1 at 3–6 months of age: 3-dose or 4-dose series (dose 2 [and dose 3 if applicable] ≥8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose ≥12 weeks later and after age 12 months)
	Dose 1 at 7–23 months of age: 2-dose series (dose 2 ≥12 weeks after dose 1 and after age 12 months)
MenACWY-CRM (Menveo®): children 2 years of age or older	1 dose (note: do not use the 1-vial formulation before 10 years of age)
MenACWY-TT (MenQuadfi®): children 2 years of age or older	1 dose

ACIP states that administration of a 2-dose MenACWY primary series in ***children ≥2 years of age at increased risk for meningococcal disease [off-label]***[†]*, administration of* ***>1 booster dose [off-label]***[†]*, or administration of a* ***booster dose in children <15 years of age or at an interval of <4 years since the last dose [off-label]***[†] *is considered off-label.*[228,]

Children and Adolescents Not at Increased Risk for Meningococcal Disease (Routine Vaccination)

ACIP and AAP recommend routine MenACWY vaccination of children with a 2-dose series: the first dose of MenACWY-TT or MenACWY-CRM (either presentation) is administered at 11—12 years of age, with the second (booster) dose at 16 years of age.[199,228,310,] *Children who received the MenACWY vaccine at 10 years of age do not need an additional dose at 11—12 years of age but should receive the booster at 16 years of age.*[228,] *Children not currently at increased risk for meningococcal disease who were previously vaccinated prior to 10 years of age should receive the routinely recommended dose of MenACWY at 11—12 years and the booster at 16 years of age.*[228,]

ACIP and AAP recommend catch-up MenACWY vaccination with 1 dose administered at 13—15 years of age and a booster dose at 16—18 years of age within a minimum interval of 8 weeks.[199,228,310,] *For catch-up vaccination of adolescents 16—18 years of age, 1 dose is recommended (a booster dose is not needed).*[199,228,310,]

ACIP states that administration of ***>1 booster dose [off-label]***[†]*, or administration of a* ***booster dose in children <15 years of age or at an interval of <4 years since the last dose [off-label]***[†] *is considered off-label.*[228,]

Adults at Increased Risk for Meningococcal Disease

FDA Dosage: *The manufacturers recommend a single dose of MenACWY-TT or MenACWY-CRM (either presentation) in adults for primary immunization.*[1,152,]

The manufacturer of MenACWY-TT states that a single booster dose may be administered to individuals ≥13 years of age who are at continued risk for meningococcal disease if ≥3 years have elapsed since a prior dose of a MenACWY conjugate vaccine.[1] A single dose of MenACWY-TT may be administered if ≥3 years have elapsed since a prior dose of meningococcal polysaccharide vaccine (no longer available in the US).[1]

The manufacturer of MenACWY-CRM states that a single booster dose using either the 2-vial presentation or 1-vial presentation may be administered to individuals ≥15 years of age who are at continued risk for meningococcal disease if ≥4 years have elapsed since a prior dose of a MenACWY conjugate vaccine.[152]

Expert Dosage: *ACIP recommends routine MenACWY vaccination of adults at increased risk for meningococcal disease.[228] Those at increased risk of meningococcal disease include: a) individuals with certain medical conditions such as anatomic or functional asplenia, complement component deficiencies (e.g., C3, C5-C9, properdin, factor H, or factor D), complement inhibitor (e.g., eculizumab, ravulizumab) use, or HIV infection; b) microbiologists with routine exposure to Neisseria meningitidis isolates; c) persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men); d) individuals who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic; e) unvaccinated or under-vaccinated first-year college students living in residence halls; and f) military recruits.[228] Booster doses are recommended for previously vaccinated individuals who remain at increased risk.[200,228]*

See Table 3 for ACIP's recommended dosing schedule for MenACWY vaccination in adults at increased risk, including booster doses.[200,228] Refer to the ACIP guideline for specific vaccination recommendations in an outbreak setting.[200,228]

Table 3. ACIP's Recommended Dosing Schedule for MenACWY Vaccination in Adults at Increased Risk[200,228]

VACCINE	DOSAGE RECOMMENDATION
Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use	
MenACWY-CRM (Menveo®) or MenACWY-TT (MenQuadfi®)	2-dose primary series ≥8 weeks apart; 1 booster dose 5 years after primary series and every 5 years if risk remains
Travel to countries with hyperendemic or epidemic meningococcal disease, or for microbiologists routinely exposed to Neisseria meningitidis	
MenACWY-CRM (Menveo®) or MenACWY-TT (MenQuadfi®)	1 dose; 1 booster dose 5 years after primary series and every 5 years if risk remains
First-year college students living in residential housing (if not previously vaccinated at 16 years of age or older) or military recruits	
MenACWY-CRM (Menveo®) or MenACWY-TT (MenQuadfi®)	1 dose

