FDA Authorization of a Third Dose of mRNA COVID-19 Vaccine Administration for Certain Immunocompromised Persons

The Pfizer-BioNTech COVID-19 vaccine is currently authorized for emergency use in persons aged 12-15 years, and fully FDA-approved for use in those 16 and older. The Moderna COVID-19 vaccine is authorized for emergency use in persons aged 18 years and older. Both vaccines are administered as a series of two injections: the Pfizer-BioNTech COVID-19 vaccine is administered three weeks apart, and the Moderna COVID-19 vaccine is administered four weeks apart.

The U.S. Food and Drug Administration (FDA) authorized the use of a third dose of mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) for certain immunocompromised persons on August 12, 2021. Of note, the FDA’s Emergency Use Authorization (EUA) amendment does not authorize the use of additional doses of the Janssen COVID-19 vaccine, nor does it authorize the administration of Pfizer-BioNTech or Moderna vaccines to a person who already received Janssen vaccine.

The authorizations for the Pfizer-BioNTech and Moderna vaccines have been amended to allow for an additional, or third, dose to be administered at least 28 days following the two-dose regimen of the same vaccine to individuals 18 years of age or older (ages 12 or older for Pfizer-BioNTech) who are moderately or severely immunocompromised. The additional mRNA COVID-19 vaccine dose should be the same vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered.

The Health Department’s vaccine appointment registration system currently does not allow patients to make an appointment for a third dose of COVID-19 vaccine. Patients can receive a third dose at a public clinic on a walk-in basis, or at most pharmacies and health care clinic sites. A map of all vaccination clinics is available at www.HealthVermont.gov/MyVaccine.

Based on this EUA amendment, the U.S. Centers for Disease Control and Prevention (CDC) has updated their guidance for the use of COVID-19 vaccines. Such conditions include but are not limited to the following:

- 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 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.

REQUESTED ACTION:

1. Be aware of the recent EUA amendment regarding administration of a third COVID-19 vaccine to those persons who have received an mRNA COVID-19 vaccine and who are moderately or severely immunocompromised.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions
Health Alert: Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: Provides important information for a specific incident or situation may not require immediate action.
Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.