**Protocol for Administration of**

**Meningococcal (Groups A, C, Y, and W-135) Polysaccharide
Diphtheria Toxoid Conjugate Vaccine (MenACWY-D)**

**(MENACTRA**®**)**

**Indications and Usage**

**MENACTRA**® quadrivalent meningococcal conjugate vaccine is indicated for active immunization of persons aged 9 months through 55 years for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135.

**Recommended Schedule**

Meningococcal conjugate vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) for these age groups:

* **Routine vaccination of adolescents**: Administer meningococcal conjugate vaccine, either **MENACTRA**® or MENVEO®, to all adolescents, preferably at age 11 through 12 years with a booster dose at age 16 years.
* Administer **MENACTRA**® or MENVEO® to adolescents aged 13 through 18 years if not previously vaccinated.
	+ If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
	+ If the first dose is administered on or after age 16 years a booster dose is not needed unless the person is at increased risk for meningococcal disease.
* All persons aged 11 through 18 years should preferably receive either **MENACTRA**® or MENVEO® for routine meningococcal vaccination.
* All persons aged 19 through 55 years at increased risk for meningococcal disease (see below) should preferably receive either **MENACTRA**® or MENVEO®.
* All persons aged 56 years and older at increased risk for meningococcal disease (see below). **MENACTRA**® or MENVEO® is preferred for adults aged 56 years or older who a) were vaccinated previously with **MENACTRA**® or MENVEO® and are recommended for revaccination, or b) for whom multiple doses are anticipated (e.g., persons with asplenia, complement deficiencies, HIV infection, and microbiologists).
**Note**: Neither **MENACTRA**® nor MENVEO® is FDA approved for this age group.
* Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of **MENACTRA**® or MENVEO®, with at least 8 through 12 weeks between doses. Evidence suggests that persons with HIV do not respond optimally to a single dose.
* First year college students up through 21 years who are living in residence halls should receive one (1) primary dose of **MENACTRA**® or MENVEO®, if not previously vaccinated on or after their 16th birthday. Give a booster dose of **MENACTRA**® or MENVEO® if a previous dose was given when younger than 16 years of age.
* All persons aged 2 months through 23 months of age at increased risk for meningococcal disease (see below) **SHOULD ONLY RECEIVE** age-appropriate doses of MENVEO® or **Menactra**® as described below and in the Table below on the “Recommended Vaccination Schedule and Intervals.”
	+ For children aged 2 through 18 months with anatomic or functional asplenia (including sickle cell disease), administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age, with at least 8 weeks between doses.
	+ For children aged 2 through 18 months with persistent complement component deficiency, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months with at least 8 weeks between doses.
	+ For children aged 7 through 23 months with persistent complement component deficiency or HIV infection who have not initiated vaccination, two options exist depending on age and vaccine brand:
		- For children who initiate vaccination with MENVEO® at 7 through 23 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
		- For children who initiate vaccination with **MENACTRA**® at 9 through 23 months of age, a 2- dose series of **MENACTRA**® should be administered at least 3 months apart.
	+ In children aged 9 through 23 months, **MENACTRA**® is given as a 2-dose primary series with 12 weeks between doses.
	+ For children aged 19 through 23 months who have not completed a series of MENVEO®, administer two primary doses of MENVEO® at least 3 months apart.
	+ For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of **MENACTRA**®, administer 2 primary doses of **MENACTRA**® at least 8 weeks apart.
* For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease) or HIV infection, who have not received a complete series of MENVEO® or **MENACTRA**®, administer 2 primary doses of either **MENACTRA**® or MENVEO® at least 2 months apart.
* If **MENACTRA**® is administered to a child with anatomic or functional asplenia (including sickle cell disease) or HIV infection, do not administer **MENACTRA**® until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. MENVEO® may be given at any time before or after PCV13.
* All persons aged 2 years through 10 years at increased risk for meningococcal disease (see below) should preferably receive either **MENACTRA**® (approved for ages 9 months through 55 years) or MENVEO® (approved for ages 2 months through 55 years).
* All persons aged 2 years through 55 years with persistent complement component deficiency (e.g., C5to C9, properdin, factor H, or factor D) and anatomic or functional asplenia (including sickle cell disease), or with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series administered 2 months apart. Both **MENACTRA**® and MENVEO® are approved for this age group.
* HIV infection is an indication for routine vaccination with **MENACTRA**® or MENVEO®. Persons with HIV infection who are recommended routinely to receive vaccine (i.e., persons aged ≥9 months at increased risk for meningococcal disease and all persons aged 11 through 18 years) should receive a 2-dose primary series, administered
8–12 weeks apart, because evidence suggests that persons with HIV do not respond optimally to a single dose.