*Although safety and efficacy of MenACWY-CRM have not been established in adults **≥56 years of age [off-label]**†,[152] ACIP states that the vaccine can be used when primary immunization or booster doses are indicated in this age group.[228] Additionally, administration of a 2-dose MenACWY primary series in **adults at increased risk for meningococcal disease [off-label]**†, administration of **>1 booster dose [off-label]**†, or administration of a **booster dose at an interval of <4 years since the last dose [off-label]**† is not licensed in the US.[228]*

Special Populations

Hepatic Impairment

The manufacturers make no specific dosage recommendations for patients with hepatic impairment.[1,152]

Renal Impairment

The manufacturers make no specific dosage recommendations for patients with renal impairment.[1,152]

Geriatric Patients

MenACWY-TT is labeled by FDA for use in adults ≥56 years of age, including those ≥65 years of age.[1] The manufacturer of MenACWY-TT makes no specific dosage recommendations for geriatric patients.[1]

The manufacturer states that safety and efficacy of MenACWY-CRM have not been established in adults ≥65 years of age.[152] Although not labeled by FDA for use in adults **≥56 years of age [off-label]†**, including those ≥65 years of age,[152] ACIP states that the vaccine can be used when primary or booster immunization is indicated in this age group.[228]

Cautions

■ Contraindications

- MenACWY-CRM (Menveo®): Severe allergic reaction (e.g., anaphylaxis) to any vaccine component or after previous dose of the vaccine or any vaccine containing diphtheria toxoid.[152]
- MenACWY-TT (MenQuadfi®): Severe allergic reaction to any vaccine component or after a previous dose of the vaccine or any vaccine containing tetanus toxoid.[1]

■ Warnings/Precautions

Hypersensitivity Reactions

Appropriate agents and equipment should be available for immediate treatment if an acute allergic reaction, including an anaphylactic reactions, occurs following administration of MenACWY-CRM or MenACWY-TT.[1,152]

Syncope

Syncope (fainting) may occur following vaccination.[1,134,152] Syncope occurs most frequently in adolescents and young adults.[134]

Procedures should be in place to avoid falling injury following syncope.[1,152] Syncope and secondary injuries may be averted if vaccinees sit or lie down during and for 15 minutes after vaccination.[134] If syncope occurs, the patient should be observed until symptoms resolve.[134]

Individuals with Altered Immunocompetence

Immune responses to MenACWY-CRM or MenACWY-TT may be reduced in some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy.[1,152]

Individuals with certain complement deficiencies and those receiving treatment with a complement inhibitor (e.g., eculizumab) are at increased risk for invasive disease caused by meningococcal serogroups A, C, Y, and W-135, even if they develop antibodies following vaccination with MenACWY vaccine.[1,152]

Consult the US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) for specific information on MenACWY vaccination in individuals with altered immunocompetence (e.g., individuals with human immunodeficiency virus [HIV], those with functional or anatomic asplenia) or individuals receiving immunosuppressant therapy.[134,199,200,228]

Guillain-Barré Syndrome

The manufacturers of MenACWY-CRM and MenACWY-TT state that, because Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another US quadrivalent polysaccharide meningococcal conjugate vaccine, the decision to administer MenACWY-CRM or MenACWY-TT in an individual with a history of GBS should take into account the potential benefits and risks.[1,152]

After reviewing available safety data regarding MenACWY vaccines, ACIP concluded that the benefits of vaccination against meningococcal serogroups A,C,Y, and W-135 outweigh the potential increased risk for GBS.[228] ACIP states that, although early postmarketing surveillance raised the concern of a potential risk for GBS, subsequent evaluations have not identified an increased risk for GBS after MenACWY vaccination.[228]

Limitations of Vaccine Effectiveness

MenACWY vaccine may not protect all vaccine recipients against meningococcal serogroups A, C, Y, and W-135 infection.[1] In addition, the quadrivalent meningococcal vaccines provide protection only against those serogroups represented in the vaccine (i.e., groups A, C, Y, W-135).[1,152] MenACWY vaccine will not prevent meningococcal infection caused by *N. meningitidis* serogroup B.[1,152]

