Moderna and Pfizer/BioNTech COVID-19 vaccines, bivalent (Original and Omicron BA.4/BA.5) – New emergency use authorizations

- On August 31, 2022, the FDA announced the emergency use authorization (EUA) of two new updated COVID-19 vaccines: Moderna's COVID-19 vaccine, bivalent (Original and Omicron BA.4/BA.5) and Pfizer/BioNTech's COVID-19 vaccine, bivalent (Original and Omicron BA.4/BA.5). Both vaccines are authorized for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
    - Moderna COVID-19 vaccine, bivalent is authorized as a booster dose in individuals 18 years of age and older.
    - Pfizer/BioNTech COVID-19 vaccine, bivalent is authorized as a booster dose in individuals 12 years of age and older.
    - With today's authorization, the monovalent mRNA COVID-19 vaccines (Comirnaty®, Spikevax™, Novavax COVID-19 vaccine, adjuvanted) are no longer authorized as booster doses for individuals 12 years of age and older (Comirnaty) and 18 years of age and older (Spikevax and Novavax COVID-19 vaccine, adjuvanted).
    - The Pfizer/BioNTech COVID-19 vaccine remains authorized for administration of a single booster dose for individuals 5 through 11 years of age at least five months after completing a primary series of the Pfizer/BioNTech COVID-19 vaccine.

- The authorized bivalent COVID-19 vaccines, or updated boosters, include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component for the BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant. The spike proteins for BA.4 and BA.5 variants are identical.

- For each bivalent COVID-19 vaccine, the FDA based its decision on the totality of available evidence, including safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines, safety and immunogenicity data from a clinical study of a bivalent COVID-19 vaccine that contained mRNA from omicron variant BA.1 lineage that is similar to each of the vaccines being authorized, and nonclinical data from the bivalent COVID-19 vaccines containing mRNA of the original strain and the omicron variant (BA.4/BA.5).
    - The new bivalent COVID-19 vaccines are expected to provide increased protection against the currently circulating omicron variants.

- Warnings and precautions include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine effectiveness.

- Individuals who receive a bivalent COVID-19 vaccine may experience side effects commonly reported by individuals who receive authorized or approved monovalent mRNA COVID-19 vaccines.

- The recommended dose of Pfizer/BioNTech COVID-19 vaccine, bivalent in individuals 12 years of age and older is administered intramuscularly (IM) as a single booster dose (0.3 mL) at least 2 months after completion of primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

- The recommended dose of Moderna COVID-19 vaccine, bivalent in individuals 18 years of age and older is administered IM as a single booster dose (0.5 mL) at least 2 months after completion of

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primary vaccination or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

- The U.S. government has procured 175 million doses of the bivalent COVID-19 booster vaccines for distribution and administration. Pre-ordering of the bivalent COVID-19 booster vaccines has already begun.

    — The Moderna COVID-19 vaccine, bivalent is supplied in multiple-dose vials with dark blue caps and labels with a gray border. NDC 80777-282-99.
    — The Pfizer COVID-19 vaccine, bivalent is supplied in multiple-dose vials with gray caps and labels with gray borders. NDCs: 59267-0304-01 and 59267-0304-02.

What's Next?

- The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is scheduled to meet on September 1st to make recommendations for use of the bivalent booster COVID-19 vaccines.

- After the ACIP makes its recommendations, the CDC director must sign off on the recommendations prior to implementation.

- In addition, ACIP will also be meeting on September 2nd to further discuss COVID-19 vaccines.

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