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Additional Dose of mRNA COVID-19 Vaccine for Moderate to Severely Immunocompromised, Prohibitions of Off-label Use for FDA EUA Therapies, and Clarification of Vaccinations for Those Inoculation with Non-FDA Authorized Vaccines.

Dear Physician/Provider,

Late last week, the U.S. Food and Drug Administration (FDA) and U.S. Centers for Disease Control and Prevention (CDC) recommended that **people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series.** Available data show that these people do not always build adequate levels of protection after an initial two-dose primary mRNA COVID-19 vaccine series. Data also show that they may benefit from receiving an additional dose of an mRNA vaccine to develop as much protection as possible against COVID-19.

On August 17, 2021, the Guam Vaccine and Antiviral Prioritization Policy Committee (VAPPC) met and endorsed the expansion of the FDA's Emergency Use Authorization (EUA) of the additional dose for immunocompromised people effective immediately. There is some clinical subjectivity that surrounds the definition of someone with a moderately to severely immunocompromised status. The CDC has stated that this includes people who have:

- 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 two years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (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.

Even with this provided list to serve as a guideline, there is still clinical subjectivity at hand. Therefore, **the VAPPC has recommended that persons receiving additional doses come at the**

recommendation of a licensed physician or mid-level provider. This can be in the form of a physical or a verbal prescription that must include the qualifying diagnosis/condition, which will be documented in the recipient's immunization record. Per recommendations from the CDC, anyone who believes they meet criteria can present to a public vaccination clinic and self-attest as to their eligibility. This will be subject to the clinic provider's review.

On a related matter, it is important to remind all providers that all therapeutics must be administered following federal guidelines and timelines. **Providers do NOT have the latitude to prescribe off-label use for any pharmaceutical/therapy limited to an EUA**, unlike the autonomy that may be provided for prescribing a product with full FDA approval. For example, no provider has the latitude to vaccinate children younger than 12 years old at this time or give "booster" shots to those whom they judge might need them outside current, rigid FDA guidelines for the EUA.

However, in some circumstances, people who received a COVID-19 vaccine not currently authorized in the United States, may be offered revaccination with an FDA-authorized vaccine. The following are guidelines to assist in these unique circumstances.

- COVID-19 vaccines not authorized by FDA but listed for emergency use by the World Health Organization (WHO):
  - People who have received all recommended doses of a COVID-19 vaccine listed for emergency use by WHO do NOT need any additional doses with an FDA-authorized COVID-19 vaccine.
  - People who have NOT received all the recommended doses of a COVID-19 vaccine listed for emergency use by WHO may be offered a complete, FDA-authorized COVID-19 vaccine series.
- COVID-19 vaccines neither authorized by FDA nor listed for emergency use by WHO:
  - People who received all or some of the recommended doses of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by WHO may be offered a complete, FDA-authorized COVID-19 vaccine series.

For more information please visit:
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Should you have any questions, please call the Immunization Program at 735-7143.

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