

NEEDLE TIPS

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ACIP Expands Recommendations for the Use of Meningococcal Serogroup B Vaccine to Include Adolescents and Young Adults

Two serogroup B meningococcal (MenB) vaccines were recently licensed by the Food and Drug Administration (FDA) for use in people age 10–25 years. MenB-FHbp (Trumenba; Pfizer Inc.) was licensed in October 2014, and MenB-4C (Bexsero; GSK) in January 2015.

On October 23, 2015, *Morbidity and Mortality Weekly Report (MMWR)* published “Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2015,” available at www.cdc.gov/mmwr/pdf/wk/mm6441.pdf, pages 1171–6. These recommendations were voted upon and approved at the June 2015 ACIP meeting.

The recommendations state that adolescents and young adults age 16–23 may be vaccinated with MenB vaccine to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16–18 years.

The new MenB recommendations are classified as Category B, meaning the recommendations allow for individual clinical decision making. (Vaccines with Category A recommendations are made for all persons in an age- or risk-factor-based group.) The Category B classification enables coverage by the Vaccines For Children program and most insurance plans.

MenB vaccine should be administered either as a 3-dose series of MenB-FHbp (Trumenba) or a 2-dose series of MenB-4C (Bexsero). The two MenB vaccines are not interchangeable; the same vaccine product must be used for all doses. On the basis of available data and expert opinion, MenB-FHbp or MenB-4C may be administered concomitantly with other vaccines indicated for this age, but at a different anatomic site, if feasible.

In addition to the Category B recommendation for adolescents and young adults, CDC also has issued recommendations for routine use (i.e., Category A) of MenB vaccines in certain groups of people at increased risk for serogroup B meningococcal disease. (Available at www.cdc.gov/mmwr/pdf/wk/mm6422.pdf, pages 608–612)

These groups include:

- People age 10 years and older who have functional or anatomic asplenia
- People age 10 years and older who have persistent complement component deficiency
- People age 10 years and older who are at risk during an outbreak caused by a vaccine serogroup, such as on college campuses
- Microbiologists who work with meningococcus bacteria in a laboratory

Even though both MenB vaccines are FDA-licensed for people 10 through 25 years of age, ACIP recommends the vaccines can be used off-label for those at increased risk of serogroup B meningococcal disease who are 26 years of age or older.

In contrast to meningococcal conjugate vaccine (MCV4 [MenACWY]) recommendations, MenB vaccine is not routinely recommended for college students or international travelers.

Q&As regarding the use of both MCV4 and MenB in adolescents are available on the CDC website at www.cdc.gov/vaccines/vpd-vac/mening-faqs-hcp-adolescent-vaccine.html.

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Ask the Experts

The Immunization Action Coalition extends thanks to our experts, medical officer Andrew T. Kroger, MD, MPH, and nurse educator Donna L. Weaver, RN, MN, both with the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention (CDC).

Meningococcal vaccines

What meningococcal vaccines are currently available in the United States?

Since 2005, 2 types of meningococcal vaccines have been available in the United States that protect against meningococcal serogroups A, C, W, and Y: 1) meningococcal polysaccharide vaccine (MPSV4; Menomune, Sanofi Pasteur), which is made up of polysaccharide (sugar molecules) from the surface of the meningococcal bacteria; and 2) meningococcal conjugate vaccines (MCV4; Menactra, Sanofi Pasteur; Menveo, GSK) in

which the polysaccharide is chemically bonded (“conjugated”) to a protein to produce better protection. MCV4 is more effective in young children than the original polysaccharide vaccine.

More recently, vaccines have become available that offer protection from meningococcal serogroup B. These vaccines are composed of proteins also found on the surface of the bacteria. Neither type of vaccine contains live meningococcal bacteria.

MPSV4 and MCV4 provide no protection against serogroup B disease, and meningococcal serogroup B vaccines (MenB) provide no protection against

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Immunization questions?

- Email nipinfo@cdc.gov
- Call your state health department (phone numbers at www.immunize.org/coordinators)

Meningococcal Vaccine Licensure Information

Trade Name	Type of Vaccine	Serogroups Included	Year Licensed	FDA-approved Ages
Menomune	Polysaccharide	A, C, W, Y	1981	2 years and older
Menactra	Conjugate	A, C, W, Y	2005	9 months–55 years*
Menveo	Conjugate	A, C, W, Y	2010	2 months–55 years*
MenHibrix	Conjugate	C, Y, and Hib	2012	6 weeks–18 months
Trumenba	Protein	B	2014	10–25 years ⁺
Bexsero	Protein	B	2015	10–25 years ⁺

* May be given to people age 56 years or older (consult ACIP recommendations at www.cdc.gov/mmwr/pdf/rr/rr6202.pdf).

⁺ May be given to people age 26 years or older (consult ACIP recommendations at www.cdc.gov/mmwr/pdf/wk/mm6422.pdf).

serogroup A, C, W, or Y disease. For protection against all 5 serogroups of meningococcus, it is necessary to receive MCV4 or MPSV4 and MenB.

Where can I find the most current meningococcal vaccine recommendations?

