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 through 23 years based on shared clinical decision-making for the prevention of serogroup B meningococcal disease.

B. Men B-4C (Bexsero®) to be administered as a 3-dose series at 0, 1 to 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).

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 through 18 years*	
Booster	16 through 18 years*	8 weeks

* Menveo® is not for use in individuals ≥ 56 years of age[4].

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 age[4].

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 through 23 years	
2		6 months

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

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 to 2 months
3*		4 to 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.

MenABCWY Vaccines (Penbraya™) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	10 through 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) Additional Considerations for Use

A) Immunocompromised: individuals with altered immunocompetence may have reduced immune responses. [3-6]

B) 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]

C) Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥7years of age. [1]

D) Immunization with MenQuadfi® or Penbraya™ does not substitute for routine tetanus immunization.[3,7]

E) **Routine use of <u>Meningococcal ACWY</u> vaccine** [1]

i) All adolescents 11 through18 years of age without contraindications. Preferred age for dose one is 11 through 12 years with a booster dose at age 16 years. Catch-up vaccination age for dose one is 13 through 15 years with a booster dose at age 16 through 18 years. If series started at age 16 or older, no booster dose is indicated.

ii) Children who received MenACWY at age 10 years do not need an additional dose at age 11 through 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.

iii) Unvaccinated or under vaccinated first-year college students living in residence halls. One dose may be administered to persons 19 through 21 years who have not received a dose after their 16th birthday. Boosters are not routinely recommended unless there is another indication.

iv) Military recruits 19 through 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.

v) 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.

F) **Use of <u>Meningococcal ACWY</u> vaccine in high-risk persons** [1]

i) 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.

ii) 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.

iii) Vaccination is required for entry for persons traveling to Saudi Arabia for the Hajj and Umrah pilgrimages.

G) **Use of Meningococcal B vaccine in healthy persons** [1]

i) Vaccination of adolescents and young adults aged 16 through 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 through 23 years (preferred age 16 through 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 through 23 years who are most likely to benefit (see Appendix for guidance document).

ii) 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

H) **Use of <u>Meningococcal B</u> vaccine in high-risk persons** [1]

i) 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®.

ii) 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 to 3 years thereafter.

iii) 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®.

iv) 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).

I) **Use of <u>Meningococcal ABCWY</u> vaccine** [6,7]

i) If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead.

ii) 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

iii) The minimum interval between MenABCWY doses is 6 months.

iv) 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.

5) Pregnancy and Lactation

A) 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]

B) Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers. [1]

6) Warnings and Precautions [3-6]

A) N/A

7) Contraindications

A) Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[3-7]
B) See current prescribing information for more details about formulation and contents.

8) Storage and Handling

A) Store medications according to OAR 855-041-1036.
B) See current prescribing information for more details about storage and handling.
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).

9) 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.
4. Menveo®. [Package insert]. December 2023. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Menveo/pdf/MENVEO.PDF. Accessed 20 January 2024.
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.
6. Trumenba®. [Package insert]. November 2021. Available at: https://labeling.pfizer.com/ShowLabeling.aspx?id=1796. Accessed 20 January 2024.
7. Penbraya™. [Package insert]. October 2023. Available at: https://labeling.pfizer.com/ShowLabeling.aspx?id=19937. Accessed 20 January 2024.
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

10) 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. Available at: https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-mening-b-shared-clinical-decision-making.pdf