

State of California—Health and Human Services Agency California Department of Public Health



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TO: California Vaccines for Children (VFC) Providers

FROM: Robert Schechter, M.D., Chief

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Division of Communicable Disease Control, Immunization Branch

SUBJECT: Addition to the VFC formulary: new meningococcal vaccine product,

pentavalent Penbraya



- ✓ Penbraya, a new mingococcal vaccine (MenACWY-MenB), is now available for ordering through the VFC Program.
- ✓ ACIP) recommends Penbraya be used when both MenACWY and MenB vaccines are indicated at the same visit.

Dear VFC Provider,

The US Food and Drug Administration (FDA) has licensed a new pentavalent meningococcal vaccine (MenACWY-MenB), with the tradename of Penbraya (Pfizer).

Penbraya is licensed to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y in individuals 10 through 25 years of age. The Advisory Committee on Immunization Practices (ACIP) recommends Penbraya be used when both MenACWY and MenB vaccines are indicated at the same visit.

- Routine schedule: healthy individuals aged 16-23 years when <u>shared clinical</u> <u>decision-making favors administration of MenB</u>.
- Individuals at <u>increased risk of meningococcal disease</u> aged 10 years and older due for both vaccines.

For routine use, ACIP suggests:

- dose 1 (11-12 yrs)= Menveo (MenACWY-CRM) or MenQuadfi (MenACWY-TT)
- dose 2 (16-18 yrs) = Penbraya (MenACWY-TT/MenB-FHbp)
- dose 3 (16-18 yrs) = Trumenba (MenB-FHbp).



The MenB component in Penbraya is the same as Trumenba. MenB brands are not interchangeable. If a patient receives Penbraya (MenABCWY) for MenACWY dose 2 and MenB dose 1, the MenB series is completed when a subsequent dose of Trumenba is given at least 6 months later.

Per VFC resolution 10/23-1, Penbraya will be available through the VFC program starting May 15, 2024 to any VFC-eligible child indicated to receive both MenACWY and MenB vaccines at the same visit, including children:

- 10 to 18 years at increased risk for meningococcal disease attributable to serotypes A, B, C, W, and Y due to persistent complement deficiencies, taking complement inhibitors, and anatomic or functional asplenia, including sickle cell disease.
- 16 to 18 years for whom both MenACWY and MenB are indicated at the same visit and <u>shared clinical decision-making favors MenB administration</u>.

Storage and handling

Penbraya is supplied in a kit that includes:

- a vial of lyophilized MenACWY component,
- a prefilled syringe containing the MenB component,
- and a vial adapter.

To form Penbraya, reconstitute the Lyophilized MenACWY Component with the MenB Component as described in detail on the manufacturer's website.

Penbraya is supplied in cartons of 1, 5, and 10 kits.

Storage:

- Before reconstitution: Keep refrigerated at 36° to 46°F (2° to 8°C) in the original carton. Store horizontally.
- After reconstitution: administer immediately or store between 36° to 86°F (2° to 30°C).
- Use within 4 hours.
- DO NOT FREEZE.



Dosage and Administration

A single dose of Penbraya is 0.5 mL, administered via the intramuscular route (IM) according to <u>currently recommended ACIP immunization schedules</u> for age and indication.

VFC ORDERING

Providers may order Penbraya and other existing meningococcal vaccine products through their MyVFCvaccines account until May 24, 2024 prior to the VFC Program transition. Starting June 10, 2024, the California VFC Program is transitioning to a new vaccine management system, myCAvax, and orders of Penbraya and other VFC vaccines will be in the new system. Refer to the communication sent on May 14, 2024 for more information about the transition.

If your practice decides to order Penbraya, you should also be ordering Trumenba to complete the MenB series according to ACIP recommendations.

If your practice plans on switching to Trumenba from another MenB vaccine product because you will be using Penbraya, submit the "Provider Request Form to Update Vaccine Brand Products Administered" form and keep the following information in mind:

- Careful consideration should be given when selecting alternative brands or products in order to minimize the impact on provider practices.
- Implementation of a different vaccine brand or product should be approved by your practice's medical director or Provider of Record.
- Staff should be thoroughly informed and educated on changes to vaccines and its impact on vaccine ordering, storage, administration, and documentation.
- As your practice transitions to a new product, managing on-hand inventory
 appropriately is a key factor in preventing unnecessary vaccine wastage. Your
 initial request for a new vaccine product may be reduced to help minimize vaccine
 waste as you transition from the product currently being used by your practice.
- A plan to deplete excess inventory must be in place prior to transitioning to a new product. It is the provider's responsibility to ensure all VFC-supplied vaccines are used prior to their expiration date or transferred to another VFC Provider who can use them. Viable unused doses of these individual vaccines cannot be returned to the VFC Program.



BILLING FOR VFC VACCINE

CHDP: Claims may be submitted for VFC-supplied doses of Penbraya administered to CHDP-eligible patients through age 18 years. Please refer to the CHDP Provider manual and relevant CHDP Provider Information Notice.

CHDP providers with additional questions are advised to contact their <u>County CHDP</u> Program.

Medi-Cal Fee-For-Service (FFS): To bill Medi-Cal FFS for administration of VFC-supplied doses of Penbraya, use the appropriate CPT-4 code for Penbraya (90623), followed by the "-SL" modifier, in total 90623-SL. Providers will only be reimbursed for the administration fee when using VFC vaccines for Medi-Cal FFS-eligible patients.

For specific information and details on Medi-Cal billing, please refer to the <u>Medi-Cal provider manual on VFC</u>. Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

Medi-Cal Managed Care: Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

Other codes for the use of Penbraya not supplied by VFC:

- The CPT-4 code for Penbraya is 90623.
- The ICD-10-CM code for an encounter for immunization is Z23.

Resources

- ACIP Child and Adolescent Immunization Schedule
- ACIP Meningococcal Vaccine Recommendations | CDC
- ACIP Resolutions for Vaccines for Children (VFC) Program | CDC
- Meningococcal Vaccine Recommendations | CDC
- Penbraya FDA page
- VFA/VFC Vaccine eligibility guidelines table
- Meningococcal Vaccines Routine Schedule for Adolescents and Young Adults
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 - Schedule for High Risk Populations
- Penbraya Vaccine Fact Sheet

