

August 13, 2021

Dear COVID-19 Vaccine Provider:

Last night, the U.S. Food and Drug Administration (FDA) amended the Emergency Use Authorizations (EUA) for both the Moderna and Pfizer COVID-19 vaccinations to allow third dose administration in individuals who are immunocompromised. The Advisory Committee on Immunization Practices has voted to recommend a third dose of these vaccines for this population as per below, and the Centers for Disease Control (CDC) Director has officially adopted these recommendations.

Individuals eligible for a third dose include people with certain medical conditions or people receiving treatments that are associated with moderate to severe immune compromise:1

- Active treatment for solid tumor and hematologic malignancies.
- Receipt of 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 (e.g., DiGeorge, Wiskott-Aldrich syndromes).
- Advanced or untreated HIV infection.
- Active treatment with high-dose corticosteroids (i.e., ≥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.
- 1. Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host.

Verification of Eligibility:

- Use of testing to assess immune response and guide clinical care prior to third dose administration is not recommended.
- A doctor's note or prescription for a third dose is not required; self-attestation is all that is necessary to verify eligibility.

Dosage:

The third dose is the same dosage as the first two dosages for both the Pfizer-BioNTech (0.3 mL) and Moderna (0.5 mL) vaccines.

Age Criteria:

The age criteria remain the same as for the initial series of the Pfizer (at least 12 years old) and Moderna (at least 18 years old) vaccines.

Timing:

- The third dose of either the Pfizer or Moderna vaccine should be administered at least 28 days following the second dose.
- Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be given at least two weeks before initiation of immunosuppressive therapies.

Implementation Considerations:

- The additional dose should be the same mRNA vaccine as the primary series. However, the alternate mRNA vaccine can be used if the primary series one is not available.
- Currently there are not data to support the use of an additional mRNA COVID-19 vaccine dose
 after a primary Janssen COVID-19 vaccine in immunocompromised people. Additionally, it is
 important to note that the Emergency Use Authorization for the Janssen vaccine was not
 amended to allow for an additional dose. The FDA and CDC are actively working to provide
 guidance on this issue.

Storage and Handling:

 Please continue to follow all previous guidelines for the storage and administration of these vaccines.

Questions:

Please send any questions to <u>COVIDVaccines@dhec.sc.gov</u>.