COVID-19 Emerging Treatments Update



February 14, 2022

Emergency Use Instructions

Revised COVID-19 Vaccine Dosing for Immunocompromised Persons & Recommendations on Passive Antibody Products

CDC Emergency Use Instructions¹⁻³:

On February 11, 2022 the CDC issued <u>Emergency Use Instructions</u> (EUI) which provide information about emergency use of the licensed COVID-19 vaccines by <u>Pfizer-BioNTech</u> (<u>Comirnaty</u>) and <u>Moderna</u> (<u>Spikevax</u>). The CDC-issued EUI provide instructions and information for the use of these vaccines that are beyond the FDA-approved labeling. Authority for the issuance of Emergency Use Instructions is allowed under the <u>Pandemic and All Hazards Preparedness Reauthorization Act.</u>

<u>Summary of Revisions to CDC Interim Clinical Considerations for Use of COVID-19 Vaccines¹:</u>

- 1. Clarification & updates to **COVID-19 vaccine guidance** for people who are moderately or severely immunocompromised: (Note that this applies only to use of Spikevax (Moderna) for people ages 18 years and older and Comirnaty (Pfizer-BioNTech) for people ages 12 years and older).
 - Shorter booster interval after an mRNA COVID-19 vaccine primary series:
 - People who are moderately or severely immunocompromised should receive a booster dose at least 3 months (instead of 5 months) after the last (third) dose of an mRNA COVID-19 vaccine. for a total of four doses.
 - An additional dose (mRNA vaccine) after a Janssen COVID-19 vaccine primary series:
 - People who are moderately or severely immunocompromised should receive an additional (second) dose of an mRNA vaccine at least 28 days after the primary dose and a booster dose at least 2 months after the second dose, for a total of three doses to be up to date.
 - Revaccination for certain sub-groups:
 - Recipients of HCT, CAR-T-cell, or other B-cell depleting therapies who received doses of COVID-19 vaccine prior to or during treatment should be revaccinated for doses received before or during treatment.
 - Case-by-case clinical decision making:
 - On a case-by-case basis, providers who care for moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals **based on clinical judgement** when the benefits of vaccination are deemed to outweigh the potential and unknown risks.
- 2. Updates to recommendations on passive antibody products.
 - No recommended deferral period for passive antibody products (including monoclonal antibodies or convalescent plasma) used in treatment or post-exposure prophylaxis.
 - However, tixagevimab/cilgavimab (Evusheld®) should be deferred for at least two weeks after vaccination.
- 3. Updated contraindication and precaution section to include history of myocarditis or pericarditis after an mRNA COVID-19 vaccine as a precaution.

References:

- 1. U.S. Centers for Disease Control and Prevention, Vaccine Interim Clinical Considerations for Use of COVID-19 Vaccines. Updated: February 11, 2022.
- 2. U.S. Centers for Disease Control and Prevention, <u>Emergency Use Instructions for Healthcare Providers</u>: Pfizer-BioNTech COVID-19 vaccine for Primary, Additional, and/or Booster Doses. Version 2/11/2022.
- 3. U.S. Centers for Disease Control and Prevention, <u>Emergency Use Instructions for Healthcare Providers</u>: Moderna COVID-19 vaccine for Primary, Additional, and/or Booster Doses. CDC-issued 2/11/2022.