

**TO:** Vermont Health Care Providers and Health Care Facilities  
**FROM:** Jennifer S. Read, MD, FIDSA, Medical Epidemiologist

### **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](http://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.,  $\geq 20$ mg 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](mailto: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.