The Alabama Department of Public Health in
HAN Alert
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3rd Dose mRNA COVID-19 Vaccine in Immunocompromised and Use of Monoclonal Antibodies for High Risk Patients

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

On Friday, August 13, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommended that people with moderately to severely compromised immune systems receive an additional dose of mRNA COVID-19 vaccine at least four weeks after an initial two-dose mRNA series. CDC's director, Dr. Rochelle P. Walensky subsequently signed the recommendation. The recommendation follows FDA's decision to amend the Emergency Use Authorization for Pfizer and Moderna to allow for a 3rd dose to better protect those with severely weakened immune systems.

The data review identified that an additional dose is necessary to further increase antibody levels which remained insufficient after the second dose to provide protection against the SARS-C0V-2 virus in persons with moderate to severely weakened immune systems. The CDC does not recommend that providers check antibody status as a precursor to the 3rd vaccine. To access the information reviewed by ACIP, please go to in small studiespdf icon.

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.

Please note that CDC does **not** recommend additional doses or booster shots for any other population at this time. CDC and FDA continue to review available evidence and data on whether or when booster doses for other populations, including seniors, may be needed. Available data right now show the vaccines continue to be strongly protective against severe illness and death caused by COVID-19. ACIP also did not address whether an additional dose of vaccine is needed for those who are immunocompromised following a single dose of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine. The FDA and CDC are actively working to provide guidance on this issue.

For persons who will be referred to ADPH County Health Departments or other vaccination sites such as pharmacies for the 3rd mRNA dose, patient attestation via the completion of a form at the vaccination site (checking the qualifying condition will be required) or alternatively an order/prescription from their

physician indicating "3rd mRNA dose & Name of Qualifying Condition" is acceptable. If the name of the mRNA vaccine used for the initial series is known, please indicate this as "Pfizer" or "Moderna" instead of "mRNA".

Treatment of High-risk individuals with monoclonal antibodies

On July 30, the FDA updated the Emergency Use Authorization (EUA) for the monoclonal antibody treatments for COVID-19 mild to moderate COVID-19 infection to add the indication for post-exposure prophylaxis. Adults and pediatric patients (12 years and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, should be treated as outpatients to reduce the risk of hospitalization or death. In light of surging COVID-19 cases and increasing hospitalizations, it is strongly recommended that providers consider treatment within 10 days of symptom onset, known exposure or within 10 days of first POS test date for those who remain asymptomatic.

Please refer to the full EUA for specifics as to dosing and the definition of high risk which may vary slightly with each product https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

On August 12, CDC held a Clinician Outreach and Community Activity webinar on Therapeutic Options to Prevent Severe COVID-19 in Immunocompromised People. To access the recording, visit COCA Call webpage or to access the slide set go to "Call Materials" on the COCA Call webpage.

For more information, visit alabamapublichealth.gov.