

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

1. What's New

- A. MenB-4C (Bexsero®) to be administered as a 2-dose series at 0 and 6 months when given to healthy adolescents and young adults aged 16–23 years based on shared clinical decision-making for the prevention of serogroup B meningococcal disease.
- B. MenB-4C (Bexsero®) to be administered as a 3-dose series at 0, 1–2, and 6 months when given to persons aged ≥10 years at increased risk for serogroup B meningococcal disease (i.e., persons with anatomic or functional asplenia, complement component deficiencies, or complement inhibitor use; microbiologists routinely exposed to *N. meningitidis* isolates; and persons at increased risk during an outbreak).
- C. Meningococcal ABCWY vaccine, Penbraya™, was added as an alternative vaccine option for individuals 10-25 years of age who are intending to receive both the MenACWY and MenB vaccines at the same visit.
- D. Menveo® dosage and administration updated for 1 and 2 vial presentations.⁴
- E. Menactra® has been removed from the market, all guidance related to Menactra® removed from protocol.

Commented [GR1]: Summary of tables at bottom of page.

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. The MenACWY and MenB vaccines may be given simultaneously at different sites if indicated.¹ Alternatively, patients intending to receive both MenACWY and MenB vaccines at the same visit may instead receive the MenABCWY vaccine.⁷
- 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

* Menveo® is not for use in individuals ≥ 56 years of age⁴.

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	

* Menveo® is not for use in individuals ≥ 56 years of age⁴.

Commented [GR2]: Feedback per Pharmacy Formulary Inbox:

Feedback on the Protocol for Meningococcal Containing Vaccines: I recommend under section, 3. Vaccine Schedule, that the Table labeled "MenACWY Vaccines Schedule for High-Risk Persons" be amended to include the age limit of 55 years for the Menveo vaccine. This age limit is mentioned later in the protocol but its absence in the Vaccine Schedule table caused me to buy \$1,000 worth of medication that I could not use for a patient due to the age restriction of the product and also delayed the administration of the correct vaccine to the patient. I hope that you will take this recommendation into consideration to prevent other pharmacists from making a similar mistake.

Per package insert, Menveo is approved for patients 2 months through 55 years of age (or 10 years through 55 years of age, depending on the formulation).

Commented [GR3]: • For intramuscular injection only (0.5 mL). (2) MENVEO is supplied as either: • Two vials: A vial containing the MenCYW-135 liquid conjugate component (gray cap) and a vial containing the MenA lyophilized conjugate component (orange cap). The contents of the vials must be combined to form MENVEO prior to administration. This presentation is for use in individuals 2 months through 55 years of age. (2.1, 2.2), OR • One vial containing MENVEO (pink cap). This presentation does not require reconstitution before use. This presentation is for use in individuals 10 through 55 years of age. (2.1, 2.2)

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MenB Vaccines (Bexsero®, Trumenba®) Schedule for Healthy Persons*, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Recommended Spacing ^{1,9}
1	16-23 years	
2		6 months

*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.

Commented [GR4]: See new note at bottom of document. Subsequent to the 10/23 - 10/24/2024 meeting, the ACIP unified the recommended schedules for these two vaccines. Now, both are a 2-dose series give at 0 and 6 months.

MenB Vaccines (Bexsero®, Trumenba®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Recommended Spacing ^{1,9}
1	≥10 years	
2		1 – 2 months
3*		4 – 5 months after dose 2 (6 months after dose 1)
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.

Commented [GR5]: See new note at bottom of document. Subsequent to the 10/23 - 10/24/2024 meeting, the ACIP unified the recommended schedules for these two vaccines. Now, both are a 3-dose series give at 0, 1-2, and 6 months.