The most current recommendations for meningococcal polysaccharide and conjugate vaccines, which include serogroups A, C, W, and Y, were published in March 2013. This document is available on the *MMWR* website at www.cdc.gov/mmwr/pdf/rr/rr6202.pdf. Recommendations for use of MenB vaccine among persons at increased risk were published in June 2015 and are available at www.cdc.gov/mmwr/pdf/wk/mm6422.pdf, pages 608–12. MenB vaccine recommendations for adolescents and young adults were published in October 2015 and are available at www.cdc.gov/mmwr/pdf/wk/mm6441.pdf, pages 1171–6.

Who is recommended to be vaccinated against meningococcal disease?

Certain groups should receive both meningococcal conjugate vaccines (MCV4: Menactra, Sanofi Pasteur; Menveo, GSK) and MenB vaccines (Trumenba, Pfizer; Bexsero, GSK). Others are recommended to receive MCV4 only. MPSV4 (Menomune, Sanofi Pasteur) is recommended only for certain people older than 55 years.

► MCV4 is recommended for these groups:

- All children and teens, ages 11 through 18 years
- People younger than 22 years of age if they are or will be a first-year college student living in a residential hall
- People age 2 months and older with functional or anatomic asplenia (MenHibrix may be used for children age 6 weeks through 18 months in this group.)
- People age 2 months and older who have persistent complement component deficiency (an immune system disorder) (MenHibrix may be used for children age 6 weeks through 18 months in this group.)
- People age 2 months and older who are at risk during an outbreak caused by a vaccine sero-

group (MenHibrix may be used for children age 6 weeks through 18 months in this group.)

- People age 2 months and older who reside in or travel to certain countries in sub-Saharan Africa as well as to other countries for which meningococcal vaccine is recommended (e.g., travel to Mecca, Saudi Arabia, for the annual Hajj)
 - Microbiologists who work with meningococcus bacteria in a laboratory
- **MenB** is routinely recommended for these groups:
- People age 10 years and older who have functional or anatomic asplenia
 - People age 10 years and older who have persistent complement component deficiency
 - People age 10 years and older who are at risk during an outbreak caused by a vaccine serogroup, such as on college campuses
 - Microbiologists who work with meningococcus bacteria in a laboratory

For adolescents and young adults, ACIP recommends that a MenB vaccine series may be administered to people 16 through 23 years of age with a preferred age of vaccination of 16 through 18 years. This Category B recommendation allows the clinician to make a MenB vaccine recommendation based on the risk and benefit for the individual patient.

ACIP now designates a vaccine recommendation as either Category “A” or “B.” My interpretation is that an A recommendation means the vaccine is routinely recommended for all people in an age or risk group, and a B recommendation is for use at the clinician’s discretion. Does the Affordable Care Act (ACA) require health plans (non-grandfathered) to provide benefit coverage on Category B recommended vaccines?

Your understanding of A and B recommendations is correct. ACA requires coverage of vaccines with both A and B recommendations. The Vaccines For Children program also covers vaccines with a Category B recommendation.

IAC’s “Ask the Experts” team from the Centers for Disease Control and Prevention



Andrew T. Kroger, MD, MPH



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Should college students be vaccinated against meningococcal disease?

MCV4 vaccine is recommended for previously unvaccinated first-year college students who are age 21 years and younger, who are or will be living in a residence hall. Some colleges and universities require incoming freshmen and others to be vaccinated with MCV4; some may also require that a dose of MCV4 have been given since the age of 16 years.

Although several small MenB outbreaks have occurred on college campuses since 2013, college students in general are not at higher risk of MenB than persons of the same age who are not college students. Consequently, ACIP does not routinely recommend MenB vaccination for college students. However, college students may choose to receive MenB vaccine to reduce their risk of serogroup B meningococcal disease.

What is the schedule for MCV4 vaccine?

All adolescents should receive a dose of MCV4 at 11 or 12 years of age. A second (booster) dose is recommended at 16 years of age. Adolescents who receive their first dose at age 13 through 15 years should receive a booster dose at age 16 through 18 years. The minimum interval between MCV4 doses is 8 weeks. Adolescents who receive a first dose after their 16th birthday do not need a booster dose unless they become at increased risk for meningococcal disease. Colleges may not consider a second dose given even a few days before age 16 years as valid, so keep that mind when scheduling patients.

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What is the schedule for MenB vaccine?

Trumenba (Pfizer) is a 3-dose series with the second and third doses administered 2 and 6 months after the first dose. Bexsero (GSK) is a 2-dose series with doses given at least 1 month apart.

Which previously vaccinated college students need a booster dose of MCV4?

A booster dose should be given to first-year college students age 21 years and younger who are or will be living in a residence hall if the previous dose was given before the age of 16 years.

Can you provide a comprehensive overview of the MCV4 recommendations, including those for vaccinating younger children and older adults who have risk factors?

IAC has prepared a table that provides a summary of the ACIP recommendations for use of meningococcal vaccine for people of all ages, including recommendations published by ACIP in *MMWR* in March 2013. The table is available at www.immunize.org/catg.d/p2018.pdf.

