

TO: Vermont Health Care Providers and Health Care Facilities

FROM: Mark Levine, MD; Commissioner

SARS-CoV-2 Monoclonal Antibodies for Post-Exposure Prophylaxis

The U.S. Food and Drug Administration (FDA) previously issued an Emergency Use Authorization (EUA) for the use of COVID-19 monoclonal antibody preparation REGEN-COV (casirivimab and imdevimab) for treatment of COVID-19. Now the EUA has been expanded to include post-exposure prophylaxis. Casirivimab and imdevimab are recombinant human monoclonal antibodies that bind to the spike protein of SARS-CoV-2.

The new authorization for post-exposure use is intended for:

 Adults and pediatric individuals aged 12 years or older weighing at least 40 kg who are at high risk for progression to severe COVID-19, including hospitalization or death;

AND

 Are not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (e.g., individuals with immunocompromising conditions)

AND

 Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per the U.S. Centers for Disease Control and Prevention (CDC) or who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting (e.g., nursing homes or prisons).

REGEN-COV is **expected to be effective against circulating variants**, including the Delta variant.

Post-exposure prophylaxis with REGEN-COV is **not a substitute for vaccination** against COVID-19.

REGEN-COV is **not authorized** for pre-exposure prophylaxis.

For post-exposure prophylaxis, the authorized dose is 600 mg of casirivimab and 600 mg of imdevimab. REGEN-COV may be administered as either a subcutaneous injection or a single intravenous infusion. Please refer to the <u>fact sheet</u> for complete information regarding dosing and administration.



Where to refer COVID-19 patients in Vermont for treatment with SARS-CoV-2 monoclonal antibodies: The web-based COVID-19 outpatient treatment locator maintained by the U.S. Department of Health and Human Services (HHS) has been used by healthcare providers and patients to find potential locations for treatment with monoclonal antibody therapeutics. Monoclonal antibody preparations for COVID-19 post-exposure prophylaxis may be provided at these same locations.

REQUESTED ACTIONS:

- 1. Be familiar with the most recent EUA for the use of monoclonal antibodies for COVID-19 post-exposure prophylaxis.
- 2. Be familiar with the location of sites where monoclonal antibody infusions for the treatment of and post-exposure prophylaxis for COVID-19 are available.

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.