

Immunization Protocol

Meningococcal ACWY Vaccine (MenQuadfi®, Menveo®), Meningococcal B Vaccine (Bexsero®, Trumenba®), and Meningococcal ABCWY Vaccine (Penbraya™, Penmenvy™)

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Table of contents

1.	What's new	1
2.	Oregon model immunization protocol	2
	Vaccine schedule for meningococcal vaccines	
	Licensed meningococcal vaccines	
5.	Recommendations for use of meningococcal vaccines	4
6. 0	Contraindications	7
7.	Warnings and precautions	8
8.	Other considerations	8
9.	Side effects and adverse reactions	8
10.	Storage and handling	9
	Adverse events reporting	
	Peferences	

1. What's new

The Food and Drug Administration has approved the use of an additional 5-valent (A,B,C,W,Y) meningococcal vaccine, Penmenvy™.

2. Oregon model immunization protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications and precautions.
- C. Provide a current Vaccine Information Statement (VIS), answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for IM injection.
- F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.
- G. Administer a 0.5-mL dose of meningococcal vaccine according to ACIP recommendations, age-appropriate schedules, and high-risk conditions.
- H. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.⁷
- I. Meningococcal A, B, C, W and Y vaccines are available as a combination pentavalent vaccine, or as a quadrivalent vaccine and a monovalent meningococcal B vaccine administered simultaneously at different sites if indicated.⁷
- J. Meningococcal ACWY vaccines are generally interchangeable. Any licensed vaccine may be used for any needed dose.⁷
- K. Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction. Refer to <u>Guidelines for Managing Severe Adverse Events Following Immunization</u>.
- L. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

Health Officer Signature	Date
Health Officer Signature	Date

3. Vaccine schedule for meningococcal vaccines¹⁻⁶

Vaccine Schedule: Meningococcal ACWY (MenQuadfi, Menveo)				
Age Group	Dose	No. of Doses	Route	
Menveo: ≥2 months MenQuadfi: ≥2 years	0.5	Varies by age*	la fra con con la c	
11–15 years	0.5 mL	2	Intramuscular	
16 years		1 or 2*		
Vaccine Schedule: Meningococcal B (Bexsero, Trumenba)				
Age	Dose	No. of Doses	Route	
≥10 years	0.5 mL	2 or 3*	Intramuscular	
Vaccine Schedule: Meningococcal ABCWY (Penbraya [†] , Penmenvy [‡])				
Age	Dose	No. of Doses	Route	
10–25 years	0.5 mL	2	Intramuscular	

^{*}See high-risk schedule.

4. Licensed meningococcal vaccines¹⁻⁶

Meningococcal ACWY Conjugate Vaccines			
Trade Name	Presentation	Acceptable Age Range	
MenACWY-CRM (Menveo)	2 vials (requires reconstitution) combined to form a single 0.5-mL dose	≥2 months	
MenACWY-TT (MenQuadfi)	0.5-mL single-dose vial	≥2 years	
MenACWY-CRM (Menveo)	0.5-mL single-dose vial	≥10 years	

Meningococcal B Vaccines		
Trade Name Presentation Ac		Acceptable Age Range
MenB-4C (Bexsero)	0.5-mL prefilled syringe	≥10 years

[†] High-risk patients need an additional dose of Trumenba to complete meningococcal B series. See high-risk schedule.

[‡] High-risk patients need an additional dose of Bexsero to complete meningococcal B series. See high-risk schedule.

MenB-fHbp (Trumenba) 0.5-mL prefilled syringe ≥10 years

Meningococcal ABCWY Vaccine ⁵⁻⁶		
Trade Name Presentation Acceptable Age Ra		Acceptable Age Range
MenABCWY (Penbraya)	2 syringe/vial combo (requires reconstitution) single 0.5-mL dose	≥10 years
MenABCWY (Penmenvy)	2 syringe/vial combo (requires reconstitution) single 0.5-mL dose	≥10 years

5. Recommendations for use of meningococcal vaccines

- A. Routine use of **Meningococcal ACWY** vaccine⁷
 - All adolescents 11–18 years of age without contraindications.
 - First-year college students living in dorms should receive 1 dose of quadrivalent meningococcal vaccine within the five years before college entry.
 - May be administered to adults 19–21 years of age if required for attendance at institution of higher education.
- B. Use of **Meningococcal ACWY** vaccine in high-risk persons
 - Persons aged ≥2 years with anatomical or functional asplenia, HIV or complement component deficiency or who are taking complement inhibitor medications.⁷
 - Microbiologists routinely exposed to isolates of Neisseria meningitidis.⁷
 - Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]).⁷
 - Persons aged ≥9 months traveling to Saudi Arabia for the Hajj and Umrah or to the meningitis belt in sub-Saharan Africa.⁷
- C. Use the **Meningococcal B** vaccine schedule for the following persons at high risk:⁷
 - Persons with persistent complement component deficiencies or who are

