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PUBLIC HEALTH ADVISORY

To: Health Care Providers

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Subject: **Use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people**

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Use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people

I. Introduction

On August 12, 2021, the U.S. Food and Drug Administration modified the Emergency Use Authorizations (EUAs) for the Pfizer-BioNTech and Moderna COVID-19 vaccines to allow for administration of an additional dose (*i.e.*, a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for certain immunocompromised people.

On August 13, 2021, the U.S. CDC's Advisory Committee on Immunization Practices ("ACIP") reviewed the data for use of an additional dose of mRNA COVID-19 vaccine for immunocompromised people. ACIP made an interim recommendation for use of an additional dose of Pfizer-BioNTech COVID-19 vaccine (for persons aged ≥12 years) or Moderna COVID-19 vaccine (for persons aged ≥18 years) after an initial 2-dose primary mRNA COVID-19 vaccine series for **moderately to severely immunocompromised people**.

II. Considerations for use of an additional dose of mRNA COVID-19 vaccine in moderately and severely immunocompromised people

A. Conditions and Treatments

An additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series should be considered for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:

- 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 syndrome, Wiskott-Aldrich syndrome);
- 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.

B. Additional Considerations

A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination. Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

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 2013 Infectious Diseases Society of America Clinical Practice Guideline for Vaccination of the Immunocompromised Host.

Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be completed at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine.

The utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (*e.g.*, as part of need assessment for an additional dose) has not been established. Serologic testing or cellular immune testing outside of the context of research studies is **not recommended at this time**.

The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses.

Until additional data are available, the additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series, based on expert opinion.

Currently there are insufficient data to support the use of an additional mRNA COVID-19 vaccine dose after a single-dose Janssen COVID-19 vaccination series in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue.

III. COVID-19 vaccine immune response and effectiveness in moderately and severely immunocompromised people

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 illness. The currently FDA-authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.

Studies have found evidence of reduced immune response to a 2-dose primary mRNA COVID-19 vaccine series in some groups of immunocompromised people. In addition, reduced vaccine effectiveness has been observed in immunocompromised participants compared to participants who are not immunocompromised in a limited number of studies. Immunocompromised people also may have a higher rate of breakthrough SARS-CoV-2 infections than the general population. Small studies have demonstrated that an additional mRNA COVID-19 vaccine dose in some immunocompromised people who received a primary mRNA COVID-19 vaccine series may enhance antibody response, increasing the proportion of people who respond. However, the exact correlation between antibody level and protection against COVID-19 remains unclear. The reactogenicity profile of the additional dose was similar to prior doses.

Although the clinical benefit of an additional dose of an mRNA COVID-19 vaccine in immunocompromised people who received a primary mRNA COVID-19 vaccine series is not precisely known, the potential to increase immune response coupled with an acceptable safety profile, supports use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in this population.

IV. Reinforcement of the need for prevention measures among immunocompromised people

People who are immunocompromised (including people who receive an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series) should be counseled about the potential for an ongoing, reduced immune response to COVID-19 vaccines and **the need to continue to follow current prevention measures** (including wearing a mask, staying 6 feet apart from others they don't live with, and avoiding crowds and poorly ventilated indoor spaces) to protect themselves against COVID-19 until advised otherwise by their health care professional. Close contacts of immunocompromised people should also be strongly encouraged to be vaccinated against COVID-19 to protect these people.