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Penmenvy — A Second Pentavalent Meningococcal Vaccine

The FDA has licensed the pentavalent vaccine *Penmenvy* (GSK) for prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, B, C, W, or Y (MenABCWY) in persons 10-25 years old. *Penmenvy* is the second pentavalent meningococcal vaccine to become available in the US; *Penbraya* was licensed in 2023.[1]

Pronunciation Key

Penmenvy: pen men vee

MENINGOCOCCAL DISEASE — Six serogroups of *N. meningitidis* (A, B, C, W, X, and Y) cause most cases of invasive meningococcal disease worldwide. Most US cases are caused by serogroups B, C, and Y. Infection rates are highest in infants, adolescents/young adults, and adults >80 years old.[2]

THE NEW VACCINE — *Penmenvy* contains the antigenic components of *Menveo*, a polysaccharide conjugate quadrivalent MenACWY vaccine, and *Bexsero*, a recombinant protein-based MenB vaccine.

CLINICAL STUDIES — FDA licensure of *Penmenvy* was based on the results of two randomized, observer-blind immunogenicity trials (Trials 1 and 2).[3,4]

Trial 1 included 3651 persons 10-25 years old who had never received a MenB vaccine and had either never received a MenACWY vaccine (87%) or received a single MenACWY vaccine dose >4 years earlier (13%). Patients were given a 2-dose series of *Penmenvy* (0 and 6 months), a 2- or 3-dose series of *Bexsero* (either 0 and 6 or 0, 2, and 6 months), or a single dose of *Menveo*.

Seroresponse rates against MenACWY 1 month after the final dose were noninferior with *Penmenvy* compared to *Menveo* (A: 96.8% vs 85.6%; C: 97.2% vs 50.0%; W: 97.0% vs 61.7%; Y: 96.7% vs 69.7%). Seroresponse rates with *Penmenvy* were noninferior to those with two doses of *Bexsero* against the MenB antigens NadA (92.7% vs 95.9%) and fHbp (73.2% vs 78.1%), but not against NHBA (61.8% vs 69.7%) and PorA P1.4 (42.2% vs 58.3%).[3]

Key Points: *Penmenvy*

- **Description:** The second pentavalent meningococcal vaccine (*Penbraya* was the first).
- **Indication:** FDA-licensed for prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, B, C, W, or Y in persons 10-25 years old.
- **Efficacy:** Compared to separate administration of MenACWY and MenB vaccines, seroresponse rates with *Penmenvy* were similar against MenACWY and similar or slightly inferior against MenB.
- **Adverse Effects:** Injection-site reactions, fatigue, headache, nausea, myalgia, and arthralgia can occur.
- **Dosage:** Two 0.5-mL IM doses given 6 months apart.
- **Conclusion:** Pentavalent vaccination is recommended only for persons ≥10 years old who would otherwise have received both a MenACWY and a MenB vaccine at the same visit. How *Penmenvy* compares to *Penbraya* is unknown.

In **Trial 2**, 1250 persons 15-25 years old who had received one dose of a MenACWY vaccine ≥4 years earlier were given a 2-dose series of *Penmenvy* (0 and 6 months) or a single dose of *Menveo*. Seroresponse rates against MenACWY 1 month after the final dose were noninferior with *Penmenvy* compared to *Menveo* (A: 95.8% vs 95.2%; C: 94.5% vs 94.0%; W: 95.6% vs 93.9%; Y: 95.0% vs 94.4%).[4]

ADVERSE EFFECTS — Adverse effects of *Penmenvy* in clinical trials were similar to those with *Bexsero* and included fatigue, headache, nausea, myalgia, arthralgia, and injection-site pain, erythema, swelling, and induration. Syncope, dizziness, lymphadenopathy, and hypersensitivity reactions have been reported. Administration of conjugate MenACWY vaccines has been associated with Guillain-Barré syndrome.

