



# Arkansas Department of Health

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## **Additional mRNA COVID-19 Vaccine dose after initial 2-dose primary mRNA vaccine series for Immunocompromised People**

On August 12, 2021 FDA modified the Emergency Use Authorizations (EUAs) for [Pfizer-BioNTech](#) COVID-19 vaccine and [Moderna](#) COVID-19 vaccine 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 (i.e., people who have undergone solid organ transplantation or have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise). The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series:

- Pfizer-BioNTech: aged  $\geq 12$  years
- Moderna: aged  $\geq 18$  years

On August 13, 2021, ACIP met and reviewed the data for use of an additional dose of mRNA COVID-19 vaccine for immunocompromised people within the Evidence to Recommendation Framework. ACIP made an interim recommendation for use of an additional dose of Pfizer-BioNTech COVID-19 vaccine (for persons aged  $\geq 12$  years) or Moderna COVID-19 vaccine (for persons aged  $\geq 18$  years) after an initial 2-dose primary mRNA COVID-19 vaccine series for moderately to severely immunocompromised people.

Healthcare professionals and public health officials should consider the following for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for moderately to severely immunocompromised people:

- The currently FDA-authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.
- Studies indicate some immunocompromised people have a reduced immune response following a primary COVID-19 vaccine series compared to vaccine recipients who are not immunocompromised.
- Studies have further demonstrated that including an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in some immunocompromised populations may enhance immune response.
- The clinical benefit of an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series for immunocompromised people is not precisely known. However, for people with moderate to severe immune compromise due to a medical condition or receipt of

immunosuppressive medications or treatments, the potential to increase immune response coupled with an acceptable safety profile, support the recommendation for an additional mRNA vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series.

- The additional dose should be administered **at least 28 days** after the completion of the initial mRNA COVID-19 vaccine series.
- 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 at this time. Proof of the person's immunocompromised condition is not required.
- There is not enough data at this time to determine whether immunocompromised people who received Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine also have an improved antibody response following an additional dose of the same vaccine. FDA and CDC are actively working to provide guidance on this issue.

**The clinical considerations for use of an additional dose of an mRNA COVID-19 vaccine apply only to people who are moderately or severely immunocompromised.**

For public health purposes, immunocompromised people who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series [Pfizer-BioNTech and Moderna] or single dose of the Janssen vaccine) are considered [fully vaccinated](#)  $\geq 2$  weeks after completion of the series. However, 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.,  $\geq 20$ 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.

[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.

Please visit the full CDC page for more information on this important topic:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>