- taking complement inhibitor medications.
- Persons with anatomic or functional asplenia.
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*.
- D. **Meningococcal B** vaccination is not routinely recommended for all patients who are 16–23 years of age. Instead, a Meningococcal B series is recommended based on Shared Clinical Decision-Making between the health care provider and patient or parent/guardian. Considerations for administration and timing may include:⁷
 - the serious nature of meningococcal infections, with high rates of death and permanent sequelae in those who develop invasive disease;
 - the low number of serogroup B meningococcal disease cases (between 20 and 50 cases occurred annually in 16-23 year olds in the United States in recent years);
 - the increased risk among college students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities;
 - the estimated relatively short duration of Meningococcal B protection (antibody waning within 1–2 years after completion of the primary series);
 and
 - the evidence to date suggesting that Meningococcal B vaccination has no effect on meningococcal carriage (i.e., Meningococcal B vaccines might provide individual protection against serogroup B disease, but "herd" protection is unlikely).
- E. **Meningococcal ABCWY**⁸ vaccine may be administered to persons aged ≥10 years:
 - when both a quadrivalent meningococcal ACWY and monovalent meningococcal B vaccines are indicated;
 - with functional or anatomic asplenia or with complement component deficiency. These patients will need a total of 3 doses of Meningococcal B vaccine given as pentavalent (Penbraya or Penmenvy), pentavalent (Penbraya or Penmenvy) and single antigen (Trumenba or Bexsero).



- All doses of meningococcal B vaccine must be of the same type. When using Penbraya the third dose must be Trumenba. When using Penmenvy the third dose must be Bexsero.
- F. **Meningococcal ABCWY**⁸ vaccine may be administered to persons who are:
 - microbiologists <26 years of age routinely exposed to isolates of Neisseria meningitidis;

 16–23 years of age who need Meningococcal ACWY vaccine and who would also like to receive Meningococcal B vaccine based on Shared Clinical Decision Making. To protect against serogroup B meningococcal disease these patients will need either 2 doses of pentavalent vaccine, or one dose of pentavalent vaccine and one dose of monovalent meningococcal B vaccine.

MenACWY Vaccine Routine Schedule ⁷			
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing
1	11 years	10 years	
Booster	16 years		8 weeks

MenACWY Vaccine Schedule for High-Risk Persons ⁷				
Age at Initial Dose*	Vaccine	Doses in Series	Schedule	Booster
2 months		4	2, 4, 6, 12 months	
3–6 months	MenACWY-CRM (Menveo)	3–4	Doses 8 weeks apart, followed by a dose at ≥7 months of age, and a final dose 12 weeks later and after 12 months of age.	<7 years of age at last dose, 1st booster at 3 years, then every 5 years.
7–23 months		2	12 weeks apart, 2 nd dose ≥12 months of age.	≥7 years of age at last dose, boosters
≥2 years	MenACWY-CRM (Menveo or MenQuadfi)	2	At least 8 weeks apart	every 5 years.

MenABCWY Vaccine Schedule for Healthy* Persons ⁸				
Vaccine	Dose	Minimum Spacing	Acceptable Age Range	Recommended Age
MenABCWY	1	January Charles	- tungo	7.50
(Penbraya or Penmenvy)	2	6 months	10–25 years	16–23 years

^{*}The preferred age for MenACWY vaccination is 11–16 years. The preferred age for MenB vaccination is 16–18 years.

MenABCWY Vaccine Schedule for

High-Risk Persons 10–25 years of age ⁸		
Vaccine	Dose	Minimum Spacing
MenABCWY	1	
(Penbraya or Penmenvy)	2	1 month
MenB-fHbp (Trumenba or Bexsero)	3	5 months after dose 2 and 6 months after dose 1

Meningococcal B Vaccine for Healthy* Persons ⁷				
Vaccine	Dose	Recommended Spacing	Minimum Spacing	Recommended Age
MenB-4C	1			
(Bexsero)	2	6 months [◊]	6 months	16–23 years*
MenB-FHbp	1			
(Trumenba)	2	6 months◊	6 months	

^{*}The preferred age for MenB vaccination is 16–18 years.

olf the second dose is administered earlier than 6 months after the first dose, a third dose should be administered at least 4 months after the second dose.

Meningococcal B Vaccine for High-Risk Persons ⁷					
Vaccine*	Dose	Recommended Spacing	Minimum Spacing	Recommended Age	Booster Doses
MenB-4C	1	opacing .	- Second	7.90	1 year after
(Bexsero)	2	1 month	28 days		completion of the
or MenB-fHbp (Trumenba)	3	5 months after dose 2 and 6 months after dose 1	4 months after dose 2	≥10 years	series, then every 2–3 years as long as risk factors remain.