Tetanus Immunization

Although MenACWY-TT contains meningococcal antigens conjugated to tetanus toxoid, the vaccine is not a substitute for routine immunization against tetanus.[1]

Apnea in Premature Infants

Apnea has been reported following IM administration of vaccines in some infants born prematurely.[152]

Decisions regarding when to administer an IM vaccine in infants born prematurely should be based on consideration of the individual infant's medical status and potential benefits and possible risks of vaccination.[152]

Concomitant Illness

A decision to administer or delay vaccination in an individual with a current or recent acute illness depends on the severity of symptoms and etiology of the illness.[134]

ACIP states that mild acute illness generally does not preclude vaccination.[134] However, moderate or severe acute illness (with or without fever) is a precaution for vaccination and vaccines should be deferred until the individual has recovered from the acute phase of the illness.[134] This precaution avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.[134]

Individuals with Bleeding Disorders

Individuals who have bleeding disorders or are receiving anticoagulant therapy and/or their family members should be advised about the risk of hematoma from IM injections.[134]

ACIP states that IM vaccines may be given to individuals who have bleeding disorders or are receiving anticoagulant therapy if a clinician familiar with the patient's bleeding risk determines that the vaccine can be administered IM with reasonable safety.[134] In these cases, a fine needle (23 gauge or smaller) should be used to administer the vaccine and firm pressure should be applied to the injection site (without rubbing) for at least 2 minutes.[134] In individuals receiving therapy for hemophilia, IM vaccines can be scheduled for shortly after a dose of such therapy.[134]

Bell's Palsy

There have been postmarketing reports of Bell's palsy in temporal association with administration of a dose of MenACWY-CRM in adolescents and young adults 11–21 years of age.[152] Symptoms of Bell's palsy resolved in all reported cases to date.[152] In 6 of 8 cases that occurred within 84 days after vaccination, MenACWY-CRM had been administered concomitantly with at least 1 other vaccine (i.e., human papillomavirus [HPV] vaccine; tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine adsorbed [Tdap]; influenza vaccine).[152]

Specific Populations

Pregnancy

MenACWY-CRM: There are no adequate and well-controlled studies evaluating MenACWY-CRM in pregnant women in the US.[152] A developmental toxicity study performed in female rabbits administered 0.5 mL of the vaccine (at each occasion) prior to mating and during gestation did not reveal evidence of harm to the fetus.[152] Data for 82 women enrolled in a pregnancy registry from 2014–2017 do not suggest an increased risk of major birth defects or miscarriage in women who received the vaccine within 28 days prior to conception or during pregnancy.[152]

MenACWY-TT: There are no clinical studies evaluating MenACWY-TT in pregnant women.[1] Available data on MenACWY-TT administered to pregnant women are insufficient to inform vaccine-associated risks.[1] A developmental toxicity study performed in female rabbits using 0.5 mL of the vaccine administered 30 and 10 days prior to mating and on days 6, 12, and 27 of gestation did not reveal evidence of harm to the fetus or adverse effects on postnatal development.[1] Clinicians are encouraged to report any exposure to MenACWY-TT that occurs during pregnancy to the manufacturer's pregnancy registry at 800-822-2463.[1]

ACIP states that MenACWY vaccine (MenACWY-CRM, MenACWY-TT) may be used during pregnancy if indicated.[228] ACIP states that, although data are limited, postmarketing surveillance has not identified any concerning safety signals regarding use of MenACWY vaccines during pregnancy.[228]

Lactation

It is not known whether MenACWY-CRM or MenACWY-TT is distributed into human milk.[1,152] Data are not available to assess the effects of MenACWY-CRM or MenACWY-TT on the breast-fed infant or on milk production/excretion.[1,152]

The manufacturers state that the benefits of breast-feeding and the importance of MenACWY vaccine to the woman should be considered along with the potential adverse effects on the breast-fed child from the vaccine or from the underlying maternal condition (i.e., susceptibility to meningococcal infection).[1,152]

ACIP states that breast-feeding women should receive MenACWY vaccine if indicated.[228]

Pediatric Use

MenACWY-CRM: Safety and efficacy have not been established in children younger than 2 months of age.[152] Safety and effectiveness of the 1-vial presentation of MenACWY-CRM have not been established in children younger than 10 years of age.[152] Only the 2-vial presentation is approved for use in children 2 months through 9 years of age.[152]

MenACWY-TT: Safety and efficacy have not been established in children younger than 6 weeks of age.[1] Safety and efficacy have been established in children 6 weeks through 17 years of age.[1]