MenABCWY Vaccines (Penbraya™) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	10-25 years	
2		6 months

*If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:

- Trumenba® for additional MenB dose(s) when MenACWY is not indicated
- Any MenACWY vaccine when MenB is not indicated

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	Single-dose 2 vial presentation (gray and orange caps)	2 months-55 years	None

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	oligosaccharides conjugated individually to Corynebacterium diphtheriae CRM protein	that requires reconstitution. 0.5-mL dose once reconstituted		
		0.5-mL single-dose 1 vial presentation (pink cap) that does not require reconstitution	10-55 years	None
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
Meningococcal ABCWY Vaccine				
Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
MenABCWY (Penbraya™) ⁷	Neisseria meningitidis serogroup A, C, W, and Y polysaccharides conjugated to tetanus toxoid and 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 single-dose diluent in prefilled syringe and vial with lyophilized antigen	10-25 years	None

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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.
 - 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

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- 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).
- E. Use of Meningococcal ABCWY vaccine
- a. If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead.
 - i. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:
 1. Trumenba® for additional MenB dose(s) when MenACWY is not indicated
 2. Any MenACWY vaccine when MenB is not indicated
 - ii. The minimum interval between MenABCWY doses is 6 months.
 - b. People with prolonged increased risk for serogroup A, C, W, or Y and B meningococcal disease need regular boosters. However, the recommended interval between doses varies by age and vaccine type. MenABCWY vaccine can be used only when both MenACWY and MenB vaccines are indicated at the same visit. Otherwise, MenACWY and MenB vaccines should be given separately as appropriate.

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
MenABCWY- Penbraya™	L-histidine, trometamol, sucrose, aluminum phosphate, sodium chloride, and polysorbate 80

7. Warnings and Precautions³⁻⁶

- A. N/A

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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® or Penbraya™ does not substitute for routine tetanus immunization.^{3,7}

9. Side Effects and Adverse Reactions³⁻⁷

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%
MenABCWY Vaccine	
Adverse Event	Frequency
Pain at injection site	Up to 89%
Fatigue	Up to 52%
Headache	Up to 47%
Muscle pain	Up to 26%
Injection site redness	Up to 26%
Injection site swelling	Up to 25%
Joint pain	Up to 20%
Chills	Up to 20%

10. Storage and Handling

- A. Store medications according to OAR 855-041-1036.
- B. 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.	After reconstitution, administer Menveo® immediately or store between 2°C and 25°C (36°F and 77°F) for up to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.
Menveo® ⁴ and diluent			
Bexsero® ⁵ and Trumenba® ⁶		During storage, a white deposit and clear supernatant may be observed in the prefilled syringe containing the MenB Component. Store the carton horizontally to minimize the time necessary to resuspend the MenB Component. Do not freeze. Discard if the carton has been frozen	
Penbraya™ ⁷			After reconstitution, administer PENBRAYA immediately or store between 2°C and 30°C (36°F and 86°F) and use within 4 hours. Do not freeze.

10. 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 20 January 2024.
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 20 January 2024.
3. MenQuadfi®. [Package insert]. June 2023. Available at: https://www.vaccineshoppe.com/assets/pdf/vsh/2023/Prescribing-Information_menquadfi.pdf. Accessed 20 January 2024.
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5. Bexsero®. [Package insert]. April 2023. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Bexsero/pdf/BEXSERO.PDF. Accessed 20 January 2024.

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6. Trumenba®. [Package insert]. November 2021. Available at:
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7. Penbraya™. [Package insert]. October 2023. Available at:
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8. 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 20 January 2024.
9. Centers for Disease Control and Prevention. Advisory Committee on Immunization Practices (ACIP) Vaccine Recommendations. August 29, 2024. Available at:
<https://www.cdc.gov/acip/vaccine-recommendations/index.html>

11. 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>

***Note (not part of protocol):**

Recent Meeting Recommendations

ACIP approved the following recommendations by majority vote and they have been adopted by the CDC Director. They will be published in MMWR and reflected in CDC's print and digital resources in the coming months.

October 23-24, 2024

ACIP approved the following recommendations by majority vote at its October 23-24, 2024 meeting:

Meningococcal Vaccines

ACIP recommends MenB-4C (Bexsero®) be administered as a 2-dose series at 0 and 6 months when given to healthy adolescents and young adults aged 16-23 years based on shared clinical decision-making for the prevention of serogroup B meningococcal disease

ACIP recommends MenB-4C (Bexsero®) be administered as a 3-dose series at 0, 1-2, and 6 months when given to persons aged ≥10 years at increased risk for serogroup B meningococcal disease (i.e., persons with anatomic or functional asplenia, complement component deficiencies, or complement inhibitor use; microbiologists routinely exposed to *N. meningitidis* isolates; and persons at increased risk during an outbreak)

These recommendations were adopted by the CDC Director on October 24, 2024 and are now official.

