# Meningococcal Vaccines

**Hawaii Vaccines for Children (VFC) Program**

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# Housekeeping

- Please ensure you are muted throughout the presentation unless you are speaking.
- **Reminder for QA Team:**
  - Please monitor the chat for questions you may be able to answer.
- **Reminder to Attendees:**
  - Today's session is being recorded. Slides and webinar recordings will be uploaded to: https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/
  - To be added to the Hawaii VFC Program email list, please email your request to HawaiiVFC@doh.hawaii.gov. In the subject line of the email, please write EMAIL LIST.

# Questions?

- During today's webinar, please use the chat to ask your questions so the Hawaii VFC Program subject matter experts can respond directly.
- We will be answering your questions at the end of the presentation.

# Objectives

Provide an overview of *Neisseria meningitidis* and its potential to cause serious diseases like meningitis and septicemia

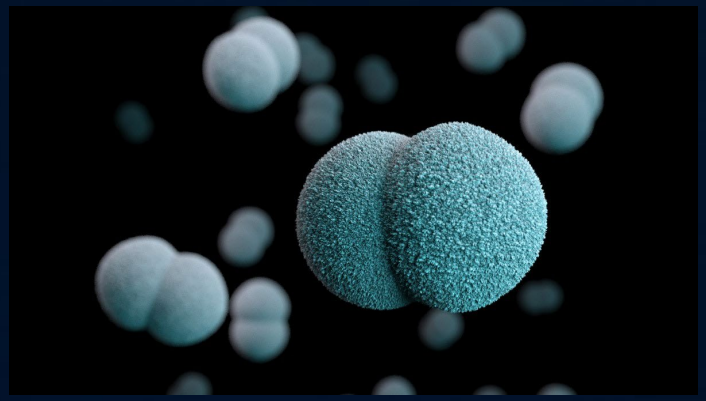
Discuss the various types of meningococcal vaccines available through the Hawaii VFC Program for administration to VFC-eligible patients

Understand best practices for storage, handling and administration of these vaccines to ensure efficacy and safety

# Meningococcal Disease

- An acute, severe illness caused by the bacterium *Neisseria meningitidis*.
- The two most common types of meningococcal infections are:
  1. **Meningitis** (inflammation of the membranes covering the brain and spinal cord)
  2. **Septicemia** (bloodstream infection or meningococcemia)
- Symptoms of meningococcal disease can first appear as a flu-like illness and rapidly worsen.
- The overall case-fatality ratio of meningococcal disease is 10% to 15%, even with appropriate antibiotic therapy, and can be higher in persons with meningococcemia.
- As many as 20% of survivors have permanent sequelae, such as hearing loss, neurologic damage, or loss of a limb.

# *Neisseria meningitidis*



- Aerobic, gram-negative bacterium
- Classified into 12 serogroups based on characteristics of the polysaccharide capsule.
- Almost all reported cases of invasive disease worldwide are caused by one of six serogroups: A, B, C, W, X, and Y.
- The relative importance of serogroups depends on geographic location and other factors such as age.
- Between 2011 and 2020 in the United States, serogroup B caused about 60% of cases among children younger than 5 years old, and serogroups C, W, or Y caused about two out of three cases in people age 11 years or older. Serogroup A is rare in the U.S. Historically, serogroup A was common in the meningitis belt of sub-Saharan Africa, but after the implementation of a meningococcal serogroup A conjugate vaccine campaign, serogroup A disease has been nearly eliminated in the meningitis belt.

# Transmission

- Meningococci are transmitted person-to-person by respiratory droplets or secretions from persons with asymptomatic colonization or meningococcal disease.
- The bacteria attach to and multiply in the mucosal cells of the nasopharynx and oropharynx and, in a small proportion (much less than 1%) of persons, penetrate the mucosal cells and enter the bloodstream.
- The bacteria can then spread through the blood to cause systemic disease and cross the blood-brain barrier into the cerebrospinal fluid (CSF) to cause meningitis.