> *Apnea has been reported following IM administration of vaccines in some infants born prematurely.[152] Decisions regarding when to administer an IM vaccine in infants born prematurely should be based on consideration of the individual infant's medical status and potential benefits and possible risks of vaccination.[152]*

> Geriatric Use
>
> *MenACWY-CRM: Safety and efficacy have not been established in* ***adults 56 years of age or older [off-label]****†, including geriatric adults 65 years of age or older.[152] However, ACIP states that MenACWY-CRM can be used when indicated in this age group.[228]*
>
> *MenACWY-TT: A clinical study in adults 56 years of age or older included 249 vaccinees 65 years of age or older (71 of these were 75 years of age or older).[1] The antibody response to all MenACWY vaccine serotypes was diminished in vaccine recipients 65 years of age or older compared with recipients 56–64 years of age.[1]*

Common Adverse Effects

MenACWY-CRM: Adverse effects reported most frequently in infants initiating vaccination at 2 months of age and receiving a 4-dose series of MenACWY-CRM were tenderness (24–41%) and erythema (11–15%) at the injection site, irritability (42–57%), sleepiness (29–50%), persistent crying (21–41%), change in eating habits (17–23%), vomiting (5–11%), and diarrhea (8–16%).[152]

Adverse effects reported most frequently in children initiating vaccination at 7 months through 23 months of age and receiving a 2-dose series of MenACWY-CRM were tenderness (10–16%) and erythema at injection site (12–15%), irritability (27–40%), sleepiness (17–29%), persistent crying (12–21%), change in eating habits (12–20%), and diarrhea (10–16%).[152]

Adverse effects reported most frequently when MenACWY-CRM was used in children 2 through 10 years of age were injection site pain (31%), erythema (23%), irritability (18%), induration (16%), sleepiness (14%), malaise (12%), and headache (11%).[152]

Among adolescents and adults 11 through 55 years of age, the most frequently reported adverse effects were injection site pain (41%), headache (30%), myalgia (18%), malaise (16%), and nausea (10%).[152] Similar rates of solicited adverse effects were observed following a single booster dose.[152]

MenACWY-TT: In infants who received a 4-dose series of MenACWY-TT administered at 2, 4, 6, and 12–18 months of age, the most common adverse effects were tenderness (39–46%), erythema (13–20%), and swelling (10–13%) at the injection site; irritability (40–52%); abnormal crying (27–42%); drowsiness (25–43%); loss of appetite (17–22%); fever (8–18%); and vomiting (4–13%).[1]

In infants who received a 2-dose series of MenACWY-TT administered at 6–7 months and 12–13 months of age, the most common adverse effects were tenderness (30–43%), erythema (21–22%), and swelling (15–16%) at the injection site; irritability (40–49%); abnormal crying (27–35%); drowsiness (28–37%); loss of appetite (15–17%); fever (9–13%); and vomiting (6–9%).[1]

In children 2 through 9 years of age, the most common adverse effects of MenACWY-TT following a primary dose were pain (39%), erythema (23%), and swelling (14%) at the injection site; myalgia (20%); malaise (21%); and headache (13%).[1]

In adolescents 10 through 17 years of age, the most common adverse effects of MenACWY-TT following a primary dose were injection site pain (35–45%), myalgia (27–35%), headache (27–30%), and malaise (19–26%).[1]

In adults 18 through 55 years of age, the most common adverse effects of MenACWY-TT following a primary dose were injection site pain (42%), myalgia (36%), headache (29%), and malaise (23%).[1]

In adults 56 years of age or older, the most common adverse effects of MenACWY-TT following a primary dose were injection site pain (26%), myalgia (22%), headache (19%), and malaise (15%).[1]

Adverse effects reported following a booster dose of MenACWY-TT in adolescents and adults were comparable to those reported following primary immunization.[1]

Drug Interactions

Immune Globulins

There is no evidence that immune globulin (immune globulin IM [IGIM], immune globulin IV [IGIV], immune globulin subcutaneous) or specific hyperimmune globulin (hepatitis B immune globulin [HBIG], rabies immune globulin [RIG], tetanus immune globulin [TIG], varicella zoster immune globulin [VZIG]) interferes with the immune response to inactivated vaccines.[134]

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) states that inactivated vaccines such as meningococcal groups A, C, Y, and W-135 vaccine (MenACWY vaccine) may be given concurrently with (using separate syringes and different injection sites) or at any interval before or after immune globulin preparations.[134]

ACIP states that patients with quantitative B-cell deficiencies should not receive inactivated vaccines while receiving immune globulin therapy due to concerns about vaccine effectiveness.[134]