^{*}Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.⁷

6. Contraindications

A. Severe allergic reaction to a previous dose or to a vaccine component, including latex² (Bexsero).

Vaccine	Vaccine Excipient Summary ¹⁻⁶	
MenACWY-TT (MenQuadfi)	sodium chloride, sodium acetate, formaldehyde, tetanus toxoid	
MenACWY-CRM (Menveo)	formaldehyde, CRM197 protein	
MenABCWY (Penbraya)	L-histidine, trometamol, sucrose, aluminum phosphate, sodium	
WellAbovi (Felblaya)	chloride, and polysorbate 80 ⁵	

MenABCWY (Penmenvy)	CRM197 protein, aluminum hydroxide, sodium chloride, histidine, sucrose, potassium phosphate, kanamycin,		
,	formaldehyde		
MenB-4C (Bexsero)	aluminum hydroxide, sodium chloride, histidine, sucrose,		
Wellb-40 (bexselo)	kanamycin		
MenB-fHbp (Trumenba)	polysorbate 80, aluminum phosphate, histidine buffered saline		

7. Warnings and precautions¹⁻⁶

- A. Immunization should be deferred during moderate or severe acute illness.
- B. Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including Menveo, to infants born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination.

8. Other considerations

- A. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses.¹⁻⁶
- 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.⁷
- C. Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers.⁷
- 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.^{1,4}
 - E. Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥7 years of age.⁷

9. Side effects and adverse reactions¹⁻⁶

MenACWY			
Low-grade fever, headache, redness at injection site, dizziness	Up to 40%		
Grade 3 - fever, headache, redness at injection site, dizziness	Up to 3%		
MenABCWY			
Pain at the injection site	Up to 92%		
Fatigue, headache	Up to 52%		
Muscle or joint pain, chills, injection site redness or swelling	Up to 26%		

Nausea ⁶	Up to 15%
MenB	
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 handling¹⁻⁶

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must <u>immediately</u> report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes	
MenQuadfi				
Menveo and diluent		Protect from light. Do not use if vaccine has	Reconstitute only with the MenACWY liquid conjugate component. It should be administered promptly after reconstituted; or stored at ≤77°F (25°C) and administered within 8 hours of reconstitution	
Bexsero and		been frozen.		
Trumenba	Store at			
Penbraya	2°–8°C 36°–46°F	Do not freeze.	Store the carton horizontally to minimize the time necessary to resuspend the MenB component. After reconstitution, vaccine may be stored at 2°–30°C (36°–86°F) and must be used within 4 hours.	
Penmenvy		Protect from light. Do not use if	Use immediately after reconstitiution.	
		vaccine has been frozen.		

11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html. VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html

Event and interval from vaccination

- A. Anaphylaxis or anaphylactic shock (7 days)
- B. Shoulder Injury Related to Vaccine Administration (7 days)
- C. Vasovagal syncope (7 days)

Event and interval from vaccination

- D. Any acute complication or sequelae (including death) of above events (interval—not applicable)
- E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval—see package insert).

12. References

- 1. Menveo® package insert, current as of 14 May 2025. Available at: www.fda.gov/media/78514/download. Accessed 22 Jul 2025.
- 2. Bexsero® package insert, August 2024. Available at: www.fda.gov/media/90996/download. Accessed 22 Jul 2025.
- 3. Trumenba® package insert, June 2024. Available at: www.fda.gov/media/89936/download. Accessed 22 Jul 2025.
- 4. MenQuadfi[®] package insert, May 2025. Available at: www.fda.gov/media/137306/download. Accessed 22 Jul 2025.
- 5. Penbraya™ package insert, November 2024. Available at: <u>www.fda.gov/media/173223/download?attachment</u>. Accessed 22 Jul 2025.
- 6. Penmenvy™ package insert, February 2025. Available at: https://www.fda.gov/media/185479/download?attachment. Accessed 22 Jul 2025.
- 7. Mbaeyi S, Bozio C, Duffy J, et al. Meningococcal vaccination:
 Recommendations of the Advisory Committee on Immunization Practices—
 United States, 2020. MMWR Recommendations and Reports 2020; 69:9.
 Available at: www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf. Accessed 22 Jul 2025.
- 8. Collins J, Crowe S, Ortega-Sanchez I, et al. Use of the Pfizer Pentavalent Meningococcal Vaccine Among Persons Aged ≥10 Years: Recommendations of the Advisory Committee on Immunization Practices—United States, 2023. MMWR Recommendations and Reports 2024; 73:345. Available at: https://www.cdc.gov/mmwr/volumes/73/wr/mm7315a4.htm. Accessed 22 Jul 2025.
- Schillie S, Loehr J, Chen W, et al. New Dosing Interval and Schedule for the Bexsero MenB-4C Vaccine: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, October 2024. MMWR Recommendations and Reports 2024; 73:1124. Available at: https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7349a3-H.pdf. Accessed 22 Jul 2025.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this protocol is available at:

www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx