

Pfizer/BioNTech COVID-19 vaccine, bivalent – Additional dose(s) in 6 months – 4 years with immunocompromise

- On April 28, 2023, the <u>FDA authorized</u> the following uses of the <u>Pfizer/BioNTech COVID-19</u> <u>vaccine, bivalent</u> for individuals 6 months through 4 years of age with certain types of immunocompromise who have previously received three 0.2 mL doses (Pfizer/BioNTech COVID-19 vaccine or Pfizer/BioNTech COVID-19 vaccine, bivalent):
 - A fourth dose administered at least 1 month following the most recent dose;
 - Additional doses that may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.
- Per the FDA, based on available safety and immunogenicity data from post-authorization experience with additional doses of mRNA vaccines in immunocompromised adults, it is reasonable to conclude a favorable benefit-risk balance in these individuals.
- The FDA stated in its updated <u>emergency use authorization (EUA) letter</u> that a fourth bivalent dose in this patient population, as well as additional doses, may be effective in preventing serious or life-threatening disease or conditions that can be caused by SARS-CoV-2, including Omicron variant sublineages BA.4/BA.5 and other Omicron subvariants such as XBB.1.5.

What's Next:

 Once the Centers for Disease Control and Prevention's (CDC) Director accepts and recommends the new dosing information, updated guidance will be posted on the CDC website located <u>here</u>. There are no plans at the moment for the CDC's Advisory Committee on Immunization Practices (ACIP) to discuss the updated indication.



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