Immunosuppressive Agents

Individuals receiving immunosuppressive therapy (e.g., alkylating agents, antimetabolites, corticosteroids at greater than physiologic dosages, cytotoxic drugs, radiation) may have reduced immune responses to MenACWY vaccine.[1,152] The immunogenicity of MenACWY-CRM has not been evaluated in persons receiving immunosuppressive therapies.[152]

ACIP states that inactivated vaccines generally can be administered safely to individuals receiving immunosuppressive therapy.[134] However, vaccination should be avoided during chemotherapy or radiation therapy if possible because the antibody response might be suboptimal.[134] Individuals vaccinated during or within 14 days of starting chemotherapy or radiation therapy should be considered unimmunized and should be revaccinated ≥3 months after such therapy is discontinued if immunocompetence has been restored.[134]

ACIP states that inactivated vaccines should be administered ≥2 weeks prior to initiation of anti-B cell agents.[134] Patients on chemotherapy with anti-B cell antibodies (e.g., rituximab) should wait ≥6 months after therapy before being vaccinated.[134] Some experts recommend waiting longer than 6 months for some anti-B cell antibodies.[134] The longer interval before administration of vaccines is recommended since anti-B cell agents suppress antibody-producing cells for a prolonged duration.[134]

Inactivated vaccines preferably should be administered ≥2 weeks prior to initiation of corticosteroid therapy that is considered immunosuppressive.[134] Corticosteroids given in greater than physiologic doses may reduce immune responses to vaccines.[134]

ACIP states that inactivated vaccines should be administered ≥2 weeks prior to initiation of therapy with certain other immunosuppressive biologic response modifiers (e.g., colony-stimulating factors, interleukins, tumor necrosis factor-α inhibitors).[134]

Vaccines

ACIP states that the MenACWY vaccine may be administered simultaneously with other age-appropriate vaccines.[306] However, each parenteral vaccine should be administered using a different syringe and at a different injection site.[306]

Inactivated Vaccines and Toxoids

Tetanus, Diphtheria, and Pertussis Vaccines

MenACWY-CRM has been administered concurrently with tetanus, diphtheria, and acellular pertussis (Tdap) vaccine or with Tdap and human papillomavirus (HPV) vaccine in a study in healthy adolescents 11 through 18 years of age.[152] There was no interference with the immune response to the meningococcal antigens compared with administration of MenACWY-CRM alone.[152] Although lower geometric mean antibody concentrations to the pertussis antigens were observed when MenACWY-CRM was administered concomitantly with Tdap and HPV vaccine compared with administration of Tdap alone, the clinical implications of the lower antibody response to the pertussis antigen in this study are not known.[152] Systemic adverse reactions (e.g., headache, malaise, myalgia, arthralgia) were reported more frequently in those who received MenACWY-CRM, Tdap, and HPV vaccine concurrently compared with those who received MenACWY-CRM alone.[152]

In a randomized, controlled study in adolescents 10 through 17 years of age, MenACWY-TT was administered concomitantly with Tdap and 4-valent HPV vaccine (4vHPV; no longer available in the US).[1] Concurrent administration of the 3 vaccines did not affect the immune responses to the diphtheria, tetanus, and meningococcal antigens.[1] Although the immune response to the filamentous hemagglutinin, pertactin, and fimbriae pertussis antigens (measured as geometric mean antibody concentration [of anti-filamentous hemagglutinin, anti-pertactin, and anti-fimbriae) was lower when Tdap was administered concurrently with MenACWY-TT, the clinical implications of the lower antibody response to the pertussis antigen in this study are not known.[1] There were no differences in adverse reactions reported within 7 days following concomitant administration of MenACWY-TT, Tdap, and 4vHPV in adolescents compared with administration of Tdap and 4vHPV without MenACWY-TT.[1]

DTaP-IPV-Hib Vaccine

Following concurrent administration of MenACWY-CRM and the combination vaccine containing diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and Haemophilus influenzae type b (DTaP-IPV-Hib) in infants at 2, 4, 6, and 12 months of age, there was no evidence for reduced antibody response to pertussis antigens, diphtheria toxoid, tetanus toxoid, poliovirus (types 1, 2, and 3), or Haemophilus influenzae type b.[152] No interference was observed when immune responses to DTaP-IPV-Hib were evaluated 1 month following the third dose.[152]