PREGNANCY AND LACTATION — No data are available on the use of *Penmenvy* in pregnant or lactating women. MenACWY vaccination during pregnancy appears to be safe, but data on MenB vaccination during pregnancy are limited. Following licensure of *Penbraya*, the CDC stated that MenB vaccination should be deferred until after pregnancy unless risk factors for infection are present and the benefits are determined to outweigh the risks. Pregnant women requiring MenACWY vaccination should generally receive a quadrivalent vaccine.[5] Breastfeeding women can receive any meningococcal vaccine.[6]

Table 1. Meningococcal Vaccines

Vaccine	Age Range	Dose/Schedule[1]	Cost[2]
Serogroups ACWY (MenACWY)			
Menveo (GSK)	2 months-55 years	0.5 mL IM/1 dose or 2 doses 8 weeks apart[3,4]	$166.70
MenQuadfi (Sanofi)	≥2 years	0.5 mL IM/1 dose or 2 doses 8 weeks apart[3,4]	172.00
Serogroup B (MenB)			
Bexsero (GSK)	10-25 years	0.5 mL IM/2 doses 6 months apart or 3 doses at 0, 1-2, and 6 months[5,6]	237.10
Trumenba (Pfizer)	10-25 years	0.5 mL IM/2 doses 6 months apart or 3 doses at 0, 1-2, and 6 months[5,6]	190.30
Serogroups ABCWY (MenABCWY)			
Penbraya (Pfizer)	10-25 years	0.5 mL IM/2 doses 6 months apart[7]	230.80
Penmenvy (GSK)	10-25 years	0.5 mL IM/2 doses 6 months apart[7]	Not yet available

1. Schedule recommended for adolescents and adults (SA Mbaeyi et al. MMWR Recomm Rep 2020; 69:1; CDC. Meningococcal vaccine recommendations. October 24, 2024. Available at https://cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html. Accessed March 27, 2025).
2. Approximate private sector cost for one dose as of March 14, 2025, according to the CDC Vaccine Price List. Available at: https://bit.ly/3FPVmCa. Accessed March 27, 2025.
3. One dose routinely recommended at age 11-12 years with a booster dose at age 16 years. Two doses 8 weeks apart are recommended for those with asplenia, HIV infection, or persistent complement component deficiencies, and those receiving complement inhibitors such as eculizumab *(Soliris)* or ravulizumab *(Ultomiris)*; one dose is recommended for those with other specific risk factors.
4. A booster dose every 5 years is recommended for those who remain at increased risk. During an outbreak, a booster dose should be given if >5 years have elapsed since the last MenACWY dose. A first booster dose can be given 3 years after completion of the primary series in children <7 years old at increased risk.
5. Persons ≥10 years old at increased risk should receive 3 doses. A 2-dose series may be considered for healthy young adults 16-23 years old (preferably at 16-18 years) who are not at increased risk based on shared clinical decision-making (S Schillie et al. MMWR Morb Mortal Wkly Rep 2024; 73:1124).
6. Persons who remain at increased risk should receive a booster dose of the same MenB vaccine 1 year after completing the primary series and every 2-3 years thereafter. During an outbreak, a booster dose should be given if ≥1 year has elapsed since completing a primary series (≥6 months if recommended by public health authorities).
7. Following licensure of *Penbraya*, the CDC Advisory Committee on Immunization Practices (ACIP) recommended that MenABCWY vaccination be considered only for persons who would otherwise receive separate MenACWY and MenB vaccine doses at the same visit (recommendations have not been updated since licensure of *Penmenvy*). If additional MenB doses are needed, *Trumenba* should be used for those who received *Penbraya* (which includes *Trumenba*), and *Bexsero* should be used for those who received *Penmenvy* (which includes *Bexsero*). MenB vaccines from different manufacturers are not interchangeable. Any MenACWY vaccine can be given after *Penbraya* or *Penmenvy*.

DOSAGE AND ADMINISTRATION — *Penmenvy* consists of a vial containing the MenACWY component (lyophilized powder) and a prefilled syringe containing the MenB component (suspension). The powder must be reconstituted with the suspension to form a single 0.5-mL dose. Components should be stored in a refrigerator, and the vaccine should be administered immediately after reconstitution. The recommended dosage is two 0.5-mL IM doses given 6 months apart.