## Meningococcal Meningitis

Symptoms:

- Fever
- Headache
- Stiff neck
- Altered mental status (confusion)
- Nausea
- Photophobia (eyes being more sensitive to light)
- Vomiting

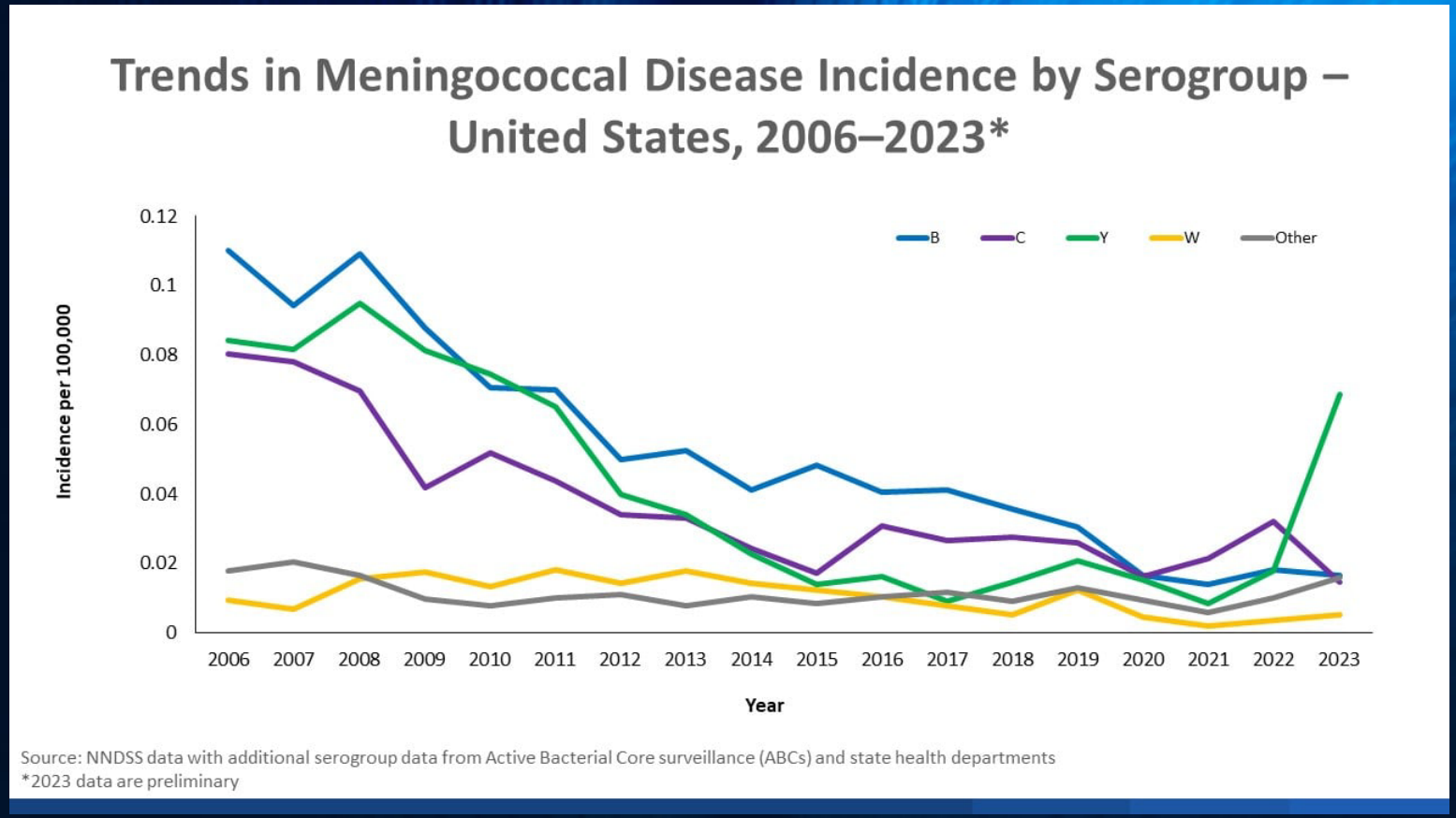
Symptoms in babies:

- Appear to be slow or inactive
- Irritability
- Feed poorly
- Bulging anterior fontanelle (the soft spot of the skull)
- Abnormal reflexes
- Vomiting

## Meningococcal Septicemia

Symptoms:

