

We are pleased to announce that the FDA authorized **COVID-19 Bivalent Vaccine Boosters** of the PfizerBioNTech and Moderna COVID-19 vaccines on August 31<sup>st</sup>. The most common type of COVID-19 virus circulating has changed since the original vaccine was formulated. The new Bivalent Booster Vaccine will cover a wider range of virus strains to provide better protection against COVID-19 circulating this fall and winter. Today the CDC advisory committee met and voted in favor to recommend the Bivalent booster. Consonus will continue to update our customers as more information becomes available.

## Key takeaways from the FDA news:

- **Who is eligible?** Individuals 12 years of age and older are eligible for a single dose of the Pfizer-BioNTech Bivalent Booster. Individuals 18 years or older to be eligible for a single dose of either the Pfizer-BioNTech or Moderna Bivalent booster.
- **When?** The Bivalent booster can be given if it has **been at least two months** since individuals have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- **How many?** The Bivalent boosters are authorized for use as a **single booster**. They are not authorized as a primary vaccine series.
- **Why was the Bivalent developed?** The original “monovalent” vaccines contain only one strain of the SARS-CoV-2 and are not providing the same protection now that the virus has changed. Bivalent vaccines, which are referred to as “updated boosters,” were formulated to contain:
  - One strain of the original SARS-CoV-2 *and*
  - One strain in common between the BA.4 and BA.5 lineages of `omicron variant of SARS-CoV-2The updated vaccine will provide better protection against the BA.4 and BA.5 strain of the Omicron variants that are currently causing the most COVID-19 cases in the U.S.
- **Can the original “monovalent” vaccines still be given?** The mRNA COVID-19 vaccines, and they are **no longer** authorized as **booster doses** for individuals 12 years and older. Individuals eligible for a booster now should get the Bivalent booster. The monovalent vaccines are **still** authorized for use for administration of a **primary series**.
- **Are the Bivalent boosters as safe as the original formulation?** Yes! The FDA has worked closely with the vaccine manufacturers to ensure the updated boosters are safe and effective. The FDA has taken a great deal of care to ensure the bivalent COVID-19 vaccines meet the rigorous safety, effectiveness, and manufacturing quality standards for EUA. The FDA has extensive experience with reviewing strain changes for annual influenza vaccines and is confident in the evidence supporting the Bivalent vaccines.

- **When will they be available?** Once the CDC Director signs off and the Western States workgroup approves, the updated boosters will be shipped into pharmacies, as early as next week. Consonus is using a preorder process to organize distribution. That order form has been sent to facilities who have ordered vaccine from us in the continuity program. Be on the lookout for additional information from our Vaccine Coordinators.

Please reach out to your nurse/ pharmacist consultant or email our Vaccine Coordinators at [vaccineorders@consonushealth.com](mailto:vaccineorders@consonushealth.com) if you have any questions or would like to be added to the preorder. Thank you.

Please refer to the amended EUA Fact Sheets for Providers for full prescribing information.

- [Moderna COVID-19 Vaccine](#)
- [Pfizer-BioNTech COVID-19 Vaccine](#)
- [COVID-19 Bivalent Vaccine Boosters](#)