



Date:	August 18, 2021
Topic:	Additional mRNA COVID-19 Dose Recommended for Moderately and Severely
	Immunocompromised Individuals
Contact:	Margaret (Peggy) Franklin, BS, RN, Nevada State Immunization Program
То:	All Health Care Providers and Facilities; Pharmacists

Background and Overview

On August 13, 2021, the Advisory Committee on Immunization Practices (ACIP) voted 11-0 to recommend an additional dose of Pfizer-BioNTech COVID-19 vaccine for individuals 12 years and older or an additional dose of Moderna COVID-19 vaccine for individuals 18 years and older for those who are moderately to severely immunocompromised. CDC Director Dr. Rochelle Walensky approved the recommendations following the decision of the Food and Drug Administration (FDA) to amend the emergency use authorizations (EUA) of the vaccines.

The additional dose should match the dose type of the mRNA vaccine used for the patient's primary COVID-19 vaccine series but administering an additional dose of a different mRNA COVID-19 vaccine product is permitted if this is not feasible at the point of administration. The additional dose of mRNA COVID-19 vaccine should be administered at least 28 days after completion of the primary mRNA vaccine series. Due to insufficient data, the EUA amendment for an additional dose does not apply to the Janssen (Johnson and Johnson) COVID-19 vaccine or to individuals who received the Janssen (J&J) COVID-19 vaccine as their primary series.

Immunocompromised individuals who are recommended to receive an additional dose of mRNA vaccine may selfattest to their immunocompromised status to reduce barriers to vaccination. Note that "fully vaccinated" status is still considered to be two weeks after two doses (primary series) of mRNA COVID-19 vaccine, even for immunocompromised individuals.

Eligible Individuals – Moderately and Severely Immunocompromised

- Approximately seven million Americans or 2.7% of U.S. adults are moderately to severely immunocompromised.
- In Nevada, this recommendation is estimated to impact a known 92,400 Nevadans.
- People with medical conditions or people receiving treatments that would make them moderately to severely immunocompromised include:
 - Active or recent treatment for solid tumor and hematologic malignancies
 - o Receipt of solid-organ or recent hematopoietic stem cell transplants
 - Severe primary immunodeficiency
 - Advanced or untreated HIV infection
 - Active treatment with high-dose corticosteroids, alkylating agents, antimetabolites, tumor-necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory
 - Chronic medical conditions such as asplenia and chronic renal disease may be associated with varying degrees of immune deficit

Additional Considerations

- Chronic medical conditions may be associated with varying degrees of immune deficiency.
- A patient's clinical team is best able to assess the degree of altered immunocompetence and optimal timing of vaccination with attention paid to current or planned immunosuppressive therapies.
- Whenever possible, mRNA COVID-19 vaccine doses (including the primary series and an additional dose) should be given at least two weeks before initiation of immunosuppressive therapies.
- Factors to consider in assessing the general level of immune competence of patients with chronic disease include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.
- The utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., the need for an additional dose) has not been established and is not recommended at this time.

Infection Prevention Measures

Immunocompromised people, including those who receive an additional dose of mRNA COVID-19 vaccine, should be counseled about the potential for reduced immune response to COVID-19 vaccination and the need to follow the prevention and mitigation strategies we know work:

- Wear a mask
- Stay six feet apart from people you do not live with
- Avoid crowds and poorly ventilated indoor spaces until advised otherwise by a health care provider
- Close contacts of immunocompromised people should be strongly encouraged to be vaccinated against COVID-19

Resources

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- ACIP Altered Immunocompetence Guidelines for Immunizations | CDC
- <u>COVID-19 Vaccines for Moderately to Severely Immunocompromised People | CDC</u>
- Additional Dose of mRNA COVID-19 Vaccine for Patients Who Are Immunocompromised | CDC
- <u>Coronavirus (COVID-19) Update: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised</u>
 <u>Individuals | FDA</u>
- Information for Health Care Providers About Talking with Patients Who Are Immunocompromised
- <u>2020 Yellow Book Home | Travelers' Health | CDC</u>

Questions:

For updated guidance, please review the DPBH Technical Bulletin <u>website</u> and Nevada's health response <u>website</u> regularly. Email <u>dpbhcovid19vax@health.nv.gov</u> with questions.

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Lisa Sherych, Administrator Division of Public and Behavioral Health

Ihsan Azzam, Ph.D., M.D. Chief Medical Officer