- Fever and chills
- Cold hands and feet
- Diarrhea or nausea with or without vomiting
- Fatigue
- Rapid breathing
- Severe aches or pain in the muscles, joints, chest, or abdomen
- Petechial or purpuric rash often associated with hypotension, shock, acute adrenal hemorrhage, and multiorgan failure




U.S. cases of meningococcal disease have increased sharply since 2021 and now exceed pre-pandemic levels.

https://www.cdc.gov/meningococcal/php/surveillance/index.html#cdc_generic_section_1-latest-news

# Meningococcal Vaccine Recommendations

# 3 Types of Meningococcal Vaccines

| | |
|---|---|
| **MenACWY vaccines** (Menveo® and MenQuadfi®) | **4 serogroups: A, C, W, and Y** |
| **MenB vaccines** (Bexsero® and Trumenba®) | **1 serogroup: B** |
| **MenABCWY** (Penbraya™) | **5 serogroups: A, B, C, W, and Y** |

# MenACWY vaccination

# MenACWY vaccines

- **Men-ACWY-CRM (Menveo®)**

Supplied as either:

- Two-vial presentation: 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.
  - The two-vial Menveo® presentation is not routinely distributed by the CDC and is considered a "special order" vaccine. It will only be supplied to VFC providers who have high-risk VFC-eligible patient aged 2 through 23 months for whom it is indicated. VFC providers must contact the Hawaii VFC Program to request this vaccine.

OR

- One-vial presentation (pink cap). This does not require reconstitution before use and is for use for individuals 10 through 18 years of age.

- **Men-ACWY-TT (MenQuadfi®)**

- Supplied in one ready-to-use vial; reconstitution is not required.
- Indicated for 2 through 18 years of age.

*Note: When more than one brand of MenACWY vaccine is age-appropriate, they are interchangeable.*

# MenACWY Vaccines

## Eligible Groups

• Children aged 2 months through 10 years who are at increased risk for meningococcal disease attributable to serogroups A, C, W, and Y, including:

- Children who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D)
- Children taking a complement inhibitor (e.g., eculizumab [Soliris], ravulizumab [Ultomiris])
- Children who have anatomic or functional asplenia, including sickle cell disease
- Children infected with human immunodeficiency virus (HIV)
- Children traveling to or residing in countries in which meningococcal disease is hyperendemic or epidemic, particularly if contact with local population will be prolonged
- Children identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroups A, C, W, or Y

• All children aged 11 through 18 years.

*Note: In addition to meeting the specified indications for vaccination, VFC-supplied vaccines may only be administered to VFC-eligible children.*

# MenACWY vaccination

## Routine Vaccination

- 2-dose series at age 11–12 years; 16 years

**Note:** MenACWY vaccines may be administered simultaneously with MenB vaccines if indicated, but at a different anatomic site, if feasible.

## Catch-up vaccination

- Age 13–15 years: 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- Age 16–18 years: 1 dose

**Note:** MenACWY vaccines may be administered simultaneously with MenB vaccines if indicated, but at a different anatomic site, if feasible.

**Hawaii School Vaccination Requirement:**

- The MenACWY vaccine is required for 7th grade attendance in Hawaii.
- It is also required for students entering Grades 7–12 for the first time in Hawaii, as well as for first-year students living in on-campus housing.

# MenACWY vaccination

## Special Situations

**Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:**

**Menveo®**

- Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
- Dose 1 at age 3–6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
- Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

**MenQuadfi®**

- Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

# MenACWY vaccination

## Special Situations

**Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/):**

**Children younger than age 24 months:**

**Menveo® (age 2–23 months)**

- Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
- Dose 1 at age 3–6 months: 3- or 4- dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
- Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)

**Children age 2 years or older:** 1 dose Menveo® or MenQuadfi®

# MenACWY vaccination

## Special Situations

**First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:** 1 dose Menveo® or MenQuadfi®

**Adolescent vaccination of children who received MenACWY prior to age 10 years:**

- **Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease** (e.g., those with complement component deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk**.**

- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years**.**

# MenACWY vaccination

## Special Situations - Booster Dose

Individuals aged 2 months and older who remain at increased risk and completed the primary dose or series should receive a regular booster dose:

**Age under 7 years:** Administer a booster dose 3 years after completion of the primary series and every 5 years thereafter.

