Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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FDA Authorizes Pfizer's Covid-19 Booster for People over 65 or at High Risk

On Wednesday, September 22, 2021, the Food and Drug Administration (FDA) granted an emergency use authorization (EUA) to Pfizer for Comirnaty vaccine booster (COVID-19 vaccine, mRNA) formerly known as Pfizer BioNTech. On Thursday, September 23, the CDC Advisory Committee on Immunization Practices' (ACIP) met and CDC's Director Rochelle P. Walensky, M.D., M.P.H., endorsed ACIP's recommendations for a booster shot of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high risk occupational and institutional settings.

The FDA and ACIP did not review data on the heterologous boosting or mixing and matching of COVID-19 vaccine products. Thus, the interim recommendations **only** apply to individuals who received the Pfizer-BioNTech COVID-19 vaccine as their primary series. Dr. Walensky stated that "We will address, with the same sense of urgency, recommendations for Moderna and J&J vaccines as soon as those data are available."

Boosters Not Authorized for Children

While Pfizer applied for full licensure for booster doses for everyone 16 years of age and older, the FDA did not approve boosters for children ages 16 and 17. The FDA did not approve boosters for a broader population citing the need for additional evidence. The FDA also did not review data for a primary vaccination series for children under the age of 12. This will be done in a separate meeting once the data is available for review.

The American Academy of Pediatrics (AAP) has asked that physicians not try to calculate doses or create dosing schedules for younger children recognizing that off-label use is legally permissible. Physicians are urged to wait until clinical trials in children are complete before giving the vaccine to children under age 12. The need for the full- evidence review and determination of appropriate dosing for children was identified as a reason for physicians to be cautious.

Vaccine Off-Label Use

The ADPH recognizes that providers have the ability to prescribe medications and vaccines "off-label". ADPH is making sure that vaccine providers are aware of the potential liability and consequences of doing this. Vaccine providers should adhere to requirements and recommendations from the FDA, CDC, and ACIP. Any vaccine given outside of these parameters constitutes "off-label" administration. Per CDC, providers administering the vaccines off-label may not be granted liability protection under the Public Readiness and Emergency Preparedness Act (PREP Act). Off label administration of the vaccine is also a violation of the CDC provider agreement and a provider may lose further privileges to provide vaccine. In addition, patients receiving vaccines off-label could also lose the benefits of the protections

provided under the Countermeasures Injury Compensation Program (CICP) in the rare event of injury or harm.
For additional information on the PREP Act please visit https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx and for additional information on the CICP please visit https://www.hrsa.gov/cicp/

Qualification for Booster Doses and Additional 3rd Doses

The Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention recognizes distinct differences between "additional doses" versus "booster doses". An "additional mRNA dose" following an initial vaccine series is given to people who may not have had a strong enough immune response after receiving the initial vaccine series. A "booster dose" is a supplemental dose given to groups whose immune response has weakened over time.

Effective immediately, a physician's order or completion of the mRNA Vaccine Attestation Form is ***no longer needed for Booster or Additional 3rd Doses.***

Qualification for Booster Doses

CDC recommends:

- people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

Qualification for Additional 3rd Doses

CDC recommends that:

• people on active treatment for solid tumor and hematologic malignancies
• people with a solid-organ transplant and taking immunosuppressive therapy
• people with CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
• people who have moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
• people who have advanced or untreated HIV infection

• people on active treatment with high-dose corticosteroids (≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Since this group remains susceptible to COVID-19 infection even after receiving the initial 2-dose series of the mRNA vaccines, a 3rd dose of mRNA should be recommended and given as soon as possible. Even following the 3rd dose, persons in this group should continue to follow all of the recommendations to reduce the risk of infection including but not limited to social distancing, wearing face masks, staying out of crowds, sanitizing their hands and frequently touched surfaces. In addition, it is strongly recommended that persons that live with them or will be in close contact with them are fully-vaccinated to further reduce their risk of infection.

FDA Press Release from September 22, 2021 is available at
https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations

For CDC Statement on ACIP Booster Recommendations is available at
CDC Statement on ACIP Booster Recommendations | CDC Online Newsroom | CDC

For FDA information on Pfizer-BioNTech Fact Sheets (English) and FAQs visit

Fact Sheet for Healthcare Providers Administering Vaccine	September 22, 2021
Fact Sheet for Recipients and Caregivers	September 22, 2021
Frequently Asked Questions on the Pfizer-BioNTech COVID-19 Vaccine	August 23, 2021

For more information, visit alabamapublichealth.gov