NOTE:

* All persons aged 9 through 23 months of age at increased risk for invasive meningococcal disease (see below) SHOULD ONLY RECEIVE **MENACTRA**® or MENVEO® for active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. In children aged 9 through 23 months, **MENACTRA**® or MENVEO® is given as a 2-dose series three months apart. **MENACTRA**® and MENVEO® are administered intramuscularly.

| **Recommended Vaccination Schedule and Intervals**[**http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/1013-mening-mcv.pdf**](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/1013-mening-mcv.pdf) |
| --- |
| **Age Group** | **Vaccine** | **Routine Recommendations** | **Dosing Schedule** |
| 2 mos through 10 years  | MenACWY(MENVEO®, Novartis)  | High-risk only¶  | **Primary:** * Age 2 through 6 months: 4 doses at 2, 4, 6, and 12 months
* Age 7 through 23 months: 2 doses

should be given with the second dose given in the second year of life * Age 2 through 10 years: 1 or 2 doses

**Booster** (for persons who remain at risk¶): * 1st booster 3 years after primary series

for children who received primary series prior to age <7 years, then every 5 years * Every 5 years for children who received primary series after 7th birthday
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| MenACWY(**MENACTRA®**, Sanofi)  | High-risk only\*  | **Primary:** * Age 9 through 23 months: 2 dose series with 12 weeks between doses
* Age 2 through 10 years: 1 or 2 doses

**Booster** (for persons who remain at risk¶): * 1st booster 3 years after primary series

for children who received primary series prior to age <7 years, then every 5 years * Every 5 years for children who received primary series after 7th birthday
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| 11 through 18 years  | MenACWY(MENVEO® or **MENACTRA®**)  | Children aged 11 through 18 years  | **Adolescents:** **Primary:** * Age 11 through 12 years

with booster dose at age 16 years **Booster** (for persons who remain at risk¶): * A booster dose is not recommended

if the first dose is given on or after the child’s 16th birthday |
| Adolescents with complement component deficiency, or functional or anatomic asplenia; HIV infection * 2 doses, 8 through 12 weeks apart

Booster for adolescents who remain at increased risk (complement component deficiency, functional or anatomic asplenia, HIV infection, traveling or part of a meningococcal outbreak more than 5 years after the prior dose):* 1st booster 5 years after primary
* Additional boosters every 5 years
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¶ For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, or traveling internationally to a region with hyperendemic or endemic meningococcal disease.

\* For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, or traveling internationally to a region with hyperendemic or endemic meningococcal disease. For infants receiving the vaccine prior to travel, the two doses may be administered as early as 8 weeks apart. Infants with functional or anatomic asplenia or HIV infection should wait until 2 years of age to prevent immune interference with PCV13.

§ For children with complement component deficiency, functional or anatomic asplenia, HIV infection, part of a community or organizational outbreak, **MENACTRA®** or MENVEO® should be used as booster doses for children.