**Age 7 years and older:** Administer a booster dose every 5 years.

Children age 10 years or older may receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.

## Contraindications and Precautions

For contraindications and precautions to Meningococcal ACWY (MenACWY) [MenACWY-CRM (Menveo®), MenACWY-TT (MenQuadfi®)], see Meningococcal ACWY (MenACWY) Appendix

For contraindications and precautions to Meningococcal ABCWY, (MenACWY-TT/MenB-FHbp) [Penbraya™], see Meningococcal ABCWY Appendix

# MenB Vaccination

# MenB vaccines

- MenB-4C (Bexsero®, GSK)
- MenB-FHbp (Trumenba®, Pfizer)

*Note: MenB vaccines are NOT interchangeable by manufacturer. Administration of a B component vaccine (MenB or MenACWY-TT/MenB-FHbp) requires that subsequent B component vaccine doses be from the same manufacturer.*

# MenB Vaccines

## Eligible Groups

•Children aged 10 through 18 years at increased risk for serogroup B meningococcal disease, including:

- Children who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D)
- Children taking a complement inhibitor (e.g., eculizumab [Soliris], ravulizumab [Ultomiris])
- Children who have anatomic or functional asplenia, including sickle cell disease
- Children identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B

• Children aged 16 through 18 years who are not at increased risk for serogroup B meningococcal disease may also be vaccinated when shared clinical decision-making favors administration of MenB.

*Note: In addition to meeting the specified indications for vaccination, VFC-supplied vaccines may only be administered to VFC-eligible children.*

# MenB vaccination

## Shared Clinical Decision-Making

**Adolescents not at increased risk age 16-18 years based on shared clinical decision-making.**

- **Bexsero® or Trumenba® (use same brand for all doses):** 2–dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision-making for MenB, see www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-mening-b-shared-clinical-decision-making.pdf

**Note:** MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

# MenB vaccination

## Special Situations

**Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use.**

- **Bexsero® or Trumenba® (use same brand for all doses including booster doses)** 3-dose series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; 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)

**Note:** MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Children age 10 years or older may receive a dose of Penbraya™ (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For age-eligible children not at increased risk, if Penbraya™ is used for dose 1 MenB, MenB-FHbp (Trumenba®) should be administered for dose 2 MenB. For age-eligible children at increased risk of meningococcal disease, Penbraya™ may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day and at least 6 months have elapsed since most recent Penbraya™ dose.

# MenB vaccination

## Booster Dose

- **For children at increased risk due to complement deficiency, complement inhibitor use, or functional or anatomic asplenia:**
  - A booster dose is recommended if it has been at least one year since primary series; repeat every 2-3 years as long as risk remains.
- **For children at increased risk due to a serogroup B outbreak:**
  - Booster dose recommended if it has been at least one year since primary series. If recommended by public health officials, booster dose may be given if it has been at least 6 months since primary series.
- **Booster doses are not recommended for adolescents who are not at increased risk for meningococcal disease.**

## Contraindications and Precautions

For contraindications and precautions to Meningococcal B (MenB), MenB-4C [Bexsero®], MenB-FHbp [Trumenba®], see MenB Appendix

For contraindications and precautions to Meningococcal ABCWY, (MenACWY-TT/MenB-FHbp) [Penbraya™], see Meningococcal ABCWY Appendix

# Combined MenACWY-MenB Vaccination

# MenABCWY vaccine

- MenACWY-TT/MenB-FHbp (Penbraya™, Pfizer)

# MenABCWY vaccine

## Eligible Groups

- Children who are indicated to receive MenACWY and MenB vaccines, including:
    - Children aged 10 through 18 years who are at increased risk for meningococcal disease attributable to serogroups A, C, W, Y, and B, including:
        - Children who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, or factor D)
        - Children taking a complement inhibitor (e.g., eculizumab [Soliris], ravulizumab [Ultomiris])
        - Children who have anatomic or functional asplenia, including sickle cell disease
    - Children aged 16 through 18 years for whom both MenACWY and MenB are indicated to be given at the same time and shared clinical decision-making favors administration of MenB vaccine.