MenACWY-TT has been administered concurrently with DTaP-IPV-Hib (along with PCV13, hepatitis B, MMR, and varicella) in infants initiating vaccination at 2 months of age.[1] Immune responses to DTaP-IPV-Hib were evaluated 1 month after the third and fourth dose of each of these vaccines.[1] In addition, immune response to DTaP-IPV-Hib when administered concomitantly with MenACWY-TT at 15–18 months of age was compared to DTaP-IPV-Hib given alone at 15–18 months.[1] No interference in immune responses to the vaccine was observed when given concomitantly with MenACWY-TT.[1]

Hepatitis A Vaccines

MenACWY-CRM and MenACWY-TT have been administered concurrently with the hepatitis A vaccine in infants initiating vaccination at 2 months of age with the 4-dose series of MenACWY vaccine.[1,152] No interference was observed for the concomitantly administered vaccines.[152]

Hepatitis B Vaccine

Following concurrent administration of MenACWY-CRM and hepatitis B vaccine in infants according to ACIP recommendations, there was no evidence for reduced antibody response to hepatitis B.[152] No interference was observed when immune responses to hepatitis B vaccine were evaluated 1 month following the third dose.[152]

MenACWY-TT has been administered concurrently with the hepatitis B vaccine (along with DTaP-IPV/Hib, PCV13, MMR, and varicella) in infants initiating vaccination at 2 months of age.[1] Immune responses to hepatitis B were evaluated 1 month after the third dose of each of these vaccines.[1] No interference in immune responses to the vaccine was observed when given concomitantly with MenACWY-TT.[1]

Human Papillomavirus Vaccine

MenACWY-CRM has been administered concurrently with 4vHPV and Tdap vaccines in adolescents 11–18 years of age.[152] There was no interference with immune responses to the meningococcal antigens compared with administration of MenACWY-CRM alone.[152] Systemic adverse reactions (e.g., headache, malaise, myalgia, arthralgia) were reported more frequently in the those who received 4vHPV, Tdap, and MenACWY-CRM concurrently compared with those who received MenACWY-CRM alone.[152]

MenACWY-TT has been administered concomitantly with 4vHPV and Tdap in adolescents 10–17 years of age.[1] Concurrent administration of the 3 vaccines did not affect the immune responses to the HPV or meningococcal antigens.[1] There were no differences in adverse reactions reported within 7 days following concomitant administration of MenACWY-TT, Tdap, and 4vHPV in adolescents compared with administration of Tdap and 4vHPV without MenACWY-TT.[1]

Meningococcal Group B Vaccine

MenACWY-TT has been administered concomitantly with meningococcal group B (MenB) vaccines (MenB-4C [Bexsero®] or MenB-FHbp [Trumenba®]) in adolescents and adults 13–26 years of age without serious adverse effects.[1]

ACIP states that MenACWY vaccine may be administered concurrently with MenB-4C or MenB-FHbp using separate syringes and different injection sites.[306]

Pneumococcal Vaccines

Concurrent administration of MenACWY-CRM and pneumococcal 7-valent conjugate vaccine (PCV7; no longer available in the US) in infants at 2, 4, 6, and 12 months of age resulted in possible interference with the antibody response to 2 of the pneumococcal vaccine serotypes at 1 month after the third dose, but no evidence of interference with immune response to any pneumococcal vaccine serotypes after the fourth dose.[152]

MenACWY-TT has been administered concurrently with pneumococcal 13-valent conjugate vaccine (PCV13; given along with DTaP-IPV/Hib, hepatitis B, MMR, and varicella) in infants initiating vaccination at 2 months of age.[1] Immune responses to PCV13 were evaluated 1 month after the third and fourth dose of each of these vaccines.[1] No interference in immune responses to the vaccine was observed when given concomitantly with MenACWY-TT.[1]

Live Vaccines

Measles, Mumps, Rubella, and Varicella Vaccines

When MenACWY-CRM was administered concurrently with MMRV in infants 12 months of age, antibody responses to the measles, mumps, rubella, and varicella antigens measured 6 weeks after vaccination were comparable to those reported in infants who received MMRV alone.[152] In addition, concurrent administration of MenACWY-CRM and MMRV in these infants did not increase the rate of solicited local or systemic adverse effects compared with administration of either vaccine alone.[152]

When MenACWY-CRM was administered concurrently with MMR and varicella vaccines in infants 12 months of age, there was no evidence for interference in the immune response to MMR and varicella vaccines (among initially seronegative children) administered concomitantly with MenACWY-CRM relative to these vaccines administered alone.[152] The immune responses to MMR and varicella vaccines were assessed 6 weeks following vaccination.[152]

