

Moderna and Pfizer/BioNTech COVID-19 vaccines, bivalent boosters – Updated emergency use authorizations and CDC approval

- On October 12, 2022, the [FDA announced](#) the amended emergency use authorization (EUA) of two COVID-19 vaccines: [Moderna's COVID-19 vaccine, bivalent \(Original and Omicron BA.4/BA.5\)](#) and [Pfizer/BioNTech's COVID-19 vaccine, bivalent \(Original and Omicron BA.4/BA.5\)](#), authorized as a single booster dose in younger age groups. 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).
 - [The Centers for Disease Control and Prevention \(CDC\) Director signed off](#) on the recommendations hours after the FDA authorization on October 12.
 - Moderna COVID-19 vaccine, bivalent is authorized as a booster dose in individuals 6 years of age and older.
 - Pfizer/BioNTech COVID-19 vaccine, bivalent is authorized as a booster dose in individuals 5 years of age and older.
 - With today's authorization, the previously authorized [monovalent](#) mRNA COVID-19 vaccine, [Comirnaty[®]](#) is no longer authorized as a booster dose for individuals 5 to 11 years of age.
- All individuals seeking a COVID-19 booster, who are age 5 years and older should receive the new bivalent 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,
 - 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.
- **Pfizer/BioNTech COVID-19 vaccine, bivalent:** The recommended dose in individuals 5 to 11 years of age is administered intramuscularly (IM) as a single booster dose (0.2 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 Pfizer COVID-19 vaccine, bivalent is supplied in multiple-dose vials with orange caps and labels with an orange border and says Age 5y to <12y. NDCs: 59267-0565-01 and 59267-0565-02.
- **Moderna COVID-19 vaccine, bivalent:** The recommended dose in individuals 6 to 11 years of age is administered IM as a single booster dose (0.25 mL) and for 12 to 17 years of age 0.5 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 Moderna COVID-19 vaccine, bivalent is supplied in multiple-dose vials with dark blue caps and labels with a gray border. NDC 80777-0282-05 and 80777-0282-99.
 - The Moderna COVID-19 vaccine, bivalent for 6-17 years is the same vial as was used for adults 18 years and older. The dose is half for 6-11 years.

What's Next?

- The U.S. government has already purchased bivalent booster doses for children. The Pfizer/BioNTech bivalent booster vials for children have been available for [pre-ordering](#). The Moderna bivalent booster vials are already available.
- Pharmacies and other administration sites may begin administering bivalent booster vaccine to appropriate children when they have supply.



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