

From: COVIDVACCINE COVIDVACCINE@odh.ohio.gov

Sent: Friday, August 13, 2021 6:05 PM

Subject: IMPORTANT UPDATE: Additional dose of mRNA COVID-19 vaccine authorized for immunocompromised individuals

Dear COVID-19 Vaccine Provider,

An additional dose of messenger RNA (mRNA) COVID-19 vaccines now can be administered to a small group of **immunocompromised individuals** following completion of a primary mRNA vaccine series, according to the U.S. Food & Drug Administration and the Centers for Disease Control and Prevention (CDC). Other fully vaccinated individuals do not need an additional vaccine dose at this time.

The FDA has updated its emergency use authorizations for the [Pfizer](#) and [Moderna](#) vaccines to include a recommended third dose for individuals with moderate to severe immunosuppression who are at heightened risk for serious outcomes from COVID-19. This includes solid organ transplant recipients or those who are “diagnosed with conditions that are considered to have an equivalent level of immunocompromise,” according to the FDA. This group of eligible individuals is estimated to include less than 3% of the U.S. population and 3% of Ohioans.

The purpose of this additional dose is to strengthen the immune response when the initial immune response to the primary two-dose vaccine series is likely to be insufficient, according to the CDC’s Advisory Committee on Immunization Practices (ACIP).

ACIP recommended Friday that an additional dose be recommended at least 28 days following completion of the primary vaccination series for qualifying immunocompromised individuals age 12 and older who have received the Pfizer series and individuals age 18 and older who have received the Moderna series, according to the CDC’s [updated clinical considerations for COVID-19 vaccinations](#). At this time, an additional dose is not recommended after the single-dose Johnson & Johnson (Janssen vaccine). Further evaluation and guidance specific to the Johnson & Johnson vaccine is pending, according to the CDC panel.

“Immunocompromised people are at a much higher risk for severe outcomes from COVID-19 and may not develop a sufficient immune response from their primary vaccination series,” said Dr. Bruce Vanderhoff, Director of the Ohio Department of Health. “These individuals have a reduced ability to fight infections and are particularly vulnerable now as the more contagious and more dangerous Delta variant is driving a surge in cases. This additional dose, combined with other prevention strategies including wearing face masks, avoiding crowds and maintaining physical distance, offers another important layer of protection for this small but important population.”

Eligibility

The CDC has further defined this eligible population to include:

- Individuals undergoing active treatment for cancer (solid tumor and hematologic malignancies).
- Individuals who have received a solid-organ transplant and are taking immunosuppressive therapy.
- Individuals who have received a CAR-T-cell or hematopoietic stem cell transplant (within two years of transplant or taking immunosuppression therapy).

- Individuals with moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
- Individuals with advanced or untreated HIV infection.
- Individuals undergoing active treatment with high-dose corticosteroids (i.e., ≥ 20 mg 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.

Recommendations for COVID-19 vaccine providers

Healthcare providers are urged to consult with immunocompromised patients under their care to offer recommendations for timing of additional doses of COVID-19 vaccine, factoring in their other treatments.

- Individuals who believe they meet the criteria are urged to consult with their healthcare providers to determine next steps. A patient's clinical team is best positioned to determine the degree of immune system compromise and appropriate timing of vaccination.
- Factors to consider include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.
- Providers should accept "self-attestation" when eligible individuals present for the additional dose.
- The additional dose should be the same mRNA vaccine as the primary two-dose series. An alternate mRNA product can be used if the primary series product is not available, provided the patient is age-eligible for that product.
- 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.

Recommended layered prevention

The CDC recommends extra precautions for immunocompromised individuals alongside an additional dose.

Immunocompromised people (including those who receive an additional mRNA dose) should be aware of the potential for reduced immune response to COVID-19 vaccination and should follow ongoing prevention measures including:

- Wearing a mask.
 - Staying 6 feet apart from others outside their household.
 - Avoiding crowds and poorly ventilated indoor spaces.
- Close contacts of immunocompromised people are *strongly encouraged* to be vaccinated against COVID-19.

Booster doses

These additional doses for immunocompromised persons should not be confused with booster doses. At this time, additional booster doses are not authorized or recommended for any individuals based upon

waning immunity over time. The need for and timing of a COVID-19 booster dose have not been established, according to the FDA.

Updated resources:

FDA

- **Pfizer**
 - [Fact Sheet for Healthcare Providers Administering Vaccine](#)
 - [Fact Sheet for Recipients and Caregivers](#)
- **Moderna**
 - [Fact Sheet for Healthcare Providers Administering Vaccine](#)
 - [Fact Sheet for Recipients and Caregivers](#)

CDC

- [Considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose COVID-19 mRNA vaccine series for immunocompromised people](#)