

## Interim Immunization Protocol

<b>Meningococcal ACWY Vaccine (MenQuadfi<sup>®</sup>, Menveo<sup>®</sup>), Meningococcal B Vaccine (Bexsero<sup>®</sup>, Trumenba<sup>®</sup>), and Meningococcal ABCWY Vaccine (Penbraya<sup>™</sup>)</b>	
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### 1. What’s new

In October 2023, the FDA approved a new pentavalent meningococcal ABCWY vaccine—Penbraya<sup>™</sup>. The Advisory Committee on Immunization Practices recommends pentavalent meningococcal vaccine when both the quadrivalent meningococcal ACWY and monovalent meningococcal B vaccines are indicated. See Section 5 for indications.

## 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. 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.<sup>8</sup>
- H. Administer a 0.5-mL dose of meningococcal vaccine according to ACIP recommendations, age-appropriate schedules, and high-risk conditions.
- I. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.<sup>6</sup>
- J. Quadrivalent meningococcal conjugate vaccine and monovalent meningococcal B vaccine may be given as a combination pentavalent vaccine, or as individual vaccines administered simultaneously at different sites if indicated.<sup>6</sup>
- K. Meningococcal ACWY vaccines are generally interchangeable. Any licensed vaccine may be used for any needed dose.<sup>6</sup>
- L. Ask client to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint.

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Health Officer Signature

Date

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Health Officer Signature

Date

### 3. Vaccine schedule for meningococcal vaccines

<b>Vaccine Schedule: Meningococcal ACWY (MenQuadfi,<sup>4</sup> Menveo<sup>1</sup>)</b>			
Age Group	Dose	No. of Doses	Route
≥2 months	0.5 mL	Varies by age	Intramuscular
11–15 years		2	
16 years		1 or 2*	
<b>Vaccine Schedule: Meningococcal B (Bexsero,<sup>2</sup> Trumenba<sup>3</sup>)</b>			
Age	Dose	No. of Doses	Route
≥10 years	0.5 mL	Trumenba: 2 or 3* Bexsero: 2	Intramuscular
<b>Vaccine Schedule: Meningococcal ABCWY (Penbraya<sup>5</sup>)</b>			
Age	Dose	No. of Doses	Route
10–25 years	0.5 mL	2†	Intramuscular

\*See high-risk schedule.

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

### 4. Licensed meningococcal vaccines

<b>Meningococcal ACWY Conjugate Vaccines</b>		
Trade Name	Presentation	Acceptable Age Range
MenACWY-TT (MenQuadfi <sup>4</sup> )	0.5-mL single-dose vials	≥2 years
MenACWY-CRM (Menveo <sup>1</sup> )	2 vials (requires reconstitution) combined to form a single 0.5-mL dose	≥2 months
MenACWY-CRM (Menveo <sup>1</sup> )	0.5-mL single-dose vials	≥10 years

<b>Meningococcal B Vaccines</b>		
Trade Name	Presentation	Acceptable Age Range
MenB-4C (Bexsero <sup>2</sup> )	0.5-mL prefilled syringes	≥10 years
MenB-fHbp (Trumenba <sup>3</sup> )	0.5-mL prefilled syringes	≥10 years

Meningococcal ABCWY Vaccine		
Trade Name	Presentation	Acceptable Age Range
MenABCWY (Penbraya <sup>5</sup> )	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** vaccine<sup>6</sup>

- 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.<sup>6</sup>
- Microbiologists routinely exposed to isolates of *Neisseria meningitidis*.<sup>6</sup>
- Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]).<sup>6</sup>
- Persons aged ≥9 months traveling to Saudi Arabia for the Hajj and Umrah or to the meningitis belt in sub-Saharan Africa.<sup>6</sup>

### C. Schedule for **Meningococcal B** vaccine in high-risk persons<sup>6</sup>

- 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:<sup>6</sup>

- 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 (average of 34 serogroup B cases annually among persons aged 16–23 years in the United States during 2015–2018);
- 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 protection provided by Meningococcal B vaccines against most strains of serogroup B *N. meningitidis*;
- 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<sup>7</sup>** vaccine may be used for patients ≥10 years of age 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), pentavalent (Penbraya) and single antigen (Trumenba).