> *MenACWY-TT has been administered concurrently with MMR (along with varicella, DTaP-IPV/Hib, PCV13, and hepatitis B) in infants initiating vaccination at 2 months of age.[1] Immune responses to MMR and varicella were evaluated 1 month after vaccination.[1] No interference in immune responses to the vaccine was observed when given concomitantly with MenACWY-TT.[1]*

> Rotavirus Vaccine
>
> *MenACWY-CRM and MenACWY-TT have been administered concurrently with the pentavalent rotavirus vaccine in infants initiating vaccination at 2 months of age with the 4-dose series of MenACWY vaccine.[1,152] No interference was observed for the concomitantly administered vaccines.[152]*

Description

Meningococcal groups A, C, Y, and W-135 (MenACWY) vaccines are inactivated (polysaccharide) vaccines that stimulate active immunity to infections caused by the *Neisseria meningitidis* serotypes represented in the vaccines (i.e., groups A, C, Y, and W-135).[1,152,228] *N. meningitidis* is a gram-negative diplococcus found exclusively in humans that causes life-threatening invasive disease (e.g., meningitis, sepsis).[1,152] Globally, invasive meningococcal infections are attributed to five serogroups: A, B, C, Y, and W-135.[152] Immunity against invasive meningococcal disease is conferred by the presence of serum bactericidal antibodies.[1,152] Vaccination with MenACWY vaccines leads to the production of bactericidal antibodies specific to the capsular polysaccharides of serogroups A, C, Y, and W-135.[1,152] These vaccines do not stimulate immunity to infection caused by meningococcal serogroup B.[1,152]

There are currently 2 different conjugated MenACWY vaccines available in the US: meningococcal (groups A, C, Y and W-135) oligosaccharide diphtheria CRM197 conjugate vaccine (MenACWY-CRM; Menveo®),[152] and meningococcal (groups A, C, Y and W-135) polysaccharide tetanus toxoid conjugate vaccine (MenACWY-TT; MenQuadfi®).[1] These quadrivalent conjugated vaccines contain capsular polysaccharide antigens extracted from 4 serotypes of *N. meningitidis* (A, C, Y, and W-135) with different carrier proteins.[1,152]

MenACWY-CRM (Menveo®) contains purified capsular oligosaccharide antigens A, C, Y, and W-135 extracted from *N. meningitidis* and conjugated to *Corynebacterium diphtheriae* CRM197 protein.[152] Each serotype of *N. meningitidis* is cultured and grown on suitable media and treated with formaldehyde.[152] The meningococcal polysaccharide antigens A, Y, and W-135 are purified by several extraction and precipitation steps; the meningococcal polysaccharide antigen C is purified by a combination of chromatography and precipitation.[152] The oligosaccharides are prepared for conjugation from purified polysaccharides by hydrolysis, sizing, and reductive amination.[152] After activation, each oligosaccharide is then individually covalently linked to the diphtheria CRM197 protein and purified to form the serogroup-specific glycoconjugates.[152] Each 0.5-mL dose of MenACWY-CRM contains 10 mcg of *N. meningitidis* oligosaccharide serotype A, 5 mcg each of *N. meningitidis* oligosaccharide serotypes C, Y, and W-135, and 25.9–64.1 mcg of diphtheria CRM197 protein.[152] Each 0.5-mL dose is estimated to contain not more than 0.3 mcg of residual formaldehyde from the manufacturing process.[152] MenACWY-CRM does not contain preservative or adjuvant.

MenACWY-TT (MenQuadfi®) is a sterile solution containing purified capsular polysaccharide antigens A, C, Y, and W-135 extracted from *N. meningitidis* and conjugated to tetanus toxoid protein.[1] Each serotype of *N. meningitidis* is cultured and grown on suitable media and the individual polysaccharides are extracted and purified using centrifugation, detergent and alcohol precipitation, solvent extraction, and diafiltration.[1] The polysaccharides are depolymerized or derivatized and then purified by diafiltration to prepare them for conjugation, and the derivatized polysaccharides are then each individually covalently linked to tetanus toxoid protein and purified by chromatography and serial diafiltration to form the serogroup-specific glycoconjugates.[1] Potency of MenACWY-TT is determined by quantification of each of the polysaccharide antigens conjugated to tetanus toxoid protein and the unconjugated polysaccharide present.[1] Each 0.5-mL dose of MenACWY-TT contains 10 mcg each of meningococcal A, C, W, and Y polysaccharide antigens conjugated to approximately 55 mcg of tetanus toxoid carrier protein.[1] Each 0.5-mL dose may contain residual amounts of formaldehyde of less than 3 mcg/mL.[1] MenACWY-TT does not contain any preservative.[1]