I have a patient with paroxysmal nocturnal hemoglobinuria who is being treated with Soliris (eculizumab). Should he receive meningococcal vaccine?

Ecuzumab binds to C5 and inhibits the terminal complement pathway. Persons with persistent complement component deficiency are at increased risk for meningococcal disease. This person should receive a series of both quadrivalent meningococcal conjugate (MCV4; 2 doses separated by at least 8 weeks) and a 2- or 3-dose series (depending on brand) of meningococcal serogroup B vaccine.

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Are people who are HIV positive in a risk group for meningococcal disease?

HIV infection does not put a person into a risk group that necessitates vaccination with either MCV4 or MenB vaccine. However, the updated ACIP recommendations for use of MCV4 vaccines state that people with HIV who are vaccinated should receive a 2-dose primary series administered 2 months apart. Accordingly, the following HIV-positive people should receive 2 initial doses of MCV4 (instead of 1), spaced 2 months apart:

- HIV-positive adolescents age 11 through 18 years who, like other adolescents, are recommended for routine MCV4 vaccination
- HIV-positive people age 2 through 55 years who are at prolonged increased risk for exposure to meningococcal disease (for example, travelers to, or residents of, countries where meningococcal disease is hyperendemic or epidemic and microbiologists who routinely work with *Neisseria meningitidis*)
- any HIV-positive adult who chooses to be vaccinated

Should all adolescents receive a routine booster dose of MCV4?

ACIP recommends people age 11 or 12 years be routinely vaccinated with quadrivalent MCV4 and receive a booster dose at age 16 years. Adolescents who receive the first dose at age 13 through 15 years should receive a one-time booster dose at age 16 through 18 years, which are the years before the peak in incidence of meningococcal disease among adolescents occurs. Teens who receive their first dose of meningococcal conjugate vaccine at or after age 16 years do not need a booster dose, as long as they have no risk factors.

Why does ACIP recommend a routine booster dose of MCV4 for adolescents age 16 years and older?

In 2005, ACIP recommended routine MCV4 vaccination for all adolescents at age 11 or 12 years to protect them from meningococcal disease as older teens. The peak age for meningococcal disease is 16 through 21 years. In 2005, ACIP reasoned that higher MCV4 vaccination rates could be achieved if, when administering the dose, it was coupled with giving the Td booster dose at the 11- or 12-year-old visit (the Td dose for 11- or 12-year-olds was replaced by Tdap in 2006). Subsequent studies indicated that the protection provided by MCV4 wanes within 5 years following vaccination. For this reason, in 2010, ACIP recommended an MCV4 vaccine booster dose to provide continuing protection during the peak years of vulnerability (see www.cdc.gov/mmwr/pdf/wk/mm6003.pdf, pages 72-76).

If someone received MPSV4 or MCV4 at age 9 years, will two additional doses of MCV4 be needed?

Yes. Doses of quadrivalent meningococcal vaccine (either MPSV4 or MCV4) given before 10 years

of age do not count as part of the series. If a child received a dose of either MPSV4 or MCV4 before age 10 years, they should receive a dose of MCV4 at 11 or 12 years and a booster dose at age 16 years.

Which groups should receive a booster dose of MenB vaccine?

ACIP does not currently recommend booster doses of MenB vaccine for any group.

By what route should meningococcal vaccines be administered?

MCV4 should be administered by the intramuscular route. MPSV4 should be given by the subcutaneous route. MenB is given by the intramuscular route.

Can MCV4 and MenB vaccines be given at the same visit?

Yes. MCV4 and MenB vaccines can be given at the same visit or at any time before or after the other.

I understand that a prior history of Guillain-Barré syndrome (GBS) is no longer a precaution for giving meningococcal conjugate vaccine. Please tell me more about this.

A history of GBS had previously been a precaution for Menactra (Sanofi Pasteur), a brand of MCV4 vaccine. Findings from two studies that examined more than 2 million doses of Menactra given since 2005 showed no evidence of an increased risk of GBS. Consequently, ACIP recommended in 2010 to remove the precaution for use of Menactra in people with a history of GBS. This precaution did not apply to other meningococcal vaccines.

HPV vaccines

If a vaccination series was started with HPV2 or HPV4, can it be completed with HPV9?

If the answer is yes, what are the spacing intervals that should be used for the remaining doses in the 3-dose series?

ACIP recommendations state that HPV9 may be used to continue or complete a series started with a different HPV vaccine product. The intervals between doses remain the same regardless of what vaccine is used to complete the series. The second dose is given 1 to 2 months after the first dose and the third dose 4 months after the second AND at least 6 months after the first dose.

Are additional HPV9 doses recommended for a person who started a series with HPV2 or HPV4 and completed the series with one or two doses of HPV9?

There is no ACIP recommendation for additional doses of HPV9 for persons who started the series with HPV2 or HPV4 and completed the series with HPV9.

For CDC's supplemental information and guidance on the use of HPV9 vaccine, go to www.cdc.gov/hpv/downloads/9vhpv-guidance.pdf.