*Note: In addition to meeting the specified indications for vaccination, VFC-supplied vaccines may only be administered to VFC-eligible children.*

# MenABCWY vaccination

## Children Not at Increased Risk

**Initial dose:** Penbraya™ may be given in lieu of MenACWY and MenB when both vaccines are indicated in the same visit (e.g., age 16 years) and shared clinical decision-making favors administration of MenB.

**Second dose:** The MenB series should then be completed with MenB-FHbp (Trumenba®).

# MenABCWY vaccination

## Children at Increased Risk

**Primary Series:**

- **For children with persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia who are due for both MenACWY and MenB vaccination:** 1 dose may be given in lieu of the first dose of MenACWY and MenB-FHbp.
- If subsequent doses of MenACWY and MenB-FHbp (3) are indicated less than 6 months after the first dose, the vaccines should be given separately according to the MenACWY and MenB recommended schedule.

**Boosters:**

- For subsequent doses, where both MenACWY and MenB are indicated and at least 6 months have passed since administration of a previous dose of MenACWYTT/MenB-FHbp, MenACWYTT/MenB-FHbp may be used.

# Meningococcal Vaccines Storage and Handling

# MenACWY

## Menveo®

## Storage and Handling

| | |
|---|---|
| Packaging | **Two-vial presentation:**<br>• Gray cap vial contains MenCYW-135 liquid conjugate and orange cap vial contains MenA lyophilized conjugate.<br>• Requires reconstitution.<br><br>**One-vial presentation:** Supplied as one ready-to-use pink cap vial in packages of 10. Reconstitution not required. |
| Dose/Route | Administer as a 0.5 mL intramuscular injection. |
| Storage | • Store at 2°C to 8°C (36°F to 46°F).<br>• Do not freeze. Do not use vaccine that has been frozen, please contact the manufacturer for guidance.<br>• Protect from light.<br>• Administer the reconstituted two-vial presentation immediately, or store it for up to 8 hours and discard if not used. |

Package insert for Menveo®: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Menveo/pdf/MENVEO.PDF

# MenACWY

## MenQuadfi® Storage and Handling

| | |
|---|---|
| Packaging | MenQuadfi® is supplied in a single-dose vial in packages of 10 |
| Dose/Route | Administer as a 0.5 mL intramuscular injection. |
| Storage | • Store at 2°C to 8°C (36°F to 46°F).<br>• Do not freeze. Do not use vaccine that has been frozen, please contact the manufacturer for guidance.<br>• Do not use after expiration date. |

Package insert for MenQuadfi®: https://www.fda.gov/media/137306/download?attachment

# MenB

## Bexsero® Storage and Handling

| | |
|---|---|
| Packaging | Bexsero® is available in 0.5 mL single-dose, disposable, prefilled TIP-LOK syringes (Luer Lock syringes) in a carton of 10 syringes, packaged without needles. To be used with Luer Lock compatible needles. |
| Dose/Route | Administer as a 0.5 mL intramuscular injection. |
| Storage | • Store refrigerated, at 36°F to 46°F (2°C to 8°C).<br>• Do not freeze. Do not use vaccine that has been frozen, please contact the manufacturer for guidance.<br>• Protect from light.<br>• Do not use after the expiration date. |

Package insert for Bexsero®: https://www.fda.gov/media/90996/download?attachment

# MenB

## Trumenba® Storage and Handling

| | |
|---|---|
| Packaging | Trumenba® is supplied in a 0.5 mL prefilled syringe (10 per package) |
| Dose/Route | Administer as a 0.5 mL intramuscular injection. |
| Storage | • Store refrigerated at 2°C to 8°C (36°F to 46°F).<br>• Store syringes in the refrigerator horizontally (laying flat on the shelf) to minimize the re-dispersion time. Shake vial well to obtain a uniform suspension prior to withdrawing dose.<br>• Do not freeze. Do not use vaccine that has been frozen, please contact the manufacturer for guidance. |

Package insert for Trumenba®: https://www.fda.gov/media/89936/download?attachment