The duration of immunity against *N. meningitidis* serogroups A, C, Y, and W-135 after primary immunization with MenACWY vaccines have not been fully determined.[309] Antibody waning occurs by 3–5 years after primary vaccination with MenACWY-CRM.[228] Booster doses of MenACWY vaccine may be indicated in individuals at increased susceptibility to meningococcal disease caused by serogroups A, C, Y, and W-135 because of certain chronic medical conditions or treatment and in those who are at continued increased risk of exposure to the disease.[199,200,228] Reduced immune responses to meningococcal vaccines may occur in immunocompromised individuals (e.g., individuals with human immunodeficiency virus, those with anatomic or functional asplenia, those receiving immunosuppressive therapy).[1,152,228]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (in English and Spanish; written at a 6th- to 8th-grade reading level).

- Prior to administration of MenACWY vaccine, provide a copy of the appropriate Centers for Disease Control and Prevention (CDC) Vaccine Information Statement (VIS) to the patient or patient's parent or guardian (VISs are available at CDC website at [Web]).[1,120,152]

- Advise the patient and/or the patient's parent or guardian of the benefits and risks of immunization with the MenACWY vaccine.[1,152]

- Advise the patient and/or patient's parent or guardian that routine meningococcal vaccination is recommended in the US for all adolescents at 11 through 12 years of age, followed by a booster dose at 16 years of age; catch-up vaccination is recommended at 13 through 18 years of age for those not previously vaccinated.[199,228] Also advise that meningococcal vaccine is recommended for certain individuals at increased risk for exposure to meningococcal disease (e.g., individuals with certain chronic medical conditions, international travelers, health-care or laboratory workers, unvaccinated or under vaccinated first-year college students living in residence halls, military personnel) or during an outbreak.[199,200,228]

- Advise the patient and/or patient's parent or guardian that revaccination or booster doses of MenACWY vaccine may be needed in individuals who receive primary immunization and remain at prolonged increased risk for disease caused by meningococcal serogroups A, C, Y, and W-135.[228]

- Advise the patient and and/or patient's parent or guardian that MenACWY vaccine dosing schedule varies by indication and age, and the interval for the booster dose varies by age at time of previous vaccination.[1,152,228] Advise patients to contact their clinician for specific guidance for vaccination.[1,152]
- Advise the patient and/or the patient's parent or guardian of the importance of completing the full vaccination series.[1,152]
- Advise the patient and/or patient's parent or guardian that MenACWY vaccine may not provide protection in all vaccinees.[1,152]
- Advise the patient and/or the patient's parent or guardian that fainting (sometimes resulting in falling with injury) has been reported following vaccination, and that patients should sit or lie down during and for 15 minutes after vaccine administration.[1,134,152]
- Advise the patient and/or the patient's parent or guardian to inform clinicians of a history of allergic reactions to MenACWY vaccine or any vaccine component.[1,152]
- Advise the patient and/or the patient's parent or guardian of the importance of contacting the clinician if any adverse reactions (including allergic reactions) occur with MenACWY vaccine.[1,152] Clinicians or individuals can report any adverse reactions that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at 800-822-7967 or [Web] .[1,152]
- Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary and herbal supplements, as well as any concomitant illnesses.[1,152]
- Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.[1,152] Inform patients that exposure to MenACWY-TT that occurs during pregnancy can be reported to the manufacturer's pregnancy registry at 800-822-2463.[1]
- Advise patients of other important precautionary information.[1,152]

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine (MenACWY-CRM)

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	*For injection, for IM use*	*10 mcg of meningococcal A capsular polysaccharide and 5 mcg each of meningococcal C, Y, W-135 capsular oligosaccharides conjugated to 25.9–64.1 mcg of diphtheria CRM_{197} protein carrier per 0.5 mL*	*Menveo®*	*GlaxoSmithKline*

Meningococcal (Groups A, C, Y and W-135) Polysaccharide Tetanus Toxoid Conjugate Vaccine (MenACWY-TT)

ROUTES	FORMS	STRENGTHS	BRAND NAMES	MANUFACTURER
Parenteral	*Injection, for IM use*	*10 mcg each of meningococcal A, C, Y, W-135 capsular polysaccharides conjugated to approximately 55 mcg of tetanus toxoid protein carrier per 0.5 mL*	*MenQuadfi®*	*Sanofi Pasteur*

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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