These changes were made from previous recommendations from the ACIP in 2020:

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TABLE 2. Recommended meningococcal vaccines and administration schedules for children and adults – Advisory Committee on Immunization Practices, United States, 2020

Age group	Serogroups A, C, W, and Y meningococcal conjugate vaccines MenACWY-D (Menactra, Sanofi Pasteur) or MenACWY-CRM (Menveo, GlaxoSmithKline) or MenACWY-TT (MenQuadfi, Sanofi Pasteur)	Serogroup B meningococcal vaccines MenB-FHbp (Trumenba, Pfizer) or MenB-4C (Bexsero, GlaxoSmithKline)
2 mos–10 yrs	Not routinely recommended See Table 3 for persons at increased risk	No recommendations for use of MenB vaccines in this population*
11–23 yrs	Primary vaccination: 1 dose at age 11–12 yrs Booster: 1 dose at age 16 yrs if first dose administered before 16th birthday Catch-up vaccination: Although routine vaccination is only recommended for adolescents aged 11–18 yrs, MenACWY may be administered to persons aged 19–21 yrs who have not received a dose after their 16th birthday Note: MenACWY vaccines are interchangeable	Primary vaccination: MenB series at age 16–23 yrs on basis of shared clinical decision making (preferred age 16–18 yrs) • MenB-FHbp: 2 doses at 0 and 6 mos • MenB-4C: 2 doses > 1 mo apart → ΔV Booster: Not routinely recommended unless the person becomes at increased risk for meningococcal disease Note: MenB-FHbp and MenB-4C are not interchangeable
≥24 yrs	Not routinely recommended See Table 3 for persons at increased risk	Not routinely recommended See Table 3 for persons at increased risk

TABLE 4. Recommended vaccination schedule and intervals for persons with persistent complement deficiencies* (including patients using a complement inhibitor)† – Advisory Committee on Immunization Practices, United States, 2020

Age group	Serogroups A, C, W, and Y meningococcal conjugate vaccines MenACWY-D (Menactra, Sanofi Pasteur)† or MenACWY-CRM (Menveo, GlaxoSmithKline)† or MenACWY-TT (MenQuadfi, Sanofi Pasteur)**	Serogroup B meningococcal vaccines MenB-FHbp (Trumenba, Pfizer) or MenB-4C (Bexsero, GlaxoSmithKline)
2–23 mos	Primary vaccination: MenACWY-D (ages ≥9 mos), 2 doses ≥12 wks apart or MenACWY-CRM (if first dose at age • 2 mos: 4 doses at 2, 4, 6, and 12 mos • 3–6 mos: See catch-up schedule§§ • 7–23 mos: 2 doses (second dose ≥12 wks after the first dose and after the 1st birthday)	No recommendations for use of MenB vaccines in this population**
2–9 yrs	Primary vaccination: MenACWY-D*** or MenACWY-CRM or MenACWY-TT: 2 doses ≥6 wks apart Boosters (if person remains at increased risk): • Aged <7 yrs: Single dose at 3 yrs after primary vaccination and every 5 yrs thereafter • Aged ≥7 yrs: Single dose at 5 yrs after primary vaccination and every 5 yrs thereafter	No recommendations for use of MenB vaccines in this population**
≥10 yrs	Primary vaccination: MenACWY-D or MenACWY-CRM or MenACWY-TT: 2 doses ≥6 wks apart Boosters (if person remains at increased risk): Single dose at 5 yrs after primary vaccination and every 5 yrs thereafter	Primary vaccination: MenB-FHbp: 1 dose at 0, 1–2, and 6 mos or MenB-4C: 2 doses ≥1 mo apart, Δ d Boosters (if person remains at increased risk): Single dose at 1 yr after completion of primary vaccination and every 2–3 yrs thereafter Note: MenB-FHbp and MenB-4C are not interchangeable