**Note**: Use of brand names is not meant to preclude the use of other meningococcal vaccines where appropriate.

**Vaccination of persons with high-risk conditions and other persons at increased risk of disease**:

* Children with anatomic or functional asplenia (including sickle cell disease) or HIV infection:
1. For children younger than 19 months of age, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age.
2. For children aged 19 through 23 months who have not completed a series of MENVEO®, administer 2 primary doses of MENVEO® at least 3 months apart.
3. For children aged 24 months through 18 years who have not received a complete MENVEO® or **MENACTRA®**, administer two primary doses of either **MENACTRA®** or MENVEO® at least 2 months apart. If **MENACTRA®** is administered to a child with asplenia (including sickle cell disease) or HIV infection, do not administer **MENACTRA®** until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.
* Children with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H):
1. For children younger than 19 months of age, administer a 4-dose infant series of MENVEO® at 2, 4, 6, and 12 through 15 months of age.
2. For children 7 through 23 months who have not initiated vaccination, two options exist depending on age and vaccine brand:
3. For children who initiate vaccination with MENVEO® at 7 months through 23 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
4. For children who initiate vaccination with **MENACTRA®** at 9 months through 23 months of age, a 2-dose series of **MENACTRA®** should be administered at least 3 months apart.
5. For children aged 24 months through 18 years who have not received a complete series of MENVEO®, or **MENACTRA®**, administer two primary doses of either **MENACTRA®** or MENVEO® at least 2 months apart.
* Adults aged 19 years through 55 years with anatomic or functional asplenia (including sickle cell disease) or HIV infection: Administer a 2-dose primary series of **MENACTRA®** or MENVEO® with doses spaced 8–12 weeks apart.
* Adults aged 19 years through 55 years with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H): Administer a 2-dose primary series of **MENACTRA®** or MENVEO® with doses spaced 8–12 weeks apart.
* Adults aged 56 years and older with anatomic or functional asplenia (including sickle cell disease), HIV infection or with persistent complement component deficiencies (C3, C5-9, Properdin, Factor D, and Factor H), see page 1 of this protocol.

**Catch-up recommendations for persons with high-risk conditions:**

* For children who initiate vaccination with MENVEO® at 7 through 9 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.

**Persons at increased risk for meningococcal disease include:**

* College freshmen who live in dormitories
* Persons with HIV infection
* Persons who travel to or reside in countries where meningococcal disease is hyperendemic, such as sub-Saharan Africa, or epidemic, particularly if contact with the local population will be prolonged administer an age-appropriate formulation and series of **MENACTRA®** or MENVEO® for protection against serogroups A and W meningococcal disease. Prior receipt of MENHIBRIX® is not sufficient for children traveling to the meningitis belt or the Hajj because it does not contain serogroups A or W. Vaccination in the 3 years before the date of travel is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.
* Persons with anatomic or functional asplenia (including sickle cell disease)
* Persons with persistent complement component deficiencies (e.g., C3, C5-9, properdin, Factor D, and Factor H)
* Microbiologists routinely exposed to isolates of *Neisseria meningitidis* use **MENACTRA®** or MENVEO®. A booster dose should be administered every 5 years if exposure is ongoing.
* Military recruits
* Children (aged 6 weeks and older) and adults who are part of a community outbreak of invasive meningococcal disease caused by a vaccine-preventable serogroup, administer or complete an age-and formulation-appropriate series of **MENACTRA®** or MENVEO®.

**Revaccination:**

* Persons previously vaccinated with **MENACTRA®** or MENVEO® who are at prolonged increased risk for meningococcal disease (see below) should be revaccinated, preferably with either **MENACTRA®** or MENVEO®.
* Persons who previously were vaccinated with the 2-dose primary series at ages 9 months through 24 months and are at prolonged increased risk should be revaccinated 3 years after their previous meningococcal vaccine.
* Persons who previously were vaccinated at ages 2 years through 6 years and are at prolonged increased risk should be revaccinated 3 years after their previous meningococcal vaccine
* Persons who previously were vaccinated at 7 years of age or older and are at prolonged increased risk should be revaccinated 5 years after their previous meningococcal vaccine.
* Persons who remain in one of the increased risk groups indefinitely should continue to be revaccinated at 5-year intervals thereafter throughout life.
* College freshmen living in dormitories who were not previously vaccinated with **MENACTRA®** or MENVEO®, five or more years ago are recommended to be revaccinated with either **MENACTRA®** or MENVEO®.
* International travelers should receive a booster dose of **MENACTRA®** or MENVEO® if the last dose was administered five or more years previously. Vaccination in the 3 years before the date of travel is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj

**NOTE**: Revaccination is not mentioned in the MENVEO® Package Insert. Kentucky Immunization Program staff inquired with the CDC National Immunization Program staff as to whether MENVEO® can be used for revaccination. The relevant part of their reply of Jun 09, 2010 was “. . . our meningococcal group agrees that MENVEO® can be used for any indication within its licensed age range, including revaccination.”