ACIP RECOMMENDATIONS — The CDC's Advisory Committee on Immunization Practices (ACIP) updated its recommendations for use of MenACWY and MenB vaccines in 2020.[7]

MenACWY *(Menveo, MenQuadfi)* – Routine vaccination with MenACWY is recommended for adolescents 11-18 years old, with a first dose given at 11-12 years and a booster dose given at 16 years. Two doses given at least 8 weeks apart and a booster dose every 5 years are recommended for adults with HIV infection, functional or anatomic asplenia, or persistent complement component deficiencies (including impairment induced by complement inhibitors). One dose of vaccine is recommended for adults who travel to or live in countries where meningococcal disease is hyperendemic or epidemic, persons who are at risk from a meningococcal disease outbreak attributed to serogroups A, C, W, or Y, microbiologists routinely exposed to *N. meningitidis*, military recruits, and first-year college students living in dormitories (if they did not receive a dose at age ≥16 years); revaccination every 5 years is recommended for those who remain at risk.

MenB *(Bexsero, Trumenba)* – MenB vaccine is recommended for adults with functional or anatomic asplenia, persons with persistent complement component deficiencies (including impairment induced by complement inhibitors), those who are at risk from a meningococcal outbreak attributed to serogroup B, and microbiologists routinely exposed to *N. meningitidis*. It may be considered for persons 16 through 23 years old (preferably age 16-18 years) who do not have risk factors for meningococcal disease, but may be at increased risk by attending college (e.g., college students living in dormitories). Persons who remain at increased risk should receive a booster dose 1 year after completing the primary series and every 2-3 years thereafter. During an outbreak, previously vaccinated persons should receive a single booster dose if ≥1 year has elapsed since completion of the primary series (≥6 months if recommended by public health authorities). MenB vaccines from different manufacturers are not interchangeable; vaccines from the same manufacturer must be used for all doses.[8]

MenABCWY *(Penbraya, Penmenvy)* – Following approval of *Penbraya* in 2023, the ACIP recommended that MenABCWY vaccination be considered only for persons ≥10 years old who would otherwise receive separate MenACWY and MenB vaccine doses at the same visit.[5] The ACIP is scheduled to discuss recommendations for *Penmenvy* in April 2025.[9]

CONCLUSION – *Penmenvy* is the second pentavalent meningococcal vaccine containing *Neisseria meningitidis* serogroups A, B, C, W, and Y (MenABCWY) to be licensed by the FDA. How it compares to *Penbraya* in efficacy and safety remains to be determined. Use of *Penmenvy* or *Penbraya* reduces the total number of injections required for full vaccination against these five serogroups, which may improve compliance. Pentavalent vaccines are recommended only for persons ≥10 years old who would otherwise receive both a MenACWY and a MenB vaccine at the same visit. ■

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3. T Nolan et al. Breadth of immune response, immunogenicity, reactogenicity, and safety for a pentavalent meningococcal ABCWY vaccine in healthy adolescents and young adults: results from a phase 3, randomised, controlled observer-blinded trial. Lancet Infect Dis 2024 December 5 (epub).
4. T Nolan et al. Immunogenicity, reactogenicity, and safety of a pentavalent meningococcal ABCWY vaccine in adolescents and young adults who had previously received a meningococcal ACWY vaccine: a phase 3, randomized controlled clinical study. Clin Infect Dis 2024 December 26 (epub).
5. JP Collins 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 Morb Mortal Wkly Rep 2024; 73:345.
6. Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Institute of Child Health and Human Development; 2006-. Meningococcal vaccines. [Updated 2024 Aug 15]. Available at: https://bit.ly/41Z4kWq. Accessed March 27, 2025.
7. SA Mbaeyi et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. MMWR Recomm Rep 2020; 69:1.
8. S Schillie 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 Morb Mortal Wkly Rep 2024; 73:1124.
9. CDC Advisory Committee on Immunization Practices. ACIP meeting information. March 24, 2025. Available at: https://bit.ly/3R2ICdN. Accessed March 27, 2025.