

Protocol for Meningococcal Containing Vaccines MenQuadfi®, Menveo®, Bexsero®, and Trumenba®

1. What's New

- A. Contraindications- Latex (Removed for Bexsero®⁵)
- B. Menveo® dosage and administration updated for 1 and 2 vial presentations.⁴
- C. Menactra® has been removed from the market, all guidance related to Menactra® removed from protocol.

2. Immunization Protocol

- A. Administer a 0.5-mL dose, IM, of meningococcal vaccine according to age-appropriate schedules and high-risk conditions.
- B. Meningococcal ACWY vaccines are interchangeable when more than one brand is age-appropriate.¹
- C. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.¹
- D. Meningococcal conjugate quadrivalent vaccine and Meningococcal B vaccine may be given simultaneously at different sites if indicated.¹
- E. Meningococcal vaccines can be given with all other routinely recommended vaccines.²

3. Vaccine Schedule

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	11-18 years	
Booster	16-18 years	8 weeks

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	≥7 years	
2		8 weeks if 2 doses indicated
Boosters (if person remains at risk)	Aged <7 years at completion of primary series: Single dose at 3 years after primary vaccination and every 5 years thereafter Aged ≥7 years at completion of primary series: Single dose at 5 years after primary vaccination and every 5 years thereafter	

MenB Vaccines (Bexsero®, Trumenba®) Schedule for Healthy Persons*, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	16-23 years	
2		28 days for Bexsero®, 6 months for Trumenba®

*ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. See section 5 for guidance.

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MenB Vaccines (Bexsero®, Trumenba®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	≥10 years	
2		28 days
3*		4 months after dose 2
Boosters (if person remains at risk)		Single dose at 1 year after completion of primary vaccination and every 2–3 years thereafter

*Dose 3 applies to Trumenba® only, not needed if dose 2 was administered at least 6 months after dose 1. If dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3.

4. Licensed Vaccines

Meningococcal ACWY Conjugate Vaccines				
Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
MenACWY-TT ³ (MenQuadfi®)	Neisseria meningitidis serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein	0.5-mL single-dose vials	≥2 years	None
MenACWY-CRM ⁴ (Menveo®)	Neisseria meningitidis serogroup A, C, Y, and W-135 oligosaccharides conjugated individually to Corynebacterium diphtheriae CRM protein	Single-dose 2 vial presentation (gray and orange caps) that requires reconstitution. 0.5-mL dose once reconstituted	2 months-55 years	None
		0.5-mL single-dose 1 vial presentation (pink cap) that does not require reconstitution	10-55 years	None

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Meningococcal B Vaccines				
Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
MenB-4C (Bexsero®) ⁵	Recombinant proteins Neisserial adhesin A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp)	0.5-mL prefilled syringes	10-25 years	None
MenB-fHbp (Trumenba®) ⁶	Two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL prefilled syringes	10-25 years	None

5. Recommendations for Use

- A. Routine use of Meningococcal ACWY vaccine¹
 - a. All adolescents 11–18 years of age without contraindications. Preferred age for dose one is 11-12 years with a booster dose at age 16 years. Catch-up vaccination age for dose one is 13–15 years with a booster dose at age 16–18 years. If series started at age 16 or older, no booster dose is indicated.
 - i. Children who received MenACWY at age 10 years do not need an additional dose at age 11–12 years but should receive the booster dose at age 16 years. Children who received MenACWY before age 10 years and with no ongoing risk for meningococcal disease for which boosters are recommended should still receive MenACWY according to the recommended adolescent schedule.
 - b. Unvaccinated or under vaccinated first-year college students living in residence halls. One dose may be administered to persons 19-21 years who have not received a dose after their 16th birthday. Boosters are not routinely recommended unless there is another indication.
 - c. Military recruits 19-21 years of age who have not received a dose after their 16th birthday. Administer one dose with booster every 5 years based on assignment. Vaccine recommendations for military personnel are made by the U.S. Department of Defense.
 - d. Booster doses for previously vaccinated persons who become or remain at increased risk. At 3 or 5 years after primary vaccination depending on age at last dose and every 5 years thereafter.
- B. Use of Meningococcal ACWY vaccine in high-risk persons¹
 - a. Persons with complement component deficiency or who are taking complement inhibitor medications, with anatomical or functional asplenia, or with HIV should receive 2 doses 8 weeks apart.

