**Protocol for Administration of
Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide
Diphtheria CRM197 Conjugate Vaccine (MenACWY-CRM)**

**(MENVEO**®**)**

**Indications and Usage**

**MENVEO**® quadrivalent meningococcal conjugate vaccine is indicated for active immunization of persons aged 2 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 adolescents 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. 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 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 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 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 human immunodeficiency virus (HIV) infection should receive a 2-dose primary series administered two 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 11 through 18 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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| 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, 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 two primary doses of **MENVEO**® at least three months apart.
3. For children aged 24 months and older 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. If MENACTRA® is administered to a child with asplenia (including sickle cell disease), 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 and older 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 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.
* 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 three 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.

**Preparation for Administration of MENVEO**® (See the Package Insert)

* **MENVEO**® is supplied in two vials that must be combined prior to administration. Vaccine must be reconstituted by using a graduated syringe to withdraw the entire contents of the vial of MenCYW-135 liquid conjugate component and injecting it into the MenA lyophilized conjugate component vial. Gently invert or swirl the reconstituted vial until vaccine is dissolved, and then withdraw 0.5 mL of reconstituted product.
* Following reconstitution, the vaccine is a clear, colorless solution, free from visible foreign particles.
* Please note that it is normal for a small amount of liquid to remain in the vial following withdrawal of the dose.
* Do not mix **MENVEO**® or any of its components with any other vaccine or diluent in the same syringe or vial.

**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 into the deltoid muscle (upper arm).

**Precautions**

* 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.
* It is not known whether this drug is excreted in human milk. Use caution in nursing mothers.
* The safety and effectiveness in adults 65 years of age and older has not been established.

**Contraindications**

* Individuals with anaphylactic reaction to previous dose of **MENVEO**®, diphtheria toxoid, or meningococcal-containing vaccine.
* Contraindications and Precautions can be found in the package inserts available at: <http://www.immunize.org/fda/#mena>.

**Warnings**:

* **MENVEO**® should not be administered to persons with any bleeding disorder, or persons receiving anticoagulant therapy, unless the potential benefit outweighs the risk of administration.
* Syncope sometimes associated with temporary tonic-clonic movements and other seizure-like activity. Observation for 15 minutes after administration is recommended.
* Safety and effectiveness has not been established in pregnant women.
* Immunocompromised individuals, including those receiving immunosuppressive therapy, may not receive the expected immune response.

**Adverse Events**

* See the product’s package insert.

**Storage and Handling**

* Store in refrigerator at 36°F – 46°F (2°C – 8°C).
* Vaccine must be maintained at 36°F to 46°F (2°C – 8°C) during transport.
* DO NOT FREEZE. Product that has been frozen or previously frozen should not be used.
* Protect from light.
* Do not use after the expiration date. The reconstituted vaccine should be used immediately but may be held at or below 77°F (25°C) for up to 8 hours.

**Other Important Notes**

* The duration of protection following immunization is not known.
* **MENVEO**® does not contain thimerosal or other preservatives and does not contain an adjuvant.
* **The stopper to the MENVEO**® **vial is synthetic rubber and does not contain latex.**

**References:**

MMWR “Recommendation 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 Resolution – 10/16-3, Vaccines to Prevent Meningococcal Disease

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

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 Resolution – 10/2016 Meningococcal
[http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.htm](http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html)

MENVEO® Package Insert (revised 1/2017):
https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\_Information/Menveo/pdf/MENVEO.PDF

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