



HEALTH ADVISORY

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To: Healthcare Providers

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Subject: FDA Approves Third Dose of Moderna and Pfizer COVID-19 Vaccine for Moderate to Severely Immunocompromised Individuals

On August 12, 2021, the U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) for both the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine to allow for the use of an additional dose in certain immunocompromised individuals, specifically, solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. This action was taken because studies indicate that some immunocompromised people do not build the same level of immunity after vaccination. Additional small studies demonstrated that fully vaccinated immunocompromised individuals have accounted for a large proportion of hospitalized post-vaccination cases and that immunocompromised people are more likely to transmit the virus to household contacts.

The Advisory Committee on Immunization Practices (ACIP) met August 13 to further discuss clinical recommendations regarding immunocompromised individuals. The CDC and ACIP guidance is summarized below.

Recommendations

The San Benito County Public Health Services recommends medical providers utilize the ACIP's guidance for determining which of their patients may benefit from a third dose of Moderna or Pfizer vaccine. ACIP defined moderate to severe immunosuppression as:

- 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, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- 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, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Additional considerations outlined by the ACIP

- Chronic medical conditions may be associated with varying degrees of immune deficit.
- Patient's clinical team is best able to assess the degree of altered immunocompetence and optimal timing of vaccination, with specific attention paid to current or planned immunosuppressive therapies.
- 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.
- Factors to consider in assessing the general level of immune competence of patients with chronic diseases include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.
- Utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., need for an additional dose) has not been established and is not recommended at this time.

Implementation Considerations

- The additional dose should be the same mRNA vaccine as the primary series.
- Alternate mRNA product can be used if primary series product not available.
- Until more data are available, the additional dose should be administered at least 28 days after completion of the initial primary series.
- Currently there are no data to support the use of an additional mRNA COVID-19 vaccine dose after a primary Janssen COVID-19 vaccine in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue.
- Age limits under the EUA remain the same (12+ years for Pfizer, 18+ years for Moderna).
- California Department of Public Health (CDPH) anticipates having a third dose option available in MyTurn later this week.

Additional Resources

- FDA Announcement, August 12: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised>
- ACIP Presentation Slides, August 13 Meeting: <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-13.html>
- CDC Statement: <https://www.cdc.gov/media/releases/2021/s0813-additional-mRNA-mrna-dose.html>
- Printable copy of this Health Advisory <https://www.co.monterey.ca.us/home/showdocument?id=104560&t=637646575071618503>

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