**Persons at prolonged increased risk for meningococcal disease who should be revaccinated include:**

* Persons with increased susceptibility such as persistent complement component deficiencies (e.g., C3, properdin, Factor D, and late complement component deficiencies),
* Persons with anatomic or functional asplenia
* Persons with HIV infection
* Persons who have prolonged exposure (e.g., microbiologists routinely working with *Neisseria meningitidis*, or travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic)

**Outbreak Control**

* **MENACTRA®** or MENVEO® are recommended for use in the control of meningococcal outbreaks caused by vaccine-preventable serogroups (A, C, Y, and W-135), as an adjunct to chemoprophylaxis.
	+ MENVEO® may be used for infants and children aged 2 months through 23 months.
	+ **MENACTRA®** may be used for infants and children aged 9 months through 23 months.
	+ **MENACTRA®** or MENVEO® is preferred for use among children, adolescents, and adults aged 2 years through 55 years for control of meningococcal disease outbreaks.
	+ For persons now aged 56 years and older who were vaccinated previously with **MENACTRA®** or MENVEO® and are recommended for revaccination, **MENACTRA®** or MENVEO® is preferred.

**Dosage and Route** (Always check the package insert prior to administration.)

* Administer 0.5 mL intramuscularly (IM). Consult “Epidemiology and Prevention of Vaccine-Preventable Diseases” (The Pink Book), Appendix D, for information about appropriate needle sizes, needle lengths, and sites for administering vaccines.
* Do not administer this product intravenously, subcutaneously, or intradermally.

**Anatomical Site**

* Intramuscularly (IM) preferably in the deltoid muscle (upper arm).

**Precautions**

* Moderate or severe illness with or without fever (temporary precaution)
* The safety and effectiveness in pregnant women has not been established therefore **MENACTRA®** or MENVEO® should only be given to a pregnant woman if clearly needed.

**Contraindications**

* Individuals with anaphylactic reaction to a previous dose of **MENACTRA®**, diphtheria toxoid, or meningococcal-containing vaccine. (See “Other Important Notes.”).
* Contraindications and Precautions can be found in the package inserts available at <http://www.immunize.org/packageinserts/pi_meningococcal.asp>

**Warnings**:

* See warnings in the package insert for administration to individuals with a history of bleeding disorders such as hemophilia or thrombocytopenia or to individuals on anticoagulant therapy.

**Adverse Events**

* See the product’s package insert.

**Storage and Handling**

* Store in refrigerator at 36oF – 46oF (2oC – 8oC)
* DO NOT FREEZE. Product that has been frozen or previously frozen should not
be used.
* Do not use after the expiration date.

**Other Important Notes**

* Pregnancy is not a contraindication to **MENACTRA®**.
* Breastfeeding is not a contraindication to **MENACTRA®**.
* Persons with a history of anaphylaxis to a vaccine component, but who are at risk for meningococcal disease, should be referred to an allergist for evaluation and possible administration of **MENACTRA®** or other age appropriate meningococcal vaccines.
* **MENACTRA®** is preferred for use among children aged 2 through 10 years for control of meningococcal disease outbreaks.
* **The vial stopper is not made with natural rubber latex.**

**References:**

MMWR “Recommendations for Use of Meningococcal Conjugate Vaccines in HIV Infected Persons”-Advisory Committee on Immunization Practices (ACIP (November 4, 2016)

<http://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm>

VFC Resolutions – 10/16 Vaccines to Prevent Meningococcal Disease

<http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2016-10-3-mening.pdf>

**MENACTRA®** Package Insert (dated September 2016):

<http://www.immunize.org/fda/#mena>

Immunization Action Coalition (IAC), “Meningococcal Vaccine Recommendations by Age and Risk Factor for Serogroups A, C, W, or Y Protection (12/16)

<http://www.immunize.org/catg.d/p2018.pdf>

MMWR “Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (March 22, 2013)

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>

Footnotes to the “Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2018”:

<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

Footnotes to the “Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018”:

<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

VFC Resolutions – 10/13 Meningococcal:

<http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>

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