Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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FDA Approves COMIRNATY (COVID-19 vaccine, mRNA) Previously Known as Pfizer-NTech

On Monday, August 23, 2021, the Food and Drug Administration (FDA) finalized the full approval of the Pfizer mRNA COVID-19 vaccine, COMIRNATY, for persons age 16 years and older. The vaccine continues to be available under Emergency Use Authorization (EUA) for children ages 12 through 15 years old while the FDA continues to review data. It is not authorized for children under age 12.

The American Academy of Pediatrics (AAP) Cautions Against Off-Label Use of COVID-19 Vaccines in Children Under Age 12

The 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.

Additional 3rd Dose of Pfizer or Moderna COVID-19 Vaccine for Immunocompromised versus Booster 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.

At this time, only "additional doses" are recommended as a 3rd dose in people with moderately to severely compromised immune systems. The additional vaccine should be considered for people with moderate to severe immune compromise due to a medical condition, or receipt of immunosuppressive medications or treatments. This includes people who have:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of a solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- 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.

Please note that CDC does **not** recommend additional doses or booster shots for any other population at this time but expects the FDA to authorize/approve changes to allow ACIP review for booster doses before the end of September.

The FDA fully approved COMIRNATY (COVID-19 vaccine, mRNA) previously known as Pfizer-BioNTech on August 23, 2021. For full prescribing information visit https://www.fda.gov/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#comirnaty
The downloadable package insert can be found at https://www.fda.gov/media/151707/download

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