Penbraya™ (meningococcal groups A, B, C, W, and Y vaccine) – New vaccine approval

- On October 20, 2023, Pfizer announced the FDA approval of Penbraya (meningococcal groups A, B, C, W, and Y), for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y.
    - Penbraya is approved for use in individuals 10 through 25 years of age.
- Penbraya is the first pentavalent vaccine that provides coverage against the most common serogroups causing meningococcal disease in adolescents and young adults 10 through 25 years of age.
- The efficacy of Penbraya was established in a randomized, active-controlled, observer-blinded study in participants 10 through 25 years of age. Patients received Penbraya at 0 and 6 months or Trumenba® (meningococcal group B vaccine) at 0 and 6 months and MenACWY-CRM at 0 months.
    - Seroresponse rates to serogroups A, C, W, and Y following 2 doses of Penbraya were demonstrated to be non-inferior to seroresponse rates following a single dose of MenACWY-CRM. Seroresponse and composite response rates to serogroup B primary strains among participants who received 2 doses of Penbraya were demonstrated to be non-inferior to seroresponse and composite response rates following 2 doses of Trumenba.
- The CDC Advisory Committee on Immunization Practices (ACIP) will meet on October 25, 2023, to discuss recommendations for the appropriate use of Penbraya in adolescents and young adults.
- Warnings and precautions for Penbraya include management of acute allergic reactions; syncope; altered immunocompetence; limitations of vaccine effectiveness; tetanus immunization; and Guillain-Barré syndrome.
- The most commonly reported solicited adverse reactions (≥ 15%) with Penbraya use were pain at the injection site, fatigue, headache, muscle pain, injection site redness, injection site swelling, joint pain, and chills.
- Penbraya is administered as 2 doses (approximately 0.5 mL each) intramuscularly 6 months apart.
- Pfizer's launch plans for Penbraya are pending. Penbraya will be available as a suspension for injection. A single dose after reconstitution is approximately 0.5 mL.