Indian Health Service
National Pharmacy and Therapeutics Committee

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 Instructions[1-3]:

On February 11, 2022 the CDC issued Emergency Use Instructions (EUI) which provide information about emergency use of the licensed COVID-19 vaccines by Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax). **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 Pandemic and All Hazards Preparedness Reauthorization Act.

Summary of Revisions to CDC Interim Clinical Considerations for Use of COVID-19 Vaccines[1]:

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, Emergency Use Instructions for Healthcare Providers: 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, Emergency Use Instructions for Healthcare Providers: Moderna COVID-19 vaccine for Primary, Additional, and/or Booster Doses. CDC-issued 2/11/2022.