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- b. Microbiologists routinely exposed to isolates of *Neisseria meningitidis*, persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]), and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic, particularly the meningitis belt in sub-Saharan Africa, should receive 1 dose.
 - i. Vaccination is required for entry for persons traveling to Saudi Arabia for the Hajj and Umrah pilgrimages.
- C. Use of Meningococcal B vaccine in healthy persons¹
 - a. Vaccination of adolescents and young adults aged 16–23 years with a 2-dose MenB series on the basis of shared clinical decision-making. MenB vaccination is not routinely recommended for all adolescents. Instead, ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss MenB vaccination with persons aged 16-23 years who are most likely to benefit.
 - i. Pharmacists are authorized to administer MenB vaccine if the following risk factor is present: College students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities
- D. Use of Meningococcal B vaccine in high-risk persons¹
 - a. Persons with persistent complement component deficiencies or who are taking complement inhibitor medications, with anatomic or functional asplenia, and Microbiologists routinely exposed to isolates of *Neisseria meningitidis* should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
 - i. A single booster dose for previously vaccinated persons who remain at increased risk should be given at 1 year after completion of primary vaccination and every 2-3 years thereafter.
 - b. Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among MSM) should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
 - i. A single booster dose for previously vaccinated persons and identified at increased risk during an outbreak should be given if ≥1 year after completion of primary series (a ≥ 6-month interval might also be considered by public health).

6. Contraindications

- A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.³⁻⁷

Vaccine	Contains
MenACWY-TT – MenQuadfi®	sodium chloride, sodium acetate, formaldehyde, tetanus toxoid
MenACWY-CRM - Menveo®	formaldehyde, CRM197 protein
MenB-4C - Bexsero®	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB-FHbp - Trumenba®	polysorbate 80, aluminum phosphate, histidine buffered saline

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7. Warnings and Precautions³⁻⁶

- A. N/A

8. Other Considerations

- A. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses.³⁻⁶
- B. Pregnant and lactating women should receive MenACWY vaccine if indicated. However, due to a lack of data, vaccination with MenB should be deferred unless the woman is at increased risk and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks.¹
- C. Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers.¹
- D. MenACWY meningococcal vaccines will stimulate protection only against infections caused by organisms from serogroups A, C, Y and W meningococci. They are not protective against serogroup B meningococci.^{5,6}
- E. Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥7years of age.¹
- F. Immunization with MenQuadfi® does not substitute for routine tetanus immunization.³

9. Side Effects and Adverse Reactions³⁻⁶

MenACWY Vaccines	
Adverse Event	Frequency
Low-grade fever, headache, redness at injection site, dizziness	Up to 40%
Grade 3 - fever, headache, redness at injection site, dizziness	Up to 3%
MenB Vaccines	
Adverse Event	Frequency
Headache, fatigue, redness at injection site	Up to 51%
Pain at injection site	Up to 26%
Chills, joint pain	Up to 20%
Fever	Up to 2.5%

10. Storage and Handling

- A. Menveo® two-vial presentation reconstitution⁴:
 - a. Use the MenCYW-135 liquid conjugate component (Vial 1, gray cap) to reconstitute the MenA lyophilized conjugate component (Vial 2, orange cap) to form Menveo®.
 - b. Invert Vial 2 and shake well until the lyophilized conjugate component is dissolved.
 - c. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine.
 - d. Administer Menveo® immediately or store between 36°F and 77°F (2°C and 25°C) for up to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.
- B. Store medications according to OAR 855-041-1036.
- C. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

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Vaccine	Temp	Storage Issues	Notes
MenQuadfi® ³	Store at 2° to 8°C (36° to 46°F)	Protect from light. Do not use if vaccine has been frozen.	
Menveo® ⁴ and diluent			See directions for Menveo 2 vial presentation reconstitution above
Bexsero® ⁵ and Trumenba® ⁶			

11. References

1. Mbaeyi S, Bozio C, Duffy J, et al. Meningococcal vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. Available at: <https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm>. Accessed 12 June 2023.
2. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>. Accessed 12 June 2023.
3. MenQuadfi® package insert. Available at: <https://www.fda.gov/media/137306/download>. Accessed 12 June 2023.
4. Menveo® package insert. Available at: <https://www.fda.gov/media/78514/download>. Accessed 12 June 2023.
5. Bexsero® package insert. Available at <https://www.fda.gov/media/90996/download>. Accessed 12 June 2023.
6. Trumenba® package insert. Available at: <https://www.fda.gov/media/89936/download>. Accessed 12 June 2023.
7. Centers for Disease Control and Prevention. Vaccine Excipient Summary. November 2021. Available at: <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf>. Accessed 12 June 2023.

12. Appendix

- A. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Meningococcal B Vaccination in Adolescents and Adults: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. <https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-mening-b-shared-clinical-decision-making.pdf>