# MenABCWY

## Penbraya™ Storage and Handling

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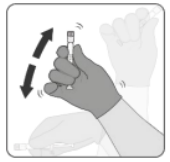
|---|---|
| Packaging | Penbraya™ is supplied in a kit that includes a vial of Lyophilized MenACWY Component (a sterile white powder), a prefilled syringe containing the MenB Component and a vial adapter.<br>• Instructions on reconstituting the vaccine is below or you may refer to the package insert. |
| Dose/Route | Administer as a 0.5 mL intramuscular injection. |
| Storage | • Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton.<br>• Do not freeze. Do not use vaccine that has been frozen, please contact the manufacturer for guidance.<br>• After reconstitution, administer immediately or store between 2°C and 30°C (36°F and 86°F) and use within 4 hours. Do not freeze. |

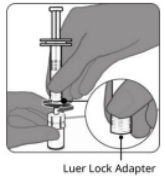
**Step 1. Attachment of the vial adapter to the vial.**

- Remove the flip top cap from the vial of Lyophilized MenACWY Component.
- Peel off the top cover from the vial adapter packaging.
- While keeping the vial adapter in its packaging, center the adapter over the vial's stopper and attach to the vial with a straight downward push.
- Remove the packaging.



**Step 2. Resuspension of the MenB Component.**

- Shake the syringe containing the MenB Component vigorously to obtain a white homogenous suspension. Do not use if the contents cannot be resuspended.




**Step 3. Connection of the syringe containing the MenB Component to the vial adapter.**

- Hold the syringe by the Luer lock adapter.
- Twist to remove the syringe cap.
- Connect the syringe to the vial adapter by turning the Luer lock.

**Step 4. Reconstitution of the Lyophilized MenACWY Component with the MenB Component to form PENBRAYA.**

- Inject the entire contents of the syringe into the vial.
- Hold the plunger rod down and gently swirl the vial until the powder is completely dissolved (less than 1 minute).

**Step 5. Withdrawal of PENBRAYA.**

- Invert the vial completely and slowly withdraw the entire contents into the syringe for an approximately 0.5 mL dose of PENBRAYA.
- Twist to disconnect the syringe from the vial adapter.
- Attach a sterile needle suitable for intramuscular injection.

Package insert for Penbraya™: https://www.fda.gov/media/173223/download?attachment

# Ordering VFC Meningococcal Vaccines

## VFC Meningococcal vaccines available for ordering through Hawaii Immunization Registry (HIR):

- Menveo® (One-vial presentation only)
- MenQuadfi ®
- Bexsero®
- Trumenba®
- Penbraya™

**Important Note** :

- The two-vial presentation of Menveo® is a “special order” vaccine not available through HIR.
- It will only be supplied to VFC providers who have a high-risk VFC-eligible patient aged 2-23 months, for whom it is indicated.
- To request this vaccine, VFC providers should contact the Hawaii VFC program via email at HawaiiVFC@doh.hawaii.gov or by phone at (808) 586-8300.

*To access our webinars regarding VFC vaccine ordering and shipment, please see these links:

- https://health.hawaii.gov/docd/for-healthcare-providers/vaccine-orders-and-shipments/
- https://health.hawaii.gov/docd/for-healthcare-providers/vaccines-for-children-program-vfc-hawaii-immunization-registry-hir-inventory-ordering/

# Questions?

- For HIR technical/login issues, please contact Registry Help Desk at 808-586-4665 or 1-888-447- 1023 (toll-free) or via e-mail: RegistryHelp@doh.hawaii.gov
- For general immunization questions, please call the Hawaii Immunization Branch at 808-286- 8349
- For any VFC-related questions/concerns, feel free to contact any member of the HDOH VFC QA Team.

# Contact Info

| VFC Vaccine Orders | | |
|---|---|---|
| Melvin Reyes | melvin.reyes@doh.hawaii.gov | 808-586-8316 |
| Elizabeth Ricon | elizabeth.ricon@doh.hawaii.gov | 808-586-8301 |
| Ji Hyun Choi | jihyun.choi@doh.hawaii.gov | 808-586-4585 |
| Heather Winfield-Smith | h.winfield-smith@doh.hawaii.gov | 808-586-8348 |
| | | |
| **VFC Program & VFC Site Visits** | | |
| Josephine Araki, RN | josephine.araki@doh.hawaii.gov | 808-723-1601 |
| Loraine Lim, RN | loraine.lim@doh.hawaii.gov | 808-723-0018 |
| Kealohi Corpos | kealohi.corpos@doh.hawaii.gov | 808-723-0091 |
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