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## **NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT**

### **Latest Guidance from CDC and FDA on Additional Doses of mRNA COVID-19 Vaccines In Certain Immunocompromised People**

August 16, 2021

#### **Background**

On August 12, 2021 FDA modified the Emergency Use Authorizations (EUAs) for the two currently authorized mRNA vaccines, Pfizer BioNTech and Moderna 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<sup>th</sup> the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (CDC/ACIP) met to weigh evidence to support a recommendation for a third dose in certain immunocompromised patients. After review, ACIP concluded that 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.

#### **Recommendations for Clinicians**

The New Mexico Department of Health (NMDOH) encourages healthcare providers caring for immunosuppressed patients to register with the agency as an approved COVID-19 vaccine provider. Providers can register online at [takecarenm.org](https://takecarenm.org).

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.

- 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 a needs 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.
- Immunocompromised patients and their close contacts should be vaccinated against COVID-19. Counsel patients who are immunocompromised about the potential for reduced immune responses to COVID-19 vaccines and to continue to practice all recommended prevention measures: wear a well fitted mask, stay 6 feet apart from others, avoid crowds and poorly ventilated spaces.
- Early treatment with monoclonal antibodies may be beneficial in this population if they develop COVID-19 infection.

#### EPIDEMIOLOGY AND RESPONSE

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### Access to Third Dose for Qualifying Patients

- New Mexico COVID19 Vaccine Providers can start providing the 3<sup>rd</sup> dose to eligible patients immediately.
- NM will follow the eligibility criteria set forth by the CDC and included in the updated EUA's.  
Moderna: [Vaccination Provider Fact Sheet | EUA | Moderna COVID-19 Vaccine \(modernatx.com\)](#)  
Pfizer: [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) \(fda.gov\)](#)
- Eligible patients are encouraged to schedule the 3<sup>rd</sup> dose with their medical team - their PCP, specialist, or pharmacy provider.
- The statewide registration app allows additional dose (3<sup>rd</sup> dose) scheduling for people who have selected an immune suppressing condition in their medical profile.
- We recognize that not all providers or patients use the registration app. Patients can schedule either through usual methods with their medical team or through the registration app.
- Proof of qualifying condition is not required; however, patients should be able to provide verbal information about their medical condition. Providers may choose to document the qualifying condition on the vaccine medical clearance form.
- We encourage medical teams to reach out to their eligible patients to inform them of the additional dose recommendations.

### Additional Resources:

For physicians wishing to register to administer COVID-19 vaccine, please contact the New Mexico Statewide Immunization Information system (NMSIIS) Help Desk at [covid.vaccines@state.nm.us](mailto:covid.vaccines@state.nm.us) or register online at [takecaresnm.org](http://takecaresnm.org)

[Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#)

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**New Mexico Health Alert Network:** To register for the New Mexico Health Alert Network, go to <https://member.everbridge.net/index/453003085613008#/login> and click "Sign Up" at the bottom of the page. Provide all information on each screen, click on "Save and Continue," and click on "Finish" at the end to begin receiving important health alerts and advisories.