F. **Meningococcal ABCWY<sup>7</sup>** vaccine may be used for microbiologists <26 years of age routinely exposed to isolates of *Neisseria meningitidis*, or for patients 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 <sup>6</sup>			
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<sup>6</sup>

Age at Initial Dose*	Vaccine	Doses in Series	Schedule	Booster
2 months	MenACWY-CRM (Menveo)	4	2, 4, 6, 12 months	<7 years of age at last dose, 1 <sup>st</sup> booster at 3 years, then every 5 years.  ≥7 years of age at last dose, boosters every 5 years.
3–6 months		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.	
7–23 months		2	12 weeks apart, 2 <sup>nd</sup> dose ≥12 months of age.	
≥2 years	Menveo or MenQuadfi	2	At least 8 weeks apart	

### MenABCWY Vaccine Schedule for Healthy\* Persons<sup>7</sup>

Vaccine	Dose	Minimum Spacing	Acceptable Age Range	Recommended Age
MenABCWY (Penbraya)	1		10–25 years	16–23 years
	2	6 months		

\*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<sup>7</sup>

Vaccine	Dose	Minimum Spacing
MenABCWY (Penbraya)	1	
	2	1 month
MenB-fHbp (Trumenba)	3	5 months after dose 2 and 6 months after dose 1

### Meningococcal B Vaccine for Healthy\* Persons<sup>6</sup>

Vaccine	Dose	Recommended Spacing	Minimum Spacing	Recommended Age
MenB-4C (Bexsero)	1			16–23 years*
	2	1 month	28 days	
MenB-FHbp (Trumenba)	1			
	2	6 months	6 months	

\*The preferred age for MenB vaccination is 16–18 years.

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

## 6. Contraindications

- A. Severe allergic reaction to a previous dose or to a vaccine component, including latex<sup>2</sup> (Bexsero<sup>®</sup>).

Vaccine	Vaccine Excipient Summary <sup>9</sup>
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 chloride, and polysorbate 80 <sup>5</sup>
MenB-4C (Bexsero)	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB-fHbp (Trumenba)	polysorbate 80, aluminum phosphate, histidine buffered saline

## 7. Warnings and precautions<sup>1-5</sup>

- A. Immunization should be deferred during the course of 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.<sup>1-5</sup>
- 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.<sup>6</sup>

- C. Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers.<sup>6</sup>
- 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.<sup>1,4</sup>
- E. Meningococcal vaccine is recommended 2 weeks before or  $\geq 2$  weeks after splenectomy surgery for persons  $\geq 7$  years of age.<sup>6</sup>

## 9. Side effects and adverse reactions<sup>1-5</sup>

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 89%
Fatigue, headache	Up to 52%
Muscle or joint pain, chills, injection site redness or swelling	Up to 26%
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 handling<sup>1-5</sup>

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).

Vaccine	Temp	Storage Issues	Notes
MenQuadfi <sup>4</sup>	Store at 2°–8°C 36°– 46°F	Protect from light. Do not use if vaccine has been frozen.	Reconstitute only with the MenACWY liquid conjugate component. It should be administered promptly after reconstituted; or stored at $\leq 77^\circ\text{F}$ (25°C) and administered within 8 hours of reconstitution
Menveo <sup>1</sup> and diluent			



Vaccine	Temp	Storage Issues	Notes
Bexsero <sup>2</sup> and Trumenba <sup>3</sup>			
Penbraya <sup>5</sup>		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.

## 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)
- 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<sup>®</sup> package insert, October 2022. Available at: [www.fda.gov/media/78514/download](http://www.fda.gov/media/78514/download). Accessed 13 Mar 2024.
2. Bexsero<sup>®</sup> package insert, April 2023. Available at: [www.fda.gov/media/90996/download](http://www.fda.gov/media/90996/download). Accessed 13 Mar 2024.
3. Trumenba<sup>®</sup> package insert, 2021. Available at: [www.fda.gov/media/89936/download](http://www.fda.gov/media/89936/download). Accessed 13 Mar 2024.
4. MenQuadfi<sup>®</sup> package insert, 2023. Available at: [www.fda.gov/media/137306/download](http://www.fda.gov/media/137306/download). Accessed 13 Mar 2024.
5. Penbraya<sup>™</sup> package insert, 2023. Available at: [www.fda.gov/media/173223/download?attachment](http://www.fda.gov/media/173223/download?attachment). Accessed 13 Mar 2024.
6. 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](http://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf). Accessed

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7. Collins J. Summary of EtR and proposed recommendations for Pfizer's MenABCWY vaccine. Presentation to the Advisory Committee on Immunization Practices, 25 Oct 2023. Available at: [www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-10-25-26/04-Meningococcal-Collins-508.pdf](http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-10-25-26/04-Meningococcal-Collins-508.pdf). Accessed 13 Mar 2024.
8. Kroger A, Bahta L, Long S, Sanchez P, Pellegrini C. General Best Practice Guidelines for Immunization. Available at: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf). Accessed 13 Mar 2024.
9. Centers for Disease Control and Prevention. Vaccine Excipient Summary. November 2021. Available at: [www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf). Accessed 13 Mar 2024.

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:

<https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/stdgordr.aspx>