Clinical Guidance for Michigan Providers Regarding Additional Dose of an mRNA COVID-19 Vaccine

Michigan.gov/Coronavirus

August 13, 2021

On August 12, 2021, the Food and Drug Administration (FDA) modified the Emergency Use Authorization (EUA) to allow for the administration of an additional dose (i.e., third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series. The additional dose of mRNA COVID-19 vaccine is for certain immunocompromised individuals.

On August 13, 2021, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization practices (ACIP) unanimously voted in favor of recommending an additional dose of an mRNA COVID-19 vaccine dose for certain immunocompromised individuals. The proposed recommendations are listed below. The official Morbidity and Mortality Weekly Report (MMWR) has not been released yet but the CDC Director Rochelle P. Walensky, MD, MPH endorsed the use of an additional dose of COVID-19 vaccine for people with moderately to severely compromised immune systems after an initial two-dose vaccine series on August 13, 2021. Further guidance regarding the considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people can be found in the Interim Clinical Considerations for Use of the COVID-19 Vaccines Currently Authorized in the United States.

mRNA COVID-19 Vaccines: The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series:

- **Pfizer-BioNTech** COVID-19 vaccine: For persons aged ≥12 years
- **Moderna** COVID-19 vaccine: For persons aged ≥18 years

Emergency Use Authorization (EUA) for mRNA Vaccines: Both mRNA COVID-19 vaccines under EUA in the U.S. were amended to reflect the FDA authorized and ACIP recommended additional dose of mRNA COVID-19 vaccine for certain immunocompromised individuals after an initial 2-dose primary series of an mRNA COVID-19 vaccine.

Use the Michigan version of the EUA, which can be found at the State of Michigan COVID-19 Vaccine Provider webpage. Vaccine Specific EUAs:

- Michigan Pfizer EUA for Recipients
- Michigan Pfizer EUA for Health Care Providers
- Michigan Moderna EUA for Recipients
- Michigan Moderna EUA for Healthcare Providers

ACIP Recommendation for the Additional mRNA COVID-19 Vaccine Dose:

One additional dose of mRNA COVID-19 vaccine is recommended for certain immunocompromised individuals after an initial 2-dose primary series of an mRNA COVID-19 vaccine has been received.

What Brand Can the Additional mRNA COVID-19 Vaccine Dose Be?

Attempts should be made to match the additional mRNA COVID-19 vaccine dose to the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series. However, 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.

Due to insufficient data, the emergency use authorization (EUA) amendment for an additional dose does **NOT** apply to Janssen COVID-19 vaccine or to individuals who received Janssen COVID-19 as a primary series. CDC and FDA are actively engaged to ensure that immunocompromised recipients of Janssen COVID-19 vaccine have optimal vaccine protection

Timing of Additional Dose: 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.

Who is Considered Immunocompromised: Data have found evidence of reduced immune response to a 2-dose primary mRNA COVID-19 vaccine series in some groups of immunocompromised individuals. 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, 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, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

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:

- ACIP The General Best Practice Guidelines—Altered Immunocompetence
- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- The CDC Yellow Book
- The Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host (pdf version)

Additional Clinical Considerations to Note for the Additional mRNA COVID-19 Vaccine Dose:

- 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.
- A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.
- 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**.

Reinforcement for the Need for Prevention Measures Among Immunocompromised Individuals:

Immunocompromised individuals, including those 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 a reduced immune response to COVID-19 vaccine and the need to continue to follow current prevention measures such as:

- Wear a mask
- Stay 6 feet apart from others they don't live with
- Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider

It is important that close contacts of immunocompromised people be vaccinated against COVID-19. Strongly encourage close contacts to complete their COVID-19 vaccine series to provide another layer of protection for their immunocompromised loved one.
Source: How to Protect Yourself & Others

Michigan Care Improvement Registry (MCIR) Reminder: Every patient's MCIR record must be assessed prior to vaccination. All administered doses must be reported within 24 hours of vaccination.

Coding Information

- COVID-19 Vaccine coding information from the Centers for Medicare & Medicaid Services (CMS). —CMS.gov

Sources:

- CDC Press Release
- FDA Press Release
- CDC U.S. COVID-19 Vaccine Product Information –updated CDC clinical materials to be posted soon
- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- ACIP Meeting Information with Meeting Materials –Slides are posted from the 8/13/21 meeting under meeting materials tab
- ACIP The General Best Practice Guidelines for Immunization