

State of California—Health and Human Services Agency California Department of Public Health



Tomás J. Aragón, M.D., Dr.P.H. Director and State Public Health Officer Acting Director

September 10, 2021

Subject: Additional COVID-19 Vaccine Dose for Moderately to Severely Immunocompromised People

Dear Colleague,

On August 12, 2021, the FDA modified the Emergency Use Authorizations (EUAs) for the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines to allow for administration of a third dose for moderately to severely immunocompromised people. Following this EUA update, the Advisory Committee on Immunization Practices (ACIP) recommended that moderately to severely immunocompromised people who have received a two-dose mRNA COVID-19 vaccine series should receive a third dose.

People with advanced HIV infection (e.g., CD4 T-cell count <200/mm³) or untreated HIV infection qualify as moderately to severely immunocompromised in these new recommendations and should be provided a third mRNA COVID-19 vaccine dose.

- Immunocompromised people may not build an adequate level of immunity after their initial two-dose vaccine series. This third dose is intended to improve their immunity to COVID-19 and is not considered a "booster dose".
- The third dose should be provided 28 or more days after the second mRNA COVID-19 vaccine dose.
- The third mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose series (Pfizer-BioNTech or Moderna). If the vaccine product given for the first two doses is not available, the other

¹ Booster doses are not currently approved, are administered after a longer time interval (e.g., 8 months after the primary series), and are being studied as an vaccination approach in the general population and/or in specific high priority groups.



- mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses.
- The recommendations advise against using COVID-19 serology or cellular immune tests to determine if a third dose is needed at this time.
- The recommendations acknowledge that clinical judgment is important in assessing immunocompromise based on a person's comorbidities or an opportunistic infection. For example, people with HIV on antiretroviral treatment with a high CD4 count may be eligible for a third dose if they meet other criteria such as being on cancer chemotherapy or high dose steroids². Notably, a small study found that people with HIV on antiretroviral treatment and with a high CD4 cell count (median 913 cells/mm³) had similar levels of neutralizing antibodies and cellular responses after vaccination as a group healthy adults without HIV³.
- Data supporting this additional third dose include a higher risk of severe COVID-19 infection in immunocompromised people as well as a lower vaccine efficacy after a two-dose mRNA COVID-19 vaccine series compared with the general population. In addition, several studies have shown enhanced antibody responses and increases in the proportion of immunocompromised people with a detectable COVID-19 immune response after an additional mRNA COVID-19 vaccine dose.
- The benefit of an additional vaccine dose for immunocompromised people who have received the Janssen (J&J) COVID-19 vaccine is still under investigation and not recommended at this time; additional information is expected soon.

As California continues to respond to COVID-19, it is critical we continue to take actions to protect immunocompromised people, including people living with HIV, who are most vulnerable to severe disease. One step is providing a third COVID-19 vaccine dose, but additional layers of protection are also important. Wearing a mask, maintaining 6 feet apart from people outside the household, and avoiding crowds and poorly ventilated indoor spaces are additional steps to prevent COVID-19 infection. In addition, all close contacts of

² CDC. COVID-19 Vaccines for Moderately to Severely Immunocompromised People. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
³ Woldemeskel BA, Karaba AH, Garliss CC, et al. *Clinical Infectious Diseases*, 2021; ciab648, https://doi.org/10.1093/cid/ciab648



immunocompromised people should be strongly encouraged to be vaccinated against COVID-19.

Sincerely,

Phil

Philip Peters, MD Office of AIDS Medical Officer California Department of Public Health

Email: Philip.Peters@cdph.ca.gov

More Information:

CDPH: Q&A: Additional COVID-19 Vaccine Doses for People Whose Immune

Systems are Compromised

Western States Scientific Safety Review Workgroup: Statement

CDC: COVID-19 Vaccines for Moderately to Severely Immunocompromised

<u>People</u>

CDC: Statement on Additional COVID-19 vaccine dose for

<u>Immunocompromised People</u>

CDC: COVID-19 Vaccines for Moderately to Severely Immunocompromised

<u>People</u>

FDA: <u>Authorization of Additional Vaccine Dose for Certain Immunocompromised</u>

Individuals

ACIP: Presentation Slides, August 